

# Code of Practice

## 8TH EDITION



This Code of Practice has been prepared and laid before Parliament by the Secretary of State for Health in accordance with section 26(4) of the Human Fertilisation and Embryology Act 1990.



This document has been clarity-checked and awarded the Clear English Standard by Plain Language Commission ([www.clearest.co.uk](http://www.clearest.co.uk)), which promotes clear and concise communication in documents and on websites.

The Clear English Standard does not apply to the boxes headed 'Mandatory requirements'.

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# Revision control of the HFEA Code of Practice

8TH EDITION



This table provides a record of revisions made to the Code of Practice 8th edition since publication in 2009. The table shows which sections have been revised and the date when the most recent revision was implemented.

Code of Practice section	Content change	Date last revised
<b>Copyright page</b>	Revision date	October 2011
<b>Contents</b>		
<b>1. Person responsible</b>	Mandatory requirement (Licence conditions) T7; 1.1–1.2, 1.5	October 2011
<b>2. Staff</b>		
<b>3. Counselling</b>	Mandatory requirements (Licence conditions) T60, T61	October 2011
<b>4. Information to be provided prior to consent</b>		
<b>5. Consent to treatment, storage, donation, and disclosure of information</b>	5A	April 2010
<b>6. Legal parenthood</b>	Mandatory requirements (Licence conditions) T60, T61 6G	October 2011 April 2010
<b>7. Multiple births</b>	Mandatory requirement (Licence conditions) T123; 7.1, 7.2 7.1 7A	October 2011 April 2011 April 2010
<b>8. Welfare of the child</b>		
<b>9. Preimplantation genetic screening (PGS)</b>	Mandatory requirements (Licence conditions) T88, T89, T90; 9.1, 9.2, 9.3; 9B	October 2011
<b>10. Embryo testing and sex selection</b>	Mandatory requirements (Licence conditions) T88, T89; 10.4 Mandatory requirements (Directions) 10.7–10.9	October 2011 April 2010
<b>11. Donor recruitment, assessment and screening</b>	Mandatory requirements (Licence conditions) T52, T53	October 2011
<b>12. Egg sharing arrangements</b>		
<b>13. Payments for donors</b>		
<b>14. Surrogacy</b>	Mandatory requirements 14.1	April 2010
<b>15. Procuring, processing and transporting gametes and embryos</b>	Mandatory requirements (Licence conditions) T66, T67 15A	October 2011 April 2010
<b>16. Imports and exports</b>	16.4–16.6 (HFEA forms)	April 2010
<b>17. Storage of gametes and embryos</b>	Mandatory requirement (Licence conditions) T84; 17.15	October 2011

Human Fertilisation and Embryology Authority

# Revision control of the HFEA Code of Practice

8TH EDITION

Code of Practice section	Content change	Date last revised
<b>18. Witnessing and assuring patient and donor identification</b>	Mandatory requirements (Licence conditions) T71; 18.21	October 2011
<b>19. Traceability</b>		
<b>20. Donor assisted conception</b>	Mandatory requirement (Licence conditions) T54	October 2011
<b>21. Intra-cytoplasmic sperm injection (ICSI)</b>	21.4	October 2011
<b>22. Research and training</b>	Mandatory requirements (Licence conditions) T96, T95	October 2011
<b>23. The quality management system</b>	Mandatory requirements (Licence conditions) T36	October 2011
<b>24. Third party agreements</b>	Mandatory requirements (Licence conditions) T115, T116	October 2011
<b>25. Premises and facilities</b>	Mandatory requirements (Licence conditions) T5; 25.9	October 2011
<b>26. Equipment and materials</b>		
<b>27. Adverse incidents</b>	27.1, 27.9	October 2011
<b>28. Complaints</b>		
<b>29. Treating people fairly</b>	Whole section	April 2011
<b>30. Confidentiality and privacy</b>	Mandatory requirements (Licence conditions) T43	October 2011
<b>31. Record keeping and document control</b>		
<b>32. Obligations and reporting requirements of centres</b>	Mandatory requirements (Licence conditions) T6 General Direction 0008	October 2011
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This document has been clarity-checked and awarded the Clear English Standard by Plain Language Commission ([www.clearest.co.uk](http://www.clearest.co.uk)), which promotes clear and concise communication in documents and on websites.

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# User guide to the Code

## What is the purpose of the Code?

The Human Fertilisation and Embryology Act (the Act) covers the use and storage of sperm, eggs and embryos for human application, as well as all research involving the use of live human and admixed embryos.

One of the ways we help licensed centres comply with the Act is by publishing the Code. We have a duty under the Act to maintain a code that gives guidance about licensed activities and the people who carry them out.

The guidance in the Code also serves as a useful reference for patients, donors, donor-conceived people, researchers and those working in the fertility sector.



## How is the Code structured?

The Code consists of:

- regulatory principles for licensed centres
- guidance notes, and
- a glossary.

## Regulatory principles for licensed centres

The Act requires the HFEA to maintain a statement of the general principles that we consider should be followed in carrying out activities covered by the Act. The principles:

- summarise the key behaviours and outcomes we expect licensed centres to demonstrate, and
- communicate the areas of compliance we regard as important.
- the principles inform every part of the Code. Each guidance note is linked to one or more of the principles and they should be read together.

## Guidance notes

For an explanation of how the guidance notes are structured, please see over page.

## Glossary

The glossary explains key terms used in the Code.

## How does the index work?

The index will help you find the relevant guidance, licence conditions and HFEA interpretation of mandatory requirements. The extracts from the Act are not indexed.

Each paragraph of guidance is numbered to indicate the guidance note in which it belongs, and where it appears in that note (eg, paragraph 2.5 is the fifth paragraph in guidance note 2 – Staff).

The interpretation boxes are identified by a number and letter in the top right-hand corner. The number relates to the relevant guidance note, and the letter to the order of the interpretation box within that note (eg, 14B is the second interpretation box in guidance note 14 – Surrogacy).

The licence conditions are identified by a letter and a number denoting the licence condition, followed by, in brackets, the guidance note in which that licence condition appears (eg, T48(31) is licence condition T48, which appears in guidance note 31 – Record keeping and document control)

# User guide to the Code

## Guidance notes

The guidance notes are the core of the Code. Each of the 32 notes covers one subject area, to make it easier to find what you are looking for.

### The guidance notes contain the following:



#### References to the regulatory principles for licensed centres

Each guidance note refers to one or more of these principles.

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#### Mandatory requirements

These sections include relevant quotes from the Act, HFEA licence conditions, and references to HFEA Directions.

Important: the Code does not provide a complete guide to the Act and other mandatory requirements. Nor is it a substitute for reading the Act.

The person responsible is expected to be familiar with all mandatory requirements that affect their centre.

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#### HFEA interpretation of mandatory requirements

The HFEA has provided an interpretation of the law where we feel centres may find it helpful, especially where the law is very complex.

Please note that our interpretations are intended only to aid understanding and are not definitive.

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#### HFEA guidance

This best-practice guidance is intended to help centres comply with the Act.

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#### Other legislation, professional guidelines and information

This section lists other useful information, including links to relevant websites.

## Compliance and enforcement

The HFEA has a duty to promote compliance with:

- the Act, and
- the Code of Practice.

Regulatory principles will inform the inspection process. If the HFEA becomes aware that a centre has not complied with the legislation or the Code, we may take action in line with the Compliance and Enforcement Policy.

The HFEA will take into account a centre's failure to observe any provision in the Code in the circumstances set out in section 25(6)(a) and (b) of the Act.

# Regulatory principles for licensed centres

The regulatory principles reflect the HFEA's key regulatory priorities from the Human Fertilisation and Embryology Act.

They provide:

- a summary of the key behaviours and outcomes the HFEA expects each licensed centre to demonstrate, and
- a means of communicating to the person responsible and staff at each licensed centre, patients, donors, donor-conceived people and the public the areas of compliance that the HFEA regards as key.

The principles inform every part of this Code of Practice. Each of the guidance notes in the Code is linked to one or more principles and should be read in conjunction with these.

## Regulatory principles

*The HFEA expects the person responsible to ensure that their licensed centre demonstrates adherence to the following principles when carrying out activities licensed under the Human Fertilisation and Embryology Act.*

Licensed centres must:

1. treat prospective and current patients and donors fairly, and ensure that all licensed activities are conducted in a non-discriminatory way
2. have respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors
3. have respect for the special status of the embryo when conducting licensed activities
4. take account of the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth
5. give prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions
6. ensure that patients and donors have provided all relevant consents before carrying out any licensed activity
7. conduct all licensed activities with skill and care and in an appropriate environment, in line 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 the 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 accurate records and information about all licensed activities
11. report all adverse incidents (including serious adverse events and serious adverse reactions) and near misses to the HFEA, investigate all complaints properly, and share lessons learned appropriately
12. ensure that all licensed research by the centre meets ethical standards, and is done only where there is both a clear scientific justification and no viable alternative to the use of embryos, and
13. conduct all licensed activities with 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 the HFEA or other agencies responsible for law enforcement or regulation of healthcare.

# 1. Person responsible


## This guidance note contains:

### Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Extracts from licence conditions

### HFEA guidance

- Appointing the person responsible ■
- The licence holder and the person responsible
- Qualifications for the role of the person responsible
- Responsibilities of the person responsible ■

 Refer to principles 7, 9, 11 and 13

■ Section includes interpretation of mandatory requirements



## Mandatory requirements

### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

#### 17 The person responsible

- (1) It shall be the duty of the individual under whose supervision the activities authorised by a licence are carried on (referred to in this Act as the “person responsible”) to secure –
- (a) that the other persons to whom the licence applies are of such character, and are so qualified by training and experience, as to be suitable persons to participate in the activities authorised by the licence,
  - (b) that proper equipment is used,
  - (c) that proper arrangements are made for the keeping of gametes, embryos and human admixed embryos and for the disposal of gametes, embryos or human admixed embryos that have been allowed to perish,
  - (d) that suitable practices are used in the course of the activities,
  - (e) that the conditions of the licence are complied with,
  - (f) that conditions of third party agreements relating to the procurement, testing, processing or distribution of gametes or embryos are complied with, and
  - (g) that the Authority is notified and provided with a report analysing the cause and the ensuing outcome of any serious adverse event or serious adverse reaction.
- (2) References in this Act to the persons to whom a licence applies are to –
- (a) the person responsible,
  - (b) any person designated in the licence, or in a notice given to the Authority by the person who holds the licence or the person responsible, as a person to whom the licence applies, and
  - (c) any person acting under the direction of the person responsible or of any person so designated.

#### 16 Grant of licence

- (1) The Authority may on application grant a licence to any person if the requirements of subsection (2) below are met.



## Mandatory requirements (cont)

- 16 (cont)
- (2) The requirements mentioned in subsection (1) above are –
- (a) that the application is for a licence designating an individual as the person under whose supervision the activities to be authorised by the licence are to be carried on,
  - (b) that either that individual is the applicant or—
    - (i) the application is made with the consent of that individual, and
    - (ii) the Authority is satisfied that the applicant is a suitable person to hold a licence,
  - (c) in relation to a licence under paragraph 1 or 1A of Schedule 2 or a licence under paragraph 2 of that Schedule authorising the storage of gametes or embryos intended for human application, that the individual—
    - (i) possesses a diploma, certificate or other evidence of formal qualifications in the field of medical or biological sciences, awarded on completion of a university course of study, or other course of study recognised in the United Kingdom as equivalent, or is otherwise considered by the Authority to be suitably qualified on the basis of academic qualifications in the field of nursing, and
    - (ii) has at least two years' practical experience which is directly relevant to the activity to be authorised by the licence,
  - (ca) in relation to a licence under paragraph 2 of Schedule 2 authorising storage of gametes, embryos or human admixed embryos not intended for human application or a licence under paragraph 3 of that Schedule, that the Authority is satisfied that the qualifications and experience of that individual are such as are required for the supervision of the activities,
  - (cb) that the Authority is satisfied that the character of that individual is such as is required for the supervision of the activities and that the individual will discharge the duty under section 17 of this Act,
  - (d) that the Authority is satisfied that the premises in respect of which the licence is to be granted and any premises which will be relevant third party premises are suitable for the activities, and
  - (e) that all the other requirements of this Act in relation to the granting of the licence are satisfied.

### Licence conditions

- T7 Where the PR is unable to carry out their duties for any reason the holder of the licence must inform the Authority immediately and apply to the Authority for a licence variation to nominate a substitute PR. This nominated substitute PR must not commence their post unless and until the Authority decides that they are suitable.
- T9 The PR must have responsibility for:
- a. ensuring the requirements imposed by section 31ZD of the Human Fertilisation and Embryology Act 1990 (as amended), in relation to the provision of information to donors about resulting children, are complied with
  - b. ensuring that the activities are carried out on suitable premises
  - c. ensuring the centre's staff co-operate fully with inspections and investigations by the Authority or other agencies responsible for law enforcement or regulation of healthcare
  - d. ensuring fees are paid to the Authority within the timescale specified in Directions or in writing
  - e. ensuring data provided to the Authority about activities and data, which the Authority is required to hold on its Register of Information, is accurate and provided by dates specified in Directions or in writing



## Mandatory requirements (cont)

T9 (cont)

- f. ensuring requests for information and/or documents from the Authority are responded to promptly, and
- g. notifying the Authority immediately if s/he becomes aware of any decision or proposal to close their centre.

T10 In the event of termination of activities, for whatever reason, the PR must ensure that all stored gametes, embryos or admixed embryos are transferred to another licensed centre or centres. The PR must ensure that all relevant information including traceability data and information concerning the quality and safety of gametes and embryos, is transferred with any stored gametes, embryos or admixed embryos, or that records containing this information are made accessible as required.

### Directions

**0008** – Information to be submitted to the HFEA as part of the licensing process

For a copy of the relevant Directions visit [www.hfea.gov.uk](http://www.hfea.gov.uk)



## HFEA guidance

### Appointing the person responsible



#### Interpretation of mandatory requirements

1A

The law requires licensable activity take place only under the supervision of the 'person responsible', as named on the centre's licence.

An individual can be appointed as the person responsible only with the approval of the HFEA. That person must complete the Persons Responsible Entry Programme (PREP) assessment before the HFEA can consider whether or not to approve them.

### The licence holder and the person responsible

- 1.1 The licence holder and the person responsible should be separate individuals. Clinics operating within a hospital or other healthcare organisation may find it advantageous for a senior hospital manager to hold the post of licence holder.
- 1.2 It is the responsibility of the licence holder to inform the HFEA if the person responsible is unable to perform their duties. Where the centre no longer has a person responsible, the licence holder should seek the advice of the HFEA as soon as possible on continuing to provide licensable activities. Either the person responsible or the licence holder may apply for a licence or for its variation or revocation. However, only the licence holder may apply to a licence committee to vary a licence in order to designate another individual to be the person responsible.

### Qualifications for the role of the person responsible

- 1.3 The person responsible should have enough understanding of the scientific, medical, legal, social, ethical and other aspects of the centre's work to be able to supervise its activities properly. It is also important that the person responsible possesses integrity, and managerial authority and capability.
- 1.4 The HFEA expects the person responsible to take any necessary specialist advice to allow them to run the centre professionally.



### Responsibilities of the person responsible



#### Interpretation of mandatory requirements

1B

The person responsible is ultimately responsible for ensuring that all licensed activities are conducted with proper regard for the regulatory framework that governs treatment and research involving gametes or embryos.

- 1.5** The role of the person responsible should include:
- (a) maintaining an up-to-date awareness and understanding of legal obligations
  - (b) responding promptly to requests for information and documents from the HFEA
  - (c) co-operating fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement, regulation or healthcare, and
  - (d) informing the HFEA of any change to their professional registration.

## 2. Staff

### This guidance note contains:

#### Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Extracts from licence conditions

 Refer to principles 2, 7 and 9

#### HFEA guidance

- Centre staff
- Medical staff
- Nursing staff ■
- Counselling staff
- Staff engaged in scientific services
- Competence and training of ICSI and embryo biopsy practitioners
- Staff involved in genetic testing

■ Section includes interpretation of mandatory requirements

#### Other legislation, professional guidelines and information



### Mandatory requirements

#### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

17 The person responsible

- (1) It shall be the duty of the individual under whose supervision the activities authorised by a licence are carried on (referred to in this Act as the “person responsible”) to secure—
- (a) that the other persons to whom the licence applies are of such character, and are so qualified by training and experience, as to be suitable persons to participate in the activities authorised by the licence,...

Schedule 3A Supplementary Licence Conditions: Human Application

Requirements for procurement of gametes and embryos

5. Licence conditions shall require all persons to whom a licence applies who are authorised to procure gametes or embryos, or both, to comply with the requirements (including as to staff training, written agreements with staff, standard operating procedures, and appropriate facilities and equipment) laid down in Article 2 (requirements for the procurement of human tissues and cells) of the second Directive.

#### Licence conditions

- T11 The centre must have an organisational chart which clearly defines accountability and reporting relationships.
- T12 Personnel in the centre must be available in sufficient number and be qualified and competent for the tasks they perform. The competency of the personnel must be evaluated at appropriate intervals.
- T13 All personnel must have job descriptions that accurately reflect their tasks, and responsibilities.
- T14 Personnel carrying out licensed activities or other activities carried out for the purposes of providing treatment services that do not require a licence must, where appropriate, be registered in accordance with the appropriate professional and/or statutory bodies, (eg, General Medical Council, Health Professions Council, Nursing and Midwifery Council).



## Mandatory requirements (cont)

- T15 Personnel must be provided with initial/basic training. Training must be updated as required when procedures change or scientific knowledge develops, and adequate opportunity for relevant professional development must be provided. The training programme must ensure and document that each individual:
- has demonstrated competence in the performance of their designated tasks
  - has an adequate knowledge and understanding of the scientific/technical processes and principles relevant to their designated tasks
  - understands the organisational framework, quality system and Health & Safety rules of the centre in which they work, and
  - is adequately informed of the broader ethical, legal and regulatory context of their work.
- T16 The centre must have access to a nominated registered medical practitioner, within the UK, to advise on and oversee medical activities.



## HFEA guidance

### Centre staff

- 2.1** The centre should establish documented procedures for staff management that ensure all staff have:
- initial basic training and updated training as required
  - on-going competence assessment, with audits of this assessment
  - an annual joint review (with their line manager)
  - continuing education and professional development
  - staff records, and
  - appropriate access to meetings and communications.
- 2.2** Staff records should include:
- job description
  - terms and conditions of employment
  - a record of staff induction and orientation
  - a record of health and safety training
  - a record of education and training, including continuing professional development
  - relevant educational and professional qualifications
  - certificate of registration, if relevant
  - absence record
  - accident record
  - a record of annual joint reviews
  - occupational health record, and
  - a record of any disciplinary action.

The centre should ensure that confidentiality of staff records is in line with best practice and relevant legislation.



- 2.3** All staff should participate in an annual joint review that examines the needs of the centre and of the individual to improve the quality of the service to users and to encourage productive working relationships. Staff performing annual reviews must receive appropriate training.
- 2.4** The centre should have an effective way of communicating information to, and receiving suggestions from, staff. Centre management should also ensure that the accountabilities and reporting relationships shown in the centre's organisational chart are communicated within the centre.
- 2.5** Centre management should ensure that staff members who are in contact with patients and donors:
- (a) are prepared to offer appropriate emotional support to people suffering distress at any stage of their investigation, counselling or treatment
  - (b) understand and can explain the role of counselling, and
  - (c) know when and how to refer people to the centre's qualified counsellor.
- 2.6** Centres should require all prospective and existing staff to report promptly all criminal convictions they have had to the person responsible. In deciding whether or not an individual shall take part in a licensed activity at the centre, the person responsible should take into account relevant previous convictions and breaches of regulations.

### Medical staff

- 2.7** The person responsible should ensure that staff who must be registered with professional bodies are registered, their registration is up to date, and records of this are kept.
- 2.8** The individual with overall clinical responsibility for treatment services involving in vitro fertilisation should:
- (a) have completed training recognised by the Royal College of Obstetricians and Gynaecologists (or an equivalent professional body)
  - (b) be on the General Medical Council's Specialist Register, and
  - (c) participate in a recognised programme of continuing medical education and professional development.
- 2.9** If the centre is licensed to provide insemination services only, the individual with overall clinical responsibility should:
- (a) be a registered medical practitioner, and
  - (b) have sufficient experience in an established fertility centre to be qualified to take full charge of the centre's treatment services.
- 2.10** Other medical staff who take part in providing treatment services should be registered medical practitioners with sufficient experience under supervision to qualify them to do so. Medical staff who do laparoscopies should be Fellows or Members of the Royal College of Obstetricians and Gynaecologists (or an equivalent professional body). Medical staff in training should follow relevant training programmes under appropriate supervision.

### Nursing staff



#### Interpretation of mandatory requirements

2A

All nursing staff must be appropriately qualified and registered by the Nursing and Midwifery Council.

- 2.11** Nurses should be:
- (a) working towards competencies set nationally, locally or both, to ensure appropriate standards of clinical competence, and



### 2.11 (cont)

- (b) able to provide evidence of competence in the duties performed (for example, a certificate for a recognised qualification or a written testimonial by another person who is suitably qualified and competent in that discipline or function).

### Counselling staff

**2.12** Treatment centres should ensure that at least one individual is appointed to fulfil the role of counsellor. All counsellors should have specialist competence in infertility counselling and:

- (a) hold a recognised counselling, clinical psychology, counselling psychology or psychotherapy qualification to the level of diploma of higher education or above, and
- (b) be accredited under the scheme of the British Infertility Counselling Association (or an equivalent body), or show evidence of working towards such accreditation.

**2.13** A member of staff appointed to the role of counsellor should be able to provide evidence of being an accredited member of, or working towards accredited membership of, a recognised professional counselling body. The body should have a complaints/disciplinary procedure, and the individual should have agreed to abide by an appropriate code of conduct or ethics.

See also guidance note:

- [3 – Counselling](#)

### Staff engaged in scientific services

**2.14** Centre management should ensure that the centre has access to a nominated registered scientist to advise on and oversee scientific activities.

**2.15** All healthcare scientists working in licensed centres should be registered or show evidence of working towards registration with the Health Professions Council (HPC), or other equivalent body where applicable. It is expected that all staff should be registered with the HPC (or other equivalent body) within one year of their becoming eligible, including those eligible as international applicants after training overseas.

**2.16** Healthcare scientists from overseas who are registered in their own country but working in a licensed centre as a visiting scientist, should seek temporary registration with the HPC (or other equivalent body).

**2.17** Healthcare scientists employed in roles not yet requiring state registration (eg, aspirant groups, healthcare science assistants and healthcare science practitioners) should follow an appropriate induction and training programme for the tasks performed. Each individual should maintain proper records of this training.

**2.18** The individual responsible for the seminology laboratory should:

- (a) possess a degree or higher national diploma in a relevant discipline
- (b) have acquired sufficient experience in such a laboratory to supervise and be responsible for one, and
- (c) be registered with the HPC as a clinical scientist or biomedical scientist, or be able to demonstrate equivalent training or expertise.

See also:

- [Guidelines for Good Practice – Association of Biomedical Andrologists](#)  
[www.aba.uk.net](http://www.aba.uk.net)



- 2.19** The individual responsible for the clinical embryology laboratory should:
- possess an appropriate scientific or medical degree
  - have had sufficient experience in such a laboratory to be able to supervise and be responsible for one, and
  - be registered with the HPC (or other equivalent body) as a clinical scientist with specific expertise in clinical embryology.

See also:

- [Accreditation Standards and Guidelines for IVF Laboratories – Association of Clinical Embryologists](http://www.embryologists.org.uk)  
[www.embryologists.org.uk](http://www.embryologists.org.uk)

### Competence and training of ICSI and embryo biopsy practitioners

- 2.20** The person responsible should ensure that micromanipulation procedures such as ICSI and embryo biopsy are carried out only by practitioners who have the necessary competence.
- 2.21** Following training, the competence of each person performing micromanipulation procedures should be evaluated at intervals specified in the quality management system. Retraining should be given when required.

### Staff involved in genetic testing

- 2.22** A senior clinical geneticist should be involved in the decision-making process when deciding whether a particular patient should receive treatment involving embryo testing.
- 2.23** The centre should ensure that a multidisciplinary team is involved in providing the embryo testing service. The team should include reproductive specialists, embryologists, clinical geneticists, genetic counsellors, cytogeneticists and molecular geneticists. It should maintain close contact with the primary care physician or the referring clinician.
- 2.24** If the centre offers an embryo testing service, the individual responsible for this laboratory should:
- hold an appropriate scientific or medical degree
  - have acquired sufficient experience in an appropriately accredited medical genetics diagnostic laboratory to supervise and be responsible for one, and
  - be registered with the HPC (or other equivalent body) as a clinical scientist with specific expertise in clinical genetics.
- 2.25** If genetic testing of those seeking treatment or considering donation is offered, the centre should ensure that an individual is available who understands the:
- nature of the tests conducted
  - scope and limitations of the tests
  - accuracy and implications of the tests, and
  - meaning of the test results.



## HFEA guidance (cont)

- 2.26** The centre should ensure that people seeking treatment have access to clinical geneticists and genetic counsellors.
- 2.27** The centre should work closely with the local genetics team of those seeking treatment.

See also guidance note:

- **10 – Embryo testing and sex selection**



## Other legislation, professional guidelines and information

- The Nursing and Midwifery Order 2001
- BICA Guidelines for Good Practice in Infertility Counselling (2008) – [www.bica.net](http://www.bica.net)
- Association of Biomedical Andrologists – Guidelines for Good Practice – [www.aba.uk.net](http://www.aba.uk.net)
- Association of Clinical Embryologists – Guidelines for IVF Laboratories Accreditation Standards – [www.embryologists.org.uk](http://www.embryologists.org.uk)
- Royal College of Nurses – [www.rcn.org.uk](http://www.rcn.org.uk)

# 3. Counselling

## This guidance note contains:


### Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Extracts from licence conditions

### HFEA guidance

- The offer of counselling ■
- The provision of counselling
- Counselling records and confidentiality

### Other legislation, professional guidelines and information

 Refer to principles 2 and 9

■ Section includes interpretation of mandatory requirements



## Mandatory requirements

### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

- 13 (6) A woman shall not be provided with treatment services of a kind specified in Part 1 of Schedule 3ZA unless she and any man or woman who is to be treated together with her have been given a suitable opportunity to receive proper counselling about the implications of her being provided with treatment services of that kind, and have been provided with such relevant information as is proper.
- 13 (6A) A woman shall not be provided with treatment services after the happening of any event falling within any paragraph of Part 2 of Schedule 3ZA unless (before or after the event) she and the intended second parent have been given a suitable opportunity to receive proper counselling about the implications of the woman being provided with treatment services after the happening of that event, and have been provided with such relevant information as is proper.
- 13A Conditions of licences for non-medical fertility services.
- (3) A woman shall not be provided with any non-medical fertility services involving the use of sperm other than partner-donated sperm unless the woman being provided with the services has been given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and has been provided with such relevant information as is proper.

#### Schedule 3ZA

##### Part 1: Kinds of treatment in relation to which counselling must be offered

1. The treatment services involve the use of the gametes of any person and that person's consent is required under paragraph 5 of Schedule 3 for the use in question.
2. The treatment services involve the use of any embryo the creation of which was brought about in vitro.
3. The treatment services involve the use of an embryo taken from a woman and the consent of the woman from whom the embryo was taken was required under paragraph 7 of Schedule 3 for the use in question.

##### Part 2: Events in connection with which counselling must be offered

4. A man gives the person responsible a notice under paragraph (a) of subsection (1) of section 37 of the Human Fertilisation and Embryology Act 2008 (agreed fatherhood conditions) in a case where the woman for whom the treatment services are provided has previously given a notice under paragraph (b) of that subsection referring to the man.



## Mandatory requirements (cont)

5. The woman for whom the treatment services are provided gives the person responsible a notice under paragraph (b) of that subsection in a case where the man to whom the notice relates has previously given a notice under paragraph (a) of that subsection.
6. A woman gives the person responsible notice under paragraph (a) of subsection (1) of section 44 of that Act (agreed female parenthood conditions) in a case where the woman for whom the treatment services are provided has previously given a notice under paragraph (b) of that subsection referring to her.
7. The woman for whom the treatment services are provided gives the person responsible a notice under paragraph (b) of that subsection in a case where the other woman to whom the notice relates has previously given a notice under paragraph (a) of that subsection.

### Schedule 3

- 3 (1) Before a person gives consent under this Schedule –
- (a) he must be given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and
  - (b) he must be provided with such relevant information as is proper.

### Licence conditions

- T60 A woman must not be provided with treatment services using embryos or donated gametes unless she and any man or woman who is to be treated together with her have been given a suitable opportunity to receive proper counselling about the implications of her being provided with treatment services of that kind, and have been provided with such relevant information as is proper.
- T61 A woman must not be provided with treatment services where there is an intended second parent unless, either before or after both have consented to the man or woman being the intended second parent, she and the intended second parent have been given a suitable opportunity to receive proper counselling about the implications of the woman being provided with treatment services and have been provided with such relevant information as is proper.



## HFEA guidance

### The offer of counselling



#### Interpretation of mandatory requirements

3A

The law requires counselling to be offered when:

- (a) a woman or couple seeks treatment with donated gametes or embryos
- (b) an individual or couple seeks treatment that will create embryos in vitro
- (c) an individual or couple seeks to store their gametes or embryos (for exceptions see Schedule 3 of the HFE Act 1990 (as amended), paragraphs 9 or 10)
- (d) an individual or couple seeks to donate their gametes or embryos for the treatment of others
- (e) an individual seeks to donate their gametes for use in non-medical fertility services
- (f) an individual or couple seeks to donate their embryos for research purposes or for training people in embryo biopsy, embryo storage or other embryological purposes



### Interpretation of mandatory requirements (cont)

3A

- (g) an individual seeks to provide their gametes or cells for the creation of embryos or human admixed embryos for research (for exceptions see mandatory requirements outlined in guidance note 22 – Research and training)
- (h) a woman provides embryos (obtained by lavage) for any purpose
- (i) written notice is served by a man or woman consenting to the man being treated as the legal father or parent of any child born as a result of the woman's treatment, or
- (j) written notice is served by a woman, or her female partner, consenting to the partner being treated as the legal parent of any child born as a result of the woman's treatment.

- 3.1** The centre should normally offer counselling after the individual or couple has received oral and written information about the services to be provided and before they consent to treatment, or to the storage or use of gametes or embryos. The timing and frequency of counselling sessions is up to the counsellor and the person or couple concerned, who should agree this together.
- 3.2** The centre should make patients aware that the offer of counselling is routine. The offer should include written information giving the name(s) of the qualified counsellor(s), explaining their role, when they are available and how to access the service. The centre should allow enough time before treatment starts for patients to consider the offer and to take up the opportunity of counselling if they so choose.
- 3.3** If the possibility of treatment with donated gametes or embryos arises, the centre should offer counselling about the implications of treatment with donated material separately from counselling about the implications of treatment in general and before treatment with donor gametes starts.
- 3.4** If the possibility of donating gametes or embryos for the treatment of others, or donating embryos for research or training arises, the centre should offer counselling about the implications of donation separately from counselling about the implications of treatment before the treatment starts. If treatment has already begun, it should continue only if the woman and, if applicable, her partner have been offered counselling about the implications of donation.
- 3.5** The centre should take all practicable steps to provide an opportunity for counselling throughout the treatment, donation or storage processes, and afterwards if requested. If a person who has previously donated gametes or embryos, or received treatment, requests further counselling at any point, the centre should take all practicable steps to help them obtain it.
- 3.6** The centre should offer people the opportunity to be counselled with a partner, if they have one, individually or both. Group sessions may be offered in addition to individual and couple sessions.

See also guidance note:

- [4 – Information to be provided prior to consent](#)
- [6 – Legal parenthood](#)
- [22 – Research and training](#)

### The provision of counselling

- 3.7** The provision of counselling should be clearly distinguished from:
- (a) the assessment of a person's suitability to receive treatment, or to store or donate their gametes or embryos
  - (b) the provision of information before obtaining consent or providing treatment, and
  - (c) the normal relationship between clinical staff and patients or donors.



## HFEA guidance (cont)

- 3.8** The counselling service should comply with current professional guidance on good practice in infertility counselling. Counselling should be provided only by qualified counsellors.

See also guidance note:

- [2 – Staff](#)

- 3.9** Counselling should be available from a counsellor attached to the centre. If this is not possible or if the patient prefers to seek counselling elsewhere, the centre should provide:

- (a) up-to-date lists of local counsellors, with the types of counselling they offer, and
- (b) organisations that can provide relevant information.

- 3.10** The centre should ensure that arrangements are in place to provide, or refer people for, specialist counselling if appropriate, taking account of their duty of confidentiality under the HFE Act. This might include genetic counselling, and counselling for oncology patients or others requiring the long-term storage of gametes or embryos.

- 3.11** The centre should ensure that counselling facilities provide quiet and comfortable surroundings for private, confidential and uninterrupted sessions.

### Counselling records and confidentiality

- 3.12** Information obtained during counselling should be confidential (although it may be disclosed in certain circumstances, for example if it gives rise to concerns about the suitability of a person to donate gametes or to receive treatment). The written records of the professional counsellor should be kept in a secure place.

See also guidance note:

- [30 – Confidentiality and privacy](#)



## Other legislation, professional guidelines and information


- BICA Guidelines for Good Practice in Infertility Counselling (2008) – [www.bica.net](http://www.bica.net)

# 4. Information to be provided prior to consent

This guidance note contains:

## Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Extracts from licence conditions
- Reference to relevant HFEA Directions

 Refer to principle 5

## HFEA guidance

- Information to provide ■
- Distinguishing the provision of information from the offer of counselling
- Information for those seeking treatment
- Information about the cost of treatment
- Further information to provide

■ Section includes interpretation of mandatory requirements

## Other legislation, professional guidelines and information



### Mandatory requirements

#### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

##### 12 General conditions

(1) The following shall be conditions of every licence granted under this Act—

...(c) except in relation to the use of gametes in the course of providing basic partner treatment services, that the provisions of Schedule 3 to this Act shall be complied with,...

##### 13 Conditions of licences for treatment

(6) A woman shall not be provided with treatment services of a kind specified in Part 1 of Schedule 3ZA unless she and any man or woman who is to be treated together with her have been given a suitable opportunity to receive proper counselling about the implications of her being provided with treatment services of that kind, and have been provided with such relevant information as is proper.

(6A) A woman shall not be provided with treatment services after the happening of any event falling within any paragraph of Part 2 of Schedule 3ZA unless (before or after the event) she and the intended second parent have been given a suitable opportunity to receive proper counselling about the implications of the woman being provided with treatment services after the happening of that event, and have been provided with such relevant information as is proper.

##### 13A Conditions of licences for non-medical fertility services

(3) A woman shall not be provided with any non-medical fertility services involving the use of sperm other than partner-donated sperm unless the woman being provided with the services has been given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and has been provided with such relevant information as is proper.

##### Schedule 3

Consent to use or storage of gametes, embryos or human admixed embryos etc.

3 (1) Before a person gives consent under this Schedule –

(a) he must be given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and



## Mandatory requirements (cont)

- 3 (1)(cont)
- (b) he must be provided with such relevant information as is proper.

### Licence conditions

T58 Prior to giving consent gamete providers must be provided with information about:

- a. the nature of the treatment
- b. its consequences and risks
- c. any analytical tests, if they are to be performed
- d. the recording and protection of personal data and confidentiality
- e. the right to withdraw or vary their consent, and
- f. the availability of counselling.

T59 The information referred to in licence condition T58 must be given by trained personnel in a manner and using terms that are easily understood by the gamete provider.

NOTE: For the mandatory requirements pertaining to consent, see guidance note 5.

### Directions

**0005** – Collecting and recording information for the HFEA

For a copy of the relevant Directions visit [www.hfea.gov.uk](http://www.hfea.gov.uk)



## HFEA guidance

### Information to provide



#### Interpretation of mandatory requirements

4A

The law requires appropriate information to be provided when:

- (a) a woman or couple seeks treatment with donated gametes or embryos
- (b) an individual or couple seeks treatment that will create embryos in vitro
- (c) an individual or couple seeks to store their gametes or embryos (for exceptions, see Schedule 3 of the HFE Act 1990 (as amended), paragraphs 9 or 10)
- (d) an individual or couple seeks to donate their gametes or embryos for the treatment of others
- (e) an individual seeks to donate their gametes for use in non-medical fertility services
- (f) an individual or couple seeks to donate their embryos for research purposes, or for training people in embryo biopsy, embryo storage or other embryological techniques
- (g) an individual seeks to provide their gametes or cells for the creation of embryos or human admixed embryos for research (for exceptions see mandatory requirements outlined in guidance note 22 – Research and training)
- (h) a woman provides embryos (obtained by lavage) for any purpose



### Interpretation of mandatory requirements (cont)

4A

- (i) written notice is served by a man or a woman consenting to the man being treated as the legal father of any child born as a result of the woman's treatment, or
- (j) written notice is served by a woman, or her female partner, consenting to the partner being treated as the legal parent of any child born as a result of the woman's treatment.

Information must always be provided before consent is given to treatment, storage, provision or donation (cases (a) to (h) above) or treatment is provided or continued (cases (i) and (j) above).

## Distinguishing the provision of information from the offer of counselling

**4.1** The provision of information should be clearly distinguished from the offer of counselling.

See also guidance note:

- [3 – Counselling](#)

## Information for those seeking treatment

**4.2** Before treatment is offered, the centre should give the woman seeking treatment and her partner, if applicable, information about:

- (a) the centre's policy on selecting patients
- (b) the centre's statutory duty to take account of the welfare of any resulting or affected child
- (c) the expected waiting time for treatment
- (d) fertility treatments available
- (e) the likely outcomes of the proposed treatment (data provided should include the centre's most recent live birth rate and clinical pregnancy rate per treatment cycle, verified by the HFEA, and the national live birth rate and clinical pregnancy rate per treatment cycle)
- (f) the nature and potential risks of the treatment, including the risk of children conceived having developmental and birth defects
- (g) the possible side effects and risks to the woman being treated and any resulting child, including ovarian hyperstimulation syndrome (OHSS)
- (h) in the case of fresh egg donation, the screening requirement of the donor and the risk of infection for the recipient
- (i) the availability of facilities for freezing embryos, and the implications of storing embryos and then using embryos
- (j) the importance of informing the treatment centre about the eventual outcome of the treatment (including if no live birth results)
- (k) the centre's complaints procedure, and
- (l) the nature and potential risks (immediate and longer term) of IVF/ICSI with in vitro matured eggs, including reference to the clinic's experience.



### Information about the cost of treatment

- 4.3** Before treatment, storage or both are offered, the centre should also give the person seeking treatment or storage, and their partner (if applicable) a personalised costed treatment plan. The plan should detail the main elements of the treatment proposed (including investigations and tests), the cost of that treatment and any possible changes to the plan, including their cost implications. The centre should give patients the opportunity to discuss the plan before treatment begins.

### Further information to provide

- 4.4** There are different kinds of information centres should give, where appropriate, to patients, patients' partners and donors prior to obtaining consent to treatment, storage or donation. Centre staff should familiarise themselves with all the appropriate information to provide. This information is contained in the following list of guidance notes:

- 5 – Consent to treatment, storage, donation, and disclosure of information
- 6 – Legal parenthood
- 7 – Multiple births
- 8 – Welfare of the child
- 9 – Preimplantation genetic screening (PGS)
- 10 – Embryo testing and sex selection
- 11 – Donor recruitment, assessment and screening
- 12 – Egg sharing arrangements
- 14 – Surrogacy
- 15 – Procuring, processing and transporting gametes and embryos
- 17 – Storage of gametes and embryos
- 20 – Donor assisted conception
- 21 – Intra-cytoplasmic sperm injection (ICSI)
- 22 – Research and training
- 30 – Confidentiality and privacy



### Other legislation, professional guidelines and information

- National Institute for Clinical Excellence – Fertility: Assessment and treatment for people with fertility problems – [www.nice.org.uk/nicemedia/pdf/CG011niceguideline.pdf](http://www.nice.org.uk/nicemedia/pdf/CG011niceguideline.pdf)
- For further information on multiple births, please go to the One at a Time website at – [www.oneatatime.org.uk](http://www.oneatatime.org.uk)

# 5. Consent to treatment, storage, donation and disclosure of information

This guidance note contains:

 Refer to principles 5, 6 and 10

## Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Extracts from licence conditions
- Reference to relevant HFEA Directions
- Reference to relevant Regulations

## HFEA guidance

- Consent to use and storage of gametes and embryos ■
- Procedure for obtaining consent ■
- Recording consent and related information ■
- Additional consent requirements for storing gametes and embryos ■
- Additional consent requirements for using gametes and embryos ■
- Additional consent requirements for those participating in an egg sharing arrangement
- Consent to examination and treatment
- Consent to the presence of observers ■
- Consent to disclose identifying information
- Cases where consent is not required for storage ●■
- Competence
- Variation and withdrawal of consent ●■

● Section includes mandatory requirements

■ Section includes interpretation of mandatory requirements

## Other legislation, professional guidelines and information



## Mandatory requirements

### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

#### 12 General conditions

(1) The following shall be conditions of every licence granted under this Act–

... (c) except in relation to the use of gametes in the course of providing basic partner treatment services, that the provisions of Schedule 3 to this Act shall be complied with..,

#### Schedule 3 – Consent to use or storage of gametes, embryos or human admixed embryos etc

- 1 (1) A consent under this Schedule, and any notice under paragraph 4 varying or withdrawing a consent under this Schedule, must be in writing and, subject to sub-paragraph (2), must be signed by the person giving it.
- (2) A consent under this Schedule by a person who is unable to sign because of illness, injury or physical disability (a “person unable to sign”), and any notice under paragraph 4 by a person unable to sign varying or withdrawing a consent under this Schedule, is to be taken to comply with the requirement of sub-paragraph (1) as to signature if it is signed at the direction of the person unable to sign, in the presence of the person unable to sign and in the presence of at least one witness who attests the signature.

Human Fertilisation and Embryology Authority



## Mandatory requirements (cont)

(3) In this Schedule “effective consent” means a consent under this Schedule which has not been withdrawn.

- 2 (1) A consent to the use of any embryo must specify one or more of the following purposes–
- (a) use in providing treatment services to the person giving consent, or that person and another specified person together,
  - (b) use in providing treatment services to persons not including the person giving consent,
  - (ba) use for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques, or
  - (c) use for the purposes of any project of research,
- and may specify conditions subject to which the embryo may be so used.

(2) A consent to the storage of any gametes, any embryo or any human admixed embryo must–

- (a) specify the maximum period of storage (if less than the statutory storage period),
- (b) except in a case falling within paragraph (c), state what is to be done with the gametes, embryo or human admixed embryo if the person who gave the consent dies or is unable, because the person lacks capacity to do so, to vary the terms of the consent or to withdraw it, and
- (c) where the consent is given by virtue of paragraph 8(2ZA) or 13(2), state what is to be done with the embryo or human admixed embryo if the person to whom the consent relates dies,

and may (in any case) specify conditions subject to which the gametes, embryo or human admixed embryo may remain in storage.

(2A) A consent to the use of a person’s human cells to bring about the creation in vitro of an embryo or human admixed embryo is to be taken unless otherwise stated to include consent to the use of the cells after the person’s death.

(2B) In relation to Scotland, the reference in sub-paragraph (2)(b) to the person lacking capacity is to be read as a reference to the person–

- (a) lacking capacity within the meaning of the Age of Legal Capacity (Scotland) Act 1991, or
- (b) being incapable within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000.

(3) A consent under this Schedule must provide for such other matters as the Authority may specify in Directions.

(4) A consent under this Schedule may apply–

- (a) to the use or storage of a particular embryo or human admixed embryo, or
- (b) in the case of a person providing gametes or human cells, to the use or storage of –
  - (i) any embryo or human admixed embryo whose creation may be brought about using those gametes or those cells, and
  - (ii) any embryo or human admixed embryo whose creation may be brought about using such an embryo or human admixed embryo.

(5) In the case of a consent falling within sub-paragraph (4)(b), the terms of the consent may be varied, or the consent may be withdrawn, in accordance with this Schedule either generally or in relation to –

- (a) a particular embryo or particular embryos, or
- (b) a particular human admixed embryo or particular human admixed embryos.



## Mandatory requirements (cont)

### Procedure for giving consent

- 3 (1) Before a person gives consent under this Schedule—
- (a) he must be given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and
  - (b) he must be provided with such relevant information as is proper.
- (2) Before a person gives consent under this Schedule he must be informed of the effect of paragraph 4 and, if relevant, paragraph 4A below.

### Use of gametes for treatment of others

- 5 (1) A person's gametes must not be used for the purposes of treatment services or non-medical fertility services unless there is an effective consent by that person to their being so used and they are used in accordance with the terms of the consent.
- (2) A person's gametes must not be received for use for those purposes unless there is an effective consent by that person to their being so used.
- (3) This paragraph does not apply to the use of a person's gametes for the purpose of that person, or that person and another together, receiving treatment services.

### In vitro fertilisation and subsequent use of embryo

- 6 (1) A person's gametes or human cells must not be used to bring about the creation of any embryo in vitro unless there is an effective consent by that person to any embryo, the creation of which may be brought about with the use of those gametes or human cells, being used for one or more of the purposes mentioned in paragraph 2(1)(a), (b) and (c) above.
- (2) An embryo the creation of which was brought about in vitro must not be received by any person unless there is an effective consent by each relevant person in relation to the embryo to the use for one or more of the purposes mentioned in paragraph 2(1) (a), (b), (ba) and (c) above of the embryo.
- (3) An embryo the creation of which was brought about in vitro must not be used for any purpose unless there is an effective consent by each relevant person in relation to the embryo to the use for that purpose of the embryo and the embryo is used in accordance with those consents.
- (3E) For the purposes of sub-paragraphs (2), (3) and (3ZB) each of the following is a relevant person in relation to an embryo the creation of which was brought about in vitro ("embryo A")—
- (a) each person whose gametes or human cells were used to bring about the creation of embryo A,
  - (b) each person whose gametes or human cells were used to bring about the creation of any other embryo, the creation of which was brought about in vitro, which was used to bring about the creation of embryo A, and
  - (c) each person whose gametes or human cells were used to bring about the creation of any human admixed embryo, the creation of which was brought about in vitro, which was used to bring about the creation of embryo A.
- (4) Any consent required by this paragraph is in addition to any consent that may be required by paragraph 5 above.

### Embryos obtained by lavage, etc

- 7 (1) An embryo taken from a woman must not be used for any purpose unless there is an effective consent by her to the use of the embryo for that purpose and it is used in accordance with the consent.
- (2) An embryo taken from a woman must not be received by any person for use for any purpose unless there is an effective consent by her to the use of the embryo for that purpose.
- (3) Sub-paragraphs (1) and (2) do not apply to the use, for the purpose of providing a woman with treatment services, of an embryo taken from her.



## Mandatory requirements (cont)

(4) An embryo taken from a woman must not be used to bring about the creation of any embryo in vitro or any human admixed embryo in vitro.

### Storage of gametes and embryos

- 8
- (1) A person's gametes must not be kept in storage unless there is an effective consent by that person to their storage and they are stored in accordance with the consent.
  - (2) An embryo the creation of which was brought about in vitro must not be kept in storage unless there is an effective consent, by each relevant person in relation to the embryo, to the storage of the embryo and the embryo is stored in accordance with those consents...
- (2C) For the purposes of sub-paragraphs (2) and (2A) each of the following is a relevant person in relation to an embryo the creation of which was brought about in vitro ("embryo A")–
- (a) each person whose gametes or human cells were used to bring about the creation of embryo A,
  - (b) each person whose gametes or human cells were used to bring about the creation of any other embryo, the creation of which was brought about in vitro, which was used to bring about the creation of embryo A, and
  - (c) each person whose gametes or human cells were used to bring about the creation of any human admixed embryo, the creation of which was brought about in vitro, which was used to bring about the creation of embryo A.
- (3) An embryo taken from a woman must not be kept in storage unless there is an effective consent by her to its storage and it is stored in accordance with the consent.
- (4) Sub-paragraph (1) has effect subject to paragraphs 9 and 10; and sub-paragraph (2) has effect subject to paragraphs 4A(4), 16 and 20.

### Interpretation

- 16
- (6) References in this Schedule to capacity are, in relation to England and Wales, to be read in accordance with the Mental Capacity Act 2005.

### Licence conditions

- T57
- Gametes or embryos must not be used in the provision of treatment services (except in the use of gametes in the course of providing basic partner treatment services or non-medical fertility services) unless effective consent is in place from each gamete provider in accordance with Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended).

### Directions

**0006** – Import and export of gametes and embryos

**0007** – Consent

For a copy of the relevant Directions visit [www.hfea.gov.uk](http://www.hfea.gov.uk)

### Regulations

The Human Fertilisation and Embryology (Special Exemptions) Regulations 1991



### Consent to use and storage of gametes and embryos



#### Interpretation of mandatory requirements

5A

The law requires the centre to obtain written informed consent from a person before it performs the following procedures:

- (a) storing their gametes (exemptions are outlined in the HFE (Special Exemptions) Regulations 1991)
- (b) using their gametes for the treatment of others or for non-medical fertility services
- (c) creating embryos in vitro with their gametes
- (d) storing embryos created with their gametes
- (e) using embryos created with their gametes for their own treatment, treatment of a partner or treatment of others
- (f) using embryos created with their gametes for training people in embryo biopsy, embryo storage or other embryological techniques
- (g) using embryos created with their gametes for any research project
- (h) using their cells to create embryos for research, or
- (i) creating human admixed embryos with their gametes or cells.

The centre must ensure it obtains written informed consent from a person before procuring their gametes. If gametes are collected without proper consent, it may be considered assault. Gametes should not be taken from a person if written, informed consent to storage has not been obtained.

If no consent is in place, because the person is unable in law to provide it, or is deceased, then the gametes must not be procured, stored or used. The provisions in the Human Tissue Act 2004 which allow next of kin to provide consent to harvesting of other body tissues do not apply to gametes.

The law allows gametes to be stored without consent if the conditions met in paragraph 9 or 10, and 11 of Schedule 3 of the HFE Act 1990 (as amended) are met.

The law requires that gametes stored without consent cannot be used, unless the gamete provider becomes competent and consents to such use.

If gametes or embryos are to be transferred to a centre outside the UK, the UK centre must obtain the consent of the gamete provider(s) to their export to the country in which the receiving centre is situated. Such consent must then be provided to the centre receiving the gametes or embryos.

If gametes or embryos are to be transferred into the UK from a centre outside the UK, the person responsible for the UK centre must be satisfied that the provider has given written consent to the transfer of the gametes or embryos to the UK, and has not withdrawn that consent.

Further requirements and the exemptions regarding obtaining consent to the use of gametes, cells and embryos for research (including for the creation of admixed embryos), and the exemptions, are outlined in guidance note 22 – Research and training.

Requirements regarding consent to parenthood are outlined in guidance note 6 – Legal parenthood.

**5.1** The centre should obtain written informed consent from a person before it carries out the following procedures:

- (a) using their gametes for their own treatment or their partner's treatment, or
- (b) using their gametes for research and training.



- 5.2** When a woman is to undergo an egg or embryo transfer, the centre should:
- obtain her consent to the proposed number of eggs or embryos to be transferred, and
  - record her consent in her medical records.
- 5.3** The centre should establish and use documented procedures to ensure that no activity involving the handling or processing of gametes or embryos is carried out without the appropriate consent having been given.

See also guidance note:

- 15 – Procuring, processing and transporting gametes and embryos**

### Procedure for obtaining consent



#### Interpretation of mandatory requirements

5B

The law requires that before a person consents to the procedures outlined in box 5A, they should be given:

- enough information to enable them to understand the nature, purpose and implications of their treatment or donation
- a suitable opportunity to receive proper counselling about the implications of the steps which they are considering taking, and
- information about the procedure for varying or withdrawing any consent given, and about the implications of doing so.

- 5.4** Centres should ensure that, before a person gives consent, they are given the information outlined in guidance note 4 – Information to be provided prior to consent.
- 5.5** The centre should inform anyone providing gametes that they can, if they wish, specify extra conditions for storing or using their gametes (or embryos created using them).
- 5.6** The centre should give anyone seeking treatment or considering donation or storage enough time to reflect on their decisions before obtaining their consent. The centre should give them an opportunity to ask questions and receive further information, advice and guidance.
- 5.7** If the possibility of donating gametes or embryos for the treatment of others, or donating embryos for research or training purposes, arises during the course of treatment, the centre should allow potential donors enough time to consider the implications and to receive counselling before giving consent.
- 5.8** The centre should ensure that consent is:
- given voluntarily (without pressure to accept treatment or agree to donation)
  - given by a person who has capacity to do so, as defined by the Mental Capacity Act 2005 (England and Wales), or the Age of Legal Capacity (Scotland) Act 1991 and the Adults with Incapacity (Scotland) Act 2000, and
  - taken by a person authorised by the centre to do so.
- 5.9** The centre should ensure that anyone giving consent declares that:
- they were given enough information to enable them to understand the nature, purpose and implications of the treatment or donation
  - they were given a suitable opportunity to receive proper counselling about the implications of the proposed procedures



- (c) they were given information about the procedure for varying or withdrawing consent, and
- (d) the information they have given in writing is correct and complete.

- 5.10** Treatment centres should take all reasonable steps to verify the identity of anyone accepted for treatment, including partners who may not visit the centre during treatment. If a patient's identity is in doubt, the centre should verify their identity, including examining photographic evidence such as a passport or a photocard driving licence. The centre should record this evidence in the patient's medical records.
- 5.11** To avoid the possibility of misrepresentation or mistake, the centre should check the identities of patients (and their partners, if applicable) against identifying information in the medical records. This should be done at each consultation, examination, treatment or donation.
- 5.12** The centre should consider the needs of people whose first language is not English and those who face other communication barriers. Where consent is obtained, the centre should record:
- (a) any difficulties in communicating the implications of giving consent and providing other information to the person (eg, language barriers or hearing impairment), and
  - (b) an explanation of how these difficulties were overcome (eg, the use of an independent interpreter).<sup>1</sup>
- 5.13** The centre should establish and follow documented procedures to obtain written informed consent.

See also guidance note:

- [3 – Counselling](#)
- [4 – Information to be provided prior to consent](#)
- [22 – Research and training](#)
- [23 – The quality management system](#)
- [29 – Treating people fairly](#)

See also:

- [HFEA consent forms available at www.hfea.gov.uk](http://www.hfea.gov.uk)

### Recording consent and related information



#### Interpretation of mandatory requirements

5C

The law requires consent, or any subsequent variation or withdrawal of consent, to be in writing and signed by the person giving consent, except in the following situation:

If the person giving consent, or varying or withdrawing consent, has the mental capacity to do so but cannot sign because of illness, injury or physical disability (for example, quadriplegia), they can direct someone to sign on their behalf, provided that:

- (a) the person giving consent, or varying or withdrawing consent is present at the time, and
- (b) the signature is also witnessed, and attested to by at least one other person.

- 5.14** The centre should keep a copy of the signed consent forms and make a copy available to those giving consent.
- 5.15** The centre should ensure that it documents in the medical records that relevant information, as outlined in guidance note 4, has been provided to the person giving consent.

<sup>1</sup> This guidance is based on a paragraph taken from the Human Tissue Authority's Code of Practice on Consent (2008).



See also guidance note:

- [4 – Information to be provided prior to consent](#)
- [31 – Record keeping and document control](#)

See also:

- [HFEA consent forms available at \[www.hfea.gov.uk\]\(http://www.hfea.gov.uk\)](#)

### Additional consent requirements for storing gametes and embryos



#### Interpretation of mandatory requirements

5D

Written consent to the storage of gametes, embryos or human admixed embryos must:

- specify the maximum period of storage (if less than the statutory storage period), and
- state what should be done with the gametes, embryos or human admixed embryos if the person giving the consent dies or cannot, because of mental incapacity, withdraw or vary the terms of the consent.

In relation to (b), where consent is given following the application of the parental consent provisions in Schedule 3, the consent needs only to specify what is to be done with the embryo or the human admixed embryo if the person to whom the consent relates dies.

The consent may also specify conditions under which the gametes, embryos or human admixed embryos may remain in storage.

If sperm was in storage on 1 August 1991, storage may legally continue without the written consent of the individual who provided the sperm. However, the centre is not obliged to continue to store sperm in the absence of a written agreement to do so.

- 5.16** The centre should normally ask patients to give consent to storage at the same time as consent to the use of gametes and embryos. However, the centre should accommodate anyone seeking long-term storage of gametes who may wish to consent to storage separately from consent to use.
- 5.17** Before the centre obtains consent from anyone wishing to store gametes or embryos for more than 10 years, it should ensure that the conditions for extended storage in the relevant regulations are satisfied.

See also guidance note:

- [6 – Legal parenthood](#)
- [17 – Storage of gametes and embryos](#)

See also:

- [HFEA consent forms](#)
- [The Human Fertilisation and Embryology \(Statutory Storage Period for Embryos and Gametes\) Regulations 2009](#)



### Additional consent requirements for using gametes and embryos



#### Interpretation of mandatory requirements

5E

The law requires the centre to ensure that consent to the use of any embryo (not a human admixed embryo) must specify one or more of the following uses for the embryo:

- (a) providing treatment for the person giving the consent, or, where applicable, that person and another named person together
- (b) providing treatment for others
- (c) training centre staff in embryo biopsy, embryo storage or other embryological techniques, or
- (d) contributing to a specified research project.

In relation to human admixed embryos, the law requires that consent to their use must specify use for a research project.

The consent may also specify conditions for how the embryo may be used.

- 5.18** Consent to the use of gametes or embryos for the treatment of others should state the number of families that may have children using the donated gametes or embryos.
- 5.19** When an individual gives consent to the use of gametes for the treatment of others, the centre need not get consent from the donor's partner or spouse. However, if the donor is married, in a civil partnership or in a long-term relationship, the centre should encourage them to seek their partner's support for the donation of their gametes.
- 5.20** Men who wish to donate embryos originally created for the treatment of their partner and themselves, and those people considering treatment with such embryos, should be:
- (a) informed of the uncertain legal status of men donating embryos created originally for the treatment of their partner and themselves, when the embryos are used in the treatment of a single woman
  - (b) referred to information on the HFEA's website on this issue, and
  - (c) advised to seek independent legal advice before consenting to donate their embryos or being treated with the embryos.

See also guidance note:

- [20 – Donor assisted conception](#)
- [22 – Research and training](#)

See also:

- [HFEA consent forms available at www.hfea.gov.uk](http://www.hfea.gov.uk)

### Additional consent requirements for those participating in an egg sharing arrangement

- 5.21** The person obtaining consent should ensure that an egg provider's consent is recorded so that different conditions can be placed on:
- (a) the use of eggs and the use and storage of embryos created for the egg provider's own treatment, and
  - (b) the use of eggs, and the use and storage of embryos created for the treatment of the recipient(s).

These conditions should be able to be varied independently of each other.



**5.22** The person obtaining consent should tell the egg provider and recipient(s) that the egg provider may withdraw or vary her consent up to when an egg or embryo created using her eggs, is:

- (a) transferred to a woman
- (b) used in a research project (defined as being under the control of the researchers and being cultured for use in research)
- (c) used for training, or
- (d) allowed to perish.

The possible consequences of this should:

- (a) be made clear to the egg provider and the recipient(s) before the egg sharing cycle begins, and
- (b) be set out in the written patient information included with the egg sharing agreement.

See also guidance note:

- [12 – Egg sharing arrangements](#)

See also:

- [HFEA consent forms available at www.hfea.gov.uk](http://www.hfea.gov.uk)

### Consent to examination and treatment

**5.23** Everyone has the right to withhold or give consent to examination and treatment. Unless there are exceptional circumstances, the centre may not examine, treat or receive gametes from people without first obtaining their consent. The only exceptional circumstance likely to arise during fertility treatment is:

- (a) where the procedure is necessary to save the patient's life, and
- (b) the treatment cannot be postponed, and
- (c) the patient is unconscious or mentally incapacitated so cannot indicate their wishes.

**5.24** The centre should comply with current professional guidelines on consent.

### Consent to the presence of observers

**5.25** If a member of the centre's team wishes an observer to be present when a patient is being examined, treated or counselled, they should explain why beforehand and state who the observer is. The centre should give the patient appropriate information about the proposed observation and ask them whether they consent to the observer's presence.

### Consent to disclose identifying information



#### Interpretation of mandatory requirements

5F

Patients have the right to decide what identifying information should be disclosed and to whom. Centres should obtain a patient's written consent before disclosing information relating to their treatment (or providing gametes for a partner's treatment), or the storage of gametes or embryos.

In addition, consent is needed from any person who could be identified through disclosure of information about a person's treatment or the storage of gametes or embryos. For example, consent would be needed from a patient's partner if they could be identified through disclosure of information about the patient's treatment.



### Interpretation of mandatory requirements (cont)

5F

If a child born as a result of treatment could be identified, consent must be obtained from the parent(s), unless identification is necessary in disclosing information about the patient's treatment. Once a child born as a result of treatment is considered competent to consent, then their consent (if given) will override the consent of the parent(s).

- 5.26** Before obtaining consent to disclose information, the centre should give the person enough information for them to make a properly informed decision, including:
- precisely what information is to be disclosed
  - the terms on which it is to be disclosed
  - the reasons for disclosure (eg, to keep the person's GP informed about the fertility treatment)
  - the implications of disclosure, in particular the fact that, once it is disclosed, the information will be subject no longer to the special provisions of the HFE Act 1990 (as amended) but only to the general law of confidentiality, and
  - the categories of people to whom the information is to be disclosed.
- 5.27** The centre should seek consent to disclosure to the following categories of people:
- the patient's GP or the patient's partner's GP
  - other healthcare professionals outside the centre (so they can provide the patient or the patient's partner with the best possible medical care)
  - auditors or administrative staff outside of the centre (so they can perform their functions in connection with the centre's licensable activities), and
  - medical or other researchers (so they can contact the patient about specific research projects or carry out non-contact research).
- 5.28** The centre should renew consent to disclosure if the nature of treatment changes after initial consent has been given (eg, if during treatment, it is proposed that donor gametes are used instead of the patient's own, or if the patient moves from unlicensed to licensed fertility treatment).
- 5.29** The centre should ensure that people to whom they disclose identifying information know that the information remains protected by the existing common law on confidentiality. Those receiving information should also be told:
- the precise terms upon which it was disclosed and for which consent has been given, and
  - that if they disclose the information they have received, a child might learn in an inappropriate way that they were born as a result of fertility treatment.

See also guidance note:

- [30 – Confidentiality and privacy \('Consent to disclose identifying information'\)](#)

See also:

- [HFEA consent forms available at www.hfea.gov.uk](http://www.hfea.gov.uk)



### Cases where consent is not required for storage



#### Mandatory requirements

##### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

##### Schedule 3

##### Cases where consent not required for storage

- 9 (1) The gametes of a person (“C”) may be kept in storage without C’s consent if the following conditions are met.
- (2) Condition A is that the gametes are lawfully taken from or provided by C before C attains the age of 18 years.
- (3) Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that C is expected to undergo medical treatment and that in the opinion of the registered medical practitioner–
- (a) the treatment is likely to cause a significant impairment of C’s fertility, and
- (b) the storage of the gametes is in C’s best interests.
- (4) Condition C is that, at the time when the gametes are first stored, either–
- (a) C has not attained the age of 16 years and is not competent to deal with the issue of consent to the storage of the gametes, or
- (b) C has attained that age but, although not lacking capacity to consent to the storage of the gametes, is not competent to deal with the issue of consent to their storage.
- (5) Condition D is that C has not, since becoming competent to deal with the issue of consent to the storage of the gametes–
- (a) given consent under this Schedule to the storage of the gametes, or
- (b) given written notice to the person keeping the gametes that C does not wish them to continue to be stored.
- (6) In relation to Scotland, sub-paragraphs (1) to (5) are to be read with the following modifications–
- (a) for sub-paragraph (4), substitute–
- “(4) Condition C is that, at the time when the gametes are first stored, C does not have capacity (within the meaning of section 2(4) of the Age of Legal Capacity (Scotland) Act 1991) to consent to the storage of the gametes.”, and
- (b) in sub-paragraph (5), for “becoming competent to deal with the issue of consent to the storage of the gametes” substitute “acquiring such capacity”.
- 10 (1) The gametes of a person (“P”) may be kept in storage without P’s consent if the following conditions are met.
- (2) Condition A is that the gametes are lawfully taken from or provided by P after P has attained the age of 16 years.
- (3) Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that P is expected to undergo medical treatment and that in the opinion of the registered medical practitioner–
- (a) the treatment is likely to cause a significant impairment of P’s fertility,
- (b) P lacks capacity to consent to the storage of the gametes,



### Mandatory requirements (cont)

(3) (cont)

(c) P is likely at some time to have that capacity, and

(d) the storage of the gametes is in P's best interests.

(4) Condition C is that, at the time when the gametes are first stored, P lacks capacity to consent to their storage.

(5) Condition D is that P has not subsequently, at a time when P has capacity to give a consent under this Schedule—

(a) given consent to the storage of the gametes, or

(b) given written notice to the person keeping the gametes that P does not wish them to continue to be stored.

(6) In relation to Scotland—

(a) references in sub-paragraphs (3) and (4) to P lacking capacity to consent are to be read as references to P being incapable, within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000, of giving such consent,

(b) the references in sub-paragraphs (3) and (5) to P having capacity are to be read as references to P not being so incapable, and

(c) that Act applies to the storage of gametes under this paragraph to the extent specified in section 84A of that Act.

11 A person's gametes must not be kept in storage by virtue of paragraph 9 or 10 after the person's death.



### Interpretation of mandatory requirements

5G

The law allows gametes to be stored without consent if the conditions met in paragraph 9 or 10, and 11 of Schedule 3 of the HFE Act 1990 (as amended) are met.

Gametes stored following the application of these paragraphs may be used only if the person from whom they were collected gives written effective consent to their use (and has sufficient capacity and competence to do so).

**5.30** Before storing someone's gametes without their consent, the centre should judge that the person is not competent to consent to the storage of gametes. When assessing the competence of children and adults to consent, the centre should follow current guidance produced by the Department of Health, the General Medical Council and other professional bodies.

**5.31** The centre should presume that it is in the child's best interests to store gametes unless circumstances suggest otherwise. When assessing whether it is in a child's best interests to procure and store their gametes, the centre should refer to the General Medical Council guidance '0-18 years: guidance for all doctors' and consider the child's short- and long-term best interests. Consent should be sought from the child when they reach competence.

**5.32** The centre should provide written information that children and young people can read and understand easily. This information should be given by a member of staff experienced in communicating with children.



### Competence

- 5.33** If the centre's staff doubt someone's competence to consent to a proposed procedure, or to the storage or use of gametes or embryos, they should:
- (a) refer to the Mental Capacity Act 2005 (England and Wales), or the Age of Legal Capacity (Scotland) Act 1991 and the Adults with Incapacity (Scotland) Act 2000, and
  - (b) follow the current guidelines of professional bodies. If they remain in any doubt, the centre should seek legal advice.

### Variation and withdrawal of consent



#### Mandatory requirements

##### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

##### Schedule 3

##### Variation and withdrawal of consent

- 4 (1) The terms of any consent under this Schedule may from time to time be varied, and the consent may be withdrawn, by notice given by the person who gave the consent to the person keeping the gametes, human cells, embryo or human admixed embryo to which the consent is relevant.
- (2) Subject to sub-paragraph (3), the terms of any consent to the use of any embryo cannot be varied, and such consent cannot be withdrawn, once the embryo has been used—
- (a) in providing treatment services,
    - (aa) in training persons in embryo biopsy, embryo storage or other embryological techniques, or
    - (b) for the purposes of any project of research.
  - (3) Where the terms of any consent to the use of an embryo ("embryo A") include consent to the use of an embryo or human admixed embryo whose creation may be brought about in vitro using embryo A, that consent to the use of that subsequent embryo or human admixed embryo cannot be varied or withdrawn once embryo A has been used for one or more of the purposes mentioned in sub-paragraph (2)(a) or (b).
- 4A (1) This paragraph applies where—
- (a) a permitted embryo, the creation of which was brought about in vitro, is in storage,
  - (b) it was created for use in providing treatment services,
  - (c) before it is used in providing treatment services, one of the persons whose gametes were used to bring about its creation ("P") gives the person keeping the embryo notice withdrawing P's consent to the storage of the embryo, and
  - (d) the embryo was not to be used in providing treatment services to P alone.
- (2) The person keeping the embryo must as soon as possible take all reasonable steps to notify each interested person in relation to the embryo of P's withdrawal of consent.
- (3) For the purposes of sub-paragraph (2), a person is an interested person in relation to an embryo if the embryo was to be used in providing treatment services to that person.
- (4) Storage of the embryo remains lawful until—
- (a) the end of the period of 12 months beginning with the day on which the notice mentioned in sub-paragraph (1) was received from P, or



### Mandatory requirements (cont)

(4) (cont)

(b) if, before the end of that period, the person keeping the embryo receives a notice from each person notified of P's withdrawal under sub-paragraph (2) stating that the person consents to the destruction of the embryo, the time at which the last of those notices is received.

(5) The reference in sub-paragraph (1)(a) to a permitted embryo is to be read in accordance with section 3ZA.



### Interpretation of mandatory requirements

5H

The law allows consent to be varied or withdrawn at any point until gametes or embryos (other than human admixed embryos) are used to provide treatment services, or used for a research project or for training.

Consent to the use of any human admixed embryo can be varied or withdrawn until the embryo has been used for a research project.

If someone wishes to withdraw consent to the storage or use of gametes, embryos or human admixed embryos, they must do so in writing, except if they are unable to do so because of illness, injury or incapacity. In these cases, they can direct someone to sign on their behalf, provided that the person withdrawing consent is present at the time, and that the signature is also witnessed and attested to by at least one other person.

If one of the gamete providers withdraws consent to the continued storage of embryos intended for treatment (created from their gametes), the law requires the centre to take all reasonable steps to notify the intended recipient(s).

The law allows embryos to be stored for 12 months from the date that the centre receives written withdrawal of consent, or less if the centre receives written signed consent from all intended recipients for the embryos to be destroyed.

This 12 month 'cooling off' period must not extend beyond the end of the statutory storage period.

- 5.34** The centre should check the identity of anyone withdrawing or varying consent against identifying information held in the medical records. The centre should also ensure that the person withdrawing or varying consent has been given sufficient information to enable them to make an informed decision about doing so.
- 5.35** The centre should have procedures for dealing with disputes that may arise when one gamete provider withdraws their consent to the use or storage of gametes or embryos in treatment. In this situation the centre should stop treatment and notify all relevant parties. Centres should provide information about counselling or mediation services as appropriate.

See also:

- [HFEA consent forms available at www.hfea.gov.uk](http://www.hfea.gov.uk)



### Consent to examination and treatment

- Reference Guide to Consent for Examination or Treatment (Department of Health, April 2001) – [www.library.nhs.uk/Emergency/ViewResource.aspx?resID=30135](http://www.library.nhs.uk/Emergency/ViewResource.aspx?resID=30135)
- Consent: patients and doctors making decisions together (General Medical Council, 2008) – [www.gmc-uk.org/news/articles/Consent\\_guidance.pdf](http://www.gmc-uk.org/news/articles/Consent_guidance.pdf)
- Human Tissue Authority Code of Practice 1: Consent (Human Tissue Authority, September 2009) – [www.hta.gov.uk](http://www.hta.gov.uk)
- Gynaecological Examinations: Guidelines for Specialist Practice (RCOG 2002) – [www.rcog.org.uk/resources/public/pdf/WP\\_GynaeExams4.pdf](http://www.rcog.org.uk/resources/public/pdf/WP_GynaeExams4.pdf)

### Competence

- Consent: patients and doctors making decisions together (General Medical Council, 2008) – [www.gmc-uk.org](http://www.gmc-uk.org)
- 0–18 years: guidance for all doctors (General Medical Council, 2007) – [www.gmc-uk.org](http://www.gmc-uk.org)
- Seeking consent: working with children (Department of Health, January 2001)
- Best Practice Guidance for Doctors and other Health Professionals on the provision of Advice and Treatment to Young People under 16 on Contraception, Sexual and Reproductive Health (Department of Health, 2004)
- Mental Capacity Act 2005
- Mental Capacity Act 2005 – Code of Practice (2007)
- Age of Legal Capacity (Scotland) Act 1991
- Adults with Incapacity (Scotland) Act 2000

Copies of the relevant legislation can be found at [www.opsi.gov.uk](http://www.opsi.gov.uk)

# 6. Legal parenthood

## This guidance note contains:

 Refer to principles 5, 6 and 10

### Mandatory requirements

- Extracts from the HFE Act 2008
- Extracts from licence conditions

### HFEA guidance

- Legal parenthood and parental responsibility
- Legal parenthood when the woman has a husband ■
- Legal parenthood when the woman has a civil partner ■
- Legal parenthood: male partner ■
- Legal parenthood: female partner ■
- Parenthood after death of a man providing sperm ■
- Parenthood after death of a partner who has not provided sperm ■
- Legal parenthood: surrogacy ■
- General procedures for obtaining consent
- People not to be treated as parents ■●
- Information provision and counselling ■●
- Notification of withdrawal of consent to parenthood ■●

● Section includes mandatory requirements

■ Section includes interpretation of mandatory requirements



## Mandatory requirements

### Human Fertilisation and Embryology (HFE) Act 2008

#### PART 2: PARENTHOOD IN CASES INVOLVING ASSISTED REPRODUCTION

##### Meaning of “mother”

#### 33 Meaning of “mother”

- (1) The woman who is carrying or has carried a child as a result of the placing in her of an embryo or of sperm and eggs, and no other woman, is to be treated as the mother of the child.
- (2) Subsection (1) does not apply to any child to the extent that the child is treated by virtue of adoption as not being the woman’s child.
- (3) Subsection (1) applies whether the woman was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or the sperm and eggs.

##### Application of sections 35 to 47

#### 34 Application of sections 35 to 47

- (1) Sections 35 to 47 apply, in the case of a child who is being or has been carried by a woman (referred to in those sections as “W”) as a result of the placing in her of an embryo or of sperm and eggs or her artificial insemination, to determine who is to be treated as the other parent of the child.
- (2) Subsection (1) has effect subject to the provisions of sections 39, 40 and 46 limiting the purposes for which a person is treated as the child’s other parent by virtue of those sections.



## Mandatory requirements (cont)

### Meaning of “father”

#### 35 Woman married at time of treatment

- (1) If–
- (a) at the time of the placing in her of the embryo or of the sperm and eggs or of her artificial insemination, W was a party to a marriage, and
  - (b) the creation of the embryo carried by her was not brought about with the sperm of the other party to the marriage, then, subject to section 38(2) to (4), the other party to the marriage is to be treated as the father of the child unless it is shown that he did not consent to the placing in her of the embryo or the sperm and eggs or to her artificial insemination (as the case may be).
- (2) This section applies whether W was in the United Kingdom or elsewhere at the time mentioned in subsection (1)(a).

#### 36 Treatment provided to woman where agreed fatherhood conditions apply

If no man is treated by virtue of section 35 as the father of the child and no woman is treated by virtue of section 42 as a parent of the child but–

- (a) the embryo or the sperm and eggs were placed in W, or W was artificially inseminated, in the course of treatment services provided in the United Kingdom by a person to whom a licence applies,
- (b) at the time when the embryo or the sperm and eggs were placed in W, or W was artificially inseminated, the agreed fatherhood conditions (as set out in section 37) were satisfied in relation to a man, in relation to treatment provided to W under the licence,
- (c) the man remained alive at that time, and
- (d) the creation of the embryo carried by W was not brought about with the man’s sperm,

then, subject to section 38(2) to (4), the man is to be treated as the father of the child.

#### 37 The agreed fatherhood conditions

- (1) The agreed fatherhood conditions referred to in section 36(b) are met in relation to a man (“M”) in relation to treatment provided to W under a licence if, but only if,–
- (a) M has given the person responsible a notice stating that he consents to being treated as the father of any child resulting from treatment provided to W under the licence,
  - (b) W has given the person responsible a notice stating that she consents to M being so treated,
  - (c) neither M nor W has, since giving notice under paragraph (a) or (b), given the person responsible notice of the withdrawal of M’s or W’s consent to M being so treated,
  - (d) W has not, since the giving of the notice under paragraph (b), given the person responsible–
    - (i) a further notice under that paragraph stating that she consents to another man being treated as the father of any resulting child, or
    - (ii) a notice under section 44(1)(b) stating that she consents to a woman being treated as a parent of any resulting child, and
  - (e) W and M are not within prohibited degrees of relationship in relation to each other.
- (2) A notice under subsection (1)(a), (b) or (c) must be in writing and must be signed by the person giving it.
- (3) A notice under subsection (1)(a), (b) or (c) by a person (“S”) who is unable to sign because of illness, injury or physical disability is to be taken to comply with the requirement of subsection (2) as to signature if it is signed at the direction of S, in the presence of S and in the presence of at least one witness who attests the signature.

#### 38 Further provision relating to sections 35 and 36



## Mandatory requirements (cont)

- (1) Where a person is to be treated as the father of the child by virtue of section 35 or 36, no other person is to be treated as the father of the child.
- (2) In England and Wales and Northern Ireland, sections 35 and 36 do not affect any presumption, applying by virtue of the rules of common law, that a child is the legitimate child of the parties to a marriage.
- (3) In Scotland, sections 35 and 36 do not apply in relation to any child who, by virtue of any enactment or other rule of law, is treated as the child of the parties to a marriage.
- (4) Sections 35 and 36 do not apply to any child to the extent that the child is treated by virtue of adoption as not being the man's child.

### 39 Use of sperm, or transfer of embryo, after death of man providing sperm

- (1) If—
  - (a) the child has been carried by W as a result of the placing in her of an embryo or of sperm and eggs or her artificial insemination,
  - (b) the creation of the embryo carried by W was brought about by using the sperm of a man after his death, or the creation of the embryo was brought about using the sperm of a man before his death but the embryo was placed in W after his death,
  - (c) the man consented in writing (and did not withdraw the consent)—
    - (i) to the use of his sperm after his death which brought about the creation of the embryo carried by W or (as the case may be) to the placing in W after his death of the embryo which was brought about using his sperm before his death, and
    - (ii) to being treated for the purpose mentioned in subsection (3) as the father of any resulting child,
  - (d) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the man to be treated for the purpose mentioned in subsection (3) as the father of the child, and
  - (e) no-one else is to be treated—
    - (i) as the father of the child by virtue of section 35 or 36 or by virtue of section 38(2) or (3), or
    - (ii) as a parent of the child by virtue of section 42 or 43 or by virtue of adoption,

then the man is to be treated for the purpose mentioned in subsection (3) as the father of the child.

- (2) Subsection (1) applies whether W was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or of the sperm and eggs or of her artificial insemination.
- (3) The purpose referred to in subsection (1) is the purpose of enabling the man's particulars to be entered as the particulars of the child's father in a relevant register of births.
- (4) In the application of this section to Scotland, for any reference to a period of 42 days there is substituted a reference to a period of 21 days.

### 40 Embryo transferred after death of husband etc. who did not provide sperm

- (1) If—
  - (a) the child has been carried by W as a result of the placing in her of an embryo,
  - (b) the embryo was created at a time when W was a party to a marriage,
  - (c) the creation of the embryo was not brought about with the sperm of the other party to the marriage,
  - (d) the other party to the marriage died before the placing of the embryo in W,



## Mandatory requirements (cont)

- (e) the other party to the marriage consented in writing (and did not withdraw the consent)–
  - (i) to the placing of the embryo in W after his death, and
  - (ii) to being treated for the purpose mentioned in subsection (4) as the father of any resulting child,
- (f) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the man to be treated for the purpose mentioned in subsection (4) as the father of the child, and
- (g) no-one else is to be treated–
  - (i) as the father of the child by virtue of section 35 or 36 or by virtue of section 38(2) or (3), or
  - (ii) as a parent of the child by virtue of section 42 or 43 or by virtue of adoption,

then the man is to be treated for the purpose mentioned in subsection (4) as the father of the child.

(2) If–

- (a) the child has been carried by W as a result of the placing in her of an embryo,
- (b) the embryo was not created at a time when W was a party to a marriage or a civil partnership but was created in the course of treatment services provided to W in the United Kingdom by a person to whom a licence applies,
- (c) a man consented in writing (and did not withdraw the consent)–
  - (i) to the placing of the embryo in W after his death, and
  - (ii) to being treated for the purpose mentioned in subsection (4) as the father of any resulting child,
- (d) the creation of the embryo was not brought about with the sperm of that man,
- (e) the man died before the placing of the embryo in W,
- (f) immediately before the man's death, the agreed fatherhood conditions set out in section 37 were met in relation to the man in relation to treatment proposed to be provided to W in the United Kingdom by a person to whom a licence applies,
- (g) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the man to be treated for the purpose mentioned in subsection (4) as the father of the child, and
- (h) no-one else is to be treated–
  - (i) as the father of the child by virtue of section 35 or 36 or by virtue of section 38(2) or (3), or
  - (ii) as a parent of the child by virtue of section 42 or 43 or by virtue of adoption,

then the man is to be treated for the purpose mentioned in subsection (4) as the father of the child.

- (3) Subsections (1) and (2) apply whether W was in the United Kingdom or elsewhere at the time of the placing in her of the embryo.
- (4) The purpose referred to in subsections (1) and (2) is the purpose of enabling the man's particulars to be entered as the particulars of the child's father in a relevant register of births.
- (5) In the application of this section to Scotland, for any reference to a period of 42 days there is substituted a reference to a period of 21 days.

Cases in which woman to be other parent



## Mandatory requirements (cont)

### 42 Woman in civil partnership at time of treatment

- (1) If at the time of the placing in her of the embryo or the sperm and eggs or of her artificial insemination, W was a party to a civil partnership, then subject to section 45(2) to (4), the other party to the civil partnership is to be treated as a parent of the child unless it is shown that she did not consent to the placing in W of the embryo or the sperm and eggs or to her artificial insemination (as the case may be).
- (2) This section applies whether W was in the United Kingdom or elsewhere at the time mentioned in subsection (1).

### 43 Treatment provided to woman who agrees that second woman to be parent

If no man is treated by virtue of section 35 as the father of the child and no woman is treated by virtue of section 42 as a parent of the child but—

- (a) the embryo or the sperm and eggs were placed in W, or she was artificially inseminated, in the course of treatment services provided in the United Kingdom by a person to whom a licence applies,
- (b) at the time when the embryo or the sperm and eggs were placed in W, or W was artificially inseminated, the agreed female parenthood conditions (as set out in section 44) were met in relation to another woman, in relation to treatment provided to W under that licence, and
- (c) the other woman remained alive at that time,

then, subject to section 45(2) to (4), the other woman is to be treated as a parent of the child.

### 44 The agreed female parenthood conditions

- (1) The agreed female parenthood conditions referred to in section 43(b) are met in relation to another woman (“P”) in relation to treatment provided to W under a licence if, but only if,—
  - (a) P has given the person responsible a notice stating that P consents to P being treated as a parent of any child resulting from treatment provided to W under the licence,
  - (b) W has given the person responsible a notice stating that W agrees to P being so treated,
  - (c) neither W nor P has, since giving notice under paragraph (a) or (b), given the person responsible notice of the withdrawal of P’s or W’s consent to P being so treated,
  - (d) W has not, since the giving of the notice under paragraph (b), given the person responsible—
    - (i) a further notice under that paragraph stating that W consents to a woman other than P being treated as a parent of any resulting child, or
    - (ii) a notice under section 37(1)(b) stating that W consents to a man being treated as the father of any resulting child, and
  - (e) W and P are not within prohibited degrees of relationship in relation to each other.
- (2) A notice under subsection (1)(a), (b) or (c) must be in writing and must be signed by the person giving it.
- (3) A notice under subsection (1)(a), (b) or (c) by a person (“S”) who is unable to sign because of illness, injury or physical disability is to be taken to comply with the requirement of subsection (2) as to signature if it is signed at the direction of S, in the presence of S and in the presence of at least one witness who attests the signature.

### 45 Further provision relating to sections 42 and 43

- (1) Where a woman is treated by virtue of section 42 or 43 as a parent of the child, no man is to be treated as the father of the child.
- (2) In England and Wales and Northern Ireland, sections 42 and 43 do not affect any presumption, applying by virtue of the rules of common law, that a child is the legitimate child of the parties to a marriage.
- (3) In Scotland, sections 42 and 43 do not apply in relation to any child who, by virtue of any enactment or other rule of law, is treated as the child of the parties to a marriage.



## Mandatory requirements (cont)

(4) Sections 42 and 43 do not apply to any child to the extent that the child is treated by virtue of adoption as not being the woman's child.

46 Embryo transferred after death of civil partner or intended female parent

(1) If–

- (a) the child has been carried by W as the result of the placing in her of an embryo,
- (b) the embryo was created at a time when W was a party to a civil partnership,
- (c) the other party to the civil partnership died before the placing of the embryo in the woman,
- (d) the other party to the civil partnership consented in writing (and did not withdraw the consent)–
  - (i) to the placing of the embryo in W after the death of the other party, and
  - (ii) to being treated for the purpose mentioned in subsection (4) as the parent of any resulting child,
- (e) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the other party to the civil partnership to be treated for the purpose mentioned in subsection (4) as the parent of the child, and
- (f) no one else is to be treated–
  - (i) as the father of the child by virtue of section 35 or 36 or by virtue of section 45(2) or (3),  
or
  - (ii) as a parent of the child by virtue of section 42 or 43 or by virtue of adoption,

then the other party to the civil partnership is to be treated for the purpose mentioned in subsection (4) as a parent of the child.

(2) If–

- (a) the child has been carried by W as the result of the placing in her of an embryo,
- (b) the embryo was not created at a time when W was a party to a marriage or a civil partnership, but was created in the course of treatment services provided to W in the United Kingdom by a person to whom a licence applies,
- (c) another woman consented in writing (and did not withdraw the consent)–
  - (i) to the placing of the embryo in W after the death of the other woman, and
  - (ii) to being treated for the purpose mentioned in subsection (4) as the parent of any resulting child,
- (d) the other woman died before the placing of the embryo in W,
- (e) immediately before the other woman's death, the agreed female parenthood conditions set out in section 44 were met in relation to the other woman in relation to treatment proposed to be provided to W in the United Kingdom by a person to whom a licence applies,
- (f) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the other woman to be treated for the purpose mentioned in subsection (4) as the parent of the child, and
- (g) no one else is to be treated–
  - (i) as the father of the child by virtue of section 35 or 36 or by virtue of section 45(2) or (3),  
or
  - (ii) as a parent of the child by virtue of section 42 or 43 or by virtue of adoption,

then the other woman is to be treated for the purpose mentioned in subsection (4) as a parent of the child.



## Mandatory requirements (cont)

- (3) Subsections (1) and (2) apply whether W was in the United Kingdom or elsewhere at the time of the placing in her of the embryo.
- (4) The purpose referred to in subsections (1) and (2) is the purpose of enabling the deceased woman's particulars to be entered as the particulars of the child's other parent in a relevant register of births.
- (5) In the application of subsections (1) and (2) to Scotland, for any reference to a period of 42 days there is substituted a reference to a period of 21 days.

### 48 Effect of sections 33 to 47

- (1) Where by virtue of section 33, 35, 36, 42 or 43 a person is to be treated as the mother, father or parent of a child, that person is to be treated in law as the mother, father or parent (as the case may be) of the child for all purposes.
- (2) Where by virtue of section 33, 38, 41, 45 or 47 a person is not to be treated as a parent of the child, that person is to be treated in law as not being a parent of the child for any purpose.
- (3) Where section 39(1) or 40(1) or (2) applies, the deceased man—
- (a) is to be treated in law as the father of the child for the purpose mentioned in section 39(3) or 40(4), but
  - (b) is to be treated in law as not being the father of the child for any other purpose.
- (4) Where section 46(1) or (2) applies, the deceased woman—
- (a) is to be treated in law as a parent of the child for the purpose mentioned in section 46(4), but
  - (b) is to be treated in law as not being a parent of the child for any other purpose.
- (5) Where any of subsections (1) to (4) has effect, references to any relationship between two people in any enactment, deed or other instrument or document (whenever passed or made) are to be read accordingly.
- (6) In relation to England and Wales and Northern Ireland, a child who—
- (a) has a parent by virtue of section 42, or
  - (b) has a parent by virtue of section 43 who is at any time during the period beginning with the time mentioned in section 43(b) and ending with the time of the child's birth a party to a civil partnership with the child's mother, is the legitimate child of the child's parents.
- (7) In relation to England and Wales and Northern Ireland, nothing in the provisions of section 33(1) or sections 35 to 47, read with this section—
- (a) affects the succession to any dignity or title of honour or renders any person capable of succeeding to or transmitting a right to succeed to any such dignity or title, or
  - (b) affects the devolution of any property limited (expressly or not) to devolve (as nearly as the law permits) along with any dignity or title of honour.
- (8) In relation to Scotland—
- (a) those provisions do not apply to any title, coat of arms, honour or dignity transmissible on the death of its holder or affect the succession to any such title, coat of arms or dignity or its devolution, and
  - (b) where the terms of any deed provide that any property or interest in property is to devolve along with a title, coat of arms, honour or dignity, nothing in those provisions is to prevent that property or interest from so devolving.



## Mandatory requirements (cont)

### References to parties to marriage or civil partnership

#### 49 Meaning of references to parties to a marriage

- (1) The references in sections 35 to 47 to the parties to a marriage at any time there referred to—
  - (a) are to the parties to a marriage subsisting at that time, unless a judicial separation was then in force, but
  - (b) include the parties to a void marriage if either or both of them reasonably believed at that time that the marriage was valid; and for the purposes of those sections it is to be presumed, unless the contrary is shown, that one of them reasonably believed at that time that the marriage was valid.
- (2) In subsection (1)(a) “judicial separation” includes a legal separation obtained in a country outside the British Islands and recognised in the United Kingdom.

#### 50 Meaning of references to parties to a civil partnership

- (1) The references in sections 35 to 47 to the parties to a civil partnership at the time there referred to—
  - (a) are to the parties to a civil partnership subsisting at that time, unless a separation order was then in force, but
  - (b) include the parties to a void civil partnership if either or both of them reasonably believed at that time that the civil partnership was valid; and for the purposes of those sections it is to be presumed, unless the contrary is shown, that one of them reasonably believed at that time that the civil partnership was valid.
- (2) The reference in section 48(6)(b) to a civil partnership includes a reference to a void civil partnership if either or both of the parties reasonably believed at the time when they registered as civil partners of each other that the civil partnership was valid; and for this purpose it is to be presumed, unless the contrary is shown, that one of them reasonably believed at that time that the civil partnership was valid.
- (3) In subsection (1)(a), “separation order” means—
  - (a) a separation order under section 37(1)(d) or 161(1)(d) of the Civil Partnership Act 2004 (c. 33),
  - (b) a decree of separation under section 120(2) of that Act, or
  - (c) a legal separation obtained in a country outside the United Kingdom and recognised in the United Kingdom.

### Further provision about registration by virtue of section 39, 40 or 46

#### 51 Meaning of “relevant register of births”

For the purposes of this Part a “relevant register of births”, in relation to a birth, is whichever of the following is relevant—

- (a) a register of live-births or still-births kept under the Births and Deaths Registration Act 1953 (c. 20),
  - (b) a register of births or still-births kept under the Registration of Births, Deaths and Marriages (Scotland) Act 1965 (c. 49), or
  - (c) a register of live-births or still-births kept under the Births and Deaths Registration (Northern Ireland) Order 1976 (S.I. 1976/1041 (N.I. 14)).
- #### 52 Late election by mother with consent of Registrar General
- (1) The requirement under section 39(1), 40(1) or (2) or 46(1) or (2) as to the making of an election (which requires an election to be made either on or before the day on which the child was born or within the period of 42 or, as the case may be, 21 days from that day) is nevertheless to be treated as satisfied if the required election is made after the end of that period but with the consent of the Registrar General under subsection (2).



## Mandatory requirements (cont)

- (2) The Registrar General may at any time consent to the making of an election after the end of the period mentioned in subsection (1) if, on an application made to him in accordance with such requirements as he may specify, he is satisfied that there is a compelling reason for giving his consent to the making of such an election.
- (3) In this section “the Registrar General” means the Registrar General for England and Wales, the Registrar General of Births, Deaths and Marriages for Scotland or (as the case may be) the Registrar General for Northern Ireland.

Interpretation of references to father etc. where woman is other parent

53 Interpretation of references to father etc.

- (1) Subsections (2) and (3) have effect, subject to subsections (4) and (6), for the interpretation of any enactment, deed or any other instrument or document (whenever passed or made).
- (2) Any reference (however expressed) to the father of a child who has a parent by virtue of section 42 or 43 is to be read as a reference to the woman who is a parent of the child by virtue of that section.
- (3) Any reference (however expressed) to evidence of paternity is, in relation to a woman who is a parent by virtue of section 42 or 43, to be read as a reference to evidence of parentage.
- (4) This section does not affect the interpretation of the enactments specified in subsection (5) (which make express provision for the case where a child has a parent by virtue of section 42 or 43).
- (5) Those enactments are—
  - (a) the Legitimacy Act (Northern Ireland) 1928 (c. 5 (N.I.)),
  - (b) the Schedule to the Population (Statistics) Act 1938 (c. 12),
  - (c) the Births and Deaths Registration Act 1953 (c. 20),
  - (d) the Registration of Births, Deaths and Marriages (Special Provisions) Act 1957 (c. 58),
  - (e) Part 2 of the Registration of Births, Deaths and Marriages (Scotland) Act 1965 (c. 49),
  - (f) the Congenital Disabilities (Civil Liability) Act 1976 (c. 28),
  - (g) the Legitimacy Act 1976 (c. 31),
  - (h) the Births and Deaths Registration (Northern Ireland) Order 1976 (S.I. 1976/1041 (N.I. 14)),
  - (i) the British Nationality Act 1981 (c. 61),
  - (j) the Family Law Reform Act 1987 (c. 42),
  - (k) Parts 1 and 2 of the Children Act 1989 (c. 41),
  - (l) Part 1 of the Children (Scotland) Act 1995 (c. 36),
  - (m) section 1 of the Criminal Law (Consolidation) (Scotland) Act 1995 (c. 39), and
  - (n) Parts 2, 3 and 14 of the Children (Northern Ireland) Order 1995 (S.I. 1995/755 (N.I. 2)).
- (6) This section does not affect the interpretation of references that fall to be read in accordance with section 1(2)(a) or (b) of the Family Law Reform Act 1987 or Article 155(2)(a) or (b) of the Children (Northern Ireland) Order 1995 (references to a person whose father and mother were, or were not, married to each other at the time of the person’s birth).

58 Interpretation of Part 2

- (2) For the purposes of this Part, two persons are within prohibited degrees of relationship if one is the other’s parent, grandparent, sister, brother, aunt or uncle; and in this subsection references to relationships—
  - (a) are to relationships of the full blood or half blood or, in the case of an adopted person, such of those relationships as would subsist but for adoption, and



## Mandatory requirements (cont)

- (2) (cont)
- (b) include the relationship of a child with his adoptive, or former adoptive, parents, but do not include any other adoptive relationships.

### Licence conditions

- T60 A woman must not be provided with treatment services using embryos or donated gametes unless she and any man or woman who is to be treated together with her have been given a suitable opportunity to receive proper counselling about the implications of her being provided with treatment services of that kind, and have been provided with such relevant information as is proper.
- T61 A woman must not be provided with treatment services where there is an intended second parent unless, either before or after both have consented to the man or woman being the intended second parent, she and the intended second parent have been given a suitable opportunity to receive proper counselling about the implications of the woman being provided with treatment services and have been provided with such relevant information as is proper.
- T62 The reference in licence conditions T60 and T61 above to the intended second parent is a reference to:
- any man with respect to whom the agreed fatherhood conditions in Section 37 of the Human Fertilisation and Embryology Act 2008 (“the 2008 Act”) are for the time being satisfied in relation to treatment provided to the woman mentioned in licence conditions T60 and T61, and
  - any woman with respect to whom the agreed female parenthood conditions in Section 44 of the 2008 Act are for the time being satisfied in relation to treatment provided to the woman mentioned in licence conditions T60 and T61.
- T63 In the case of treatment services using donated gametes, or embryos created using donated gametes, the person receiving treatment and any intended second parent, must be provided with information about:
- the importance of informing any resulting child at an early age that they were born as a result of such treatment, and
  - suitable methods of informing such a child of that fact.
- T64 In cases where the nominated second parent withdraws their consent to be treated as the parent of any child born to a named woman, the PR must:
- notify the woman in writing of the receipt of the notice from the second parent, and
  - ensure that no treatment services are provided to the named woman until she has been notified of the second parent’s withdrawal of consent.
- T65 If a woman withdraws her consent to her nominated second parent being treated as the legal parent, or consents to a different person being the legal parent of any child resulting from treatment, the PR must notify the original nominated second parent in writing of this.



## HFEA guidance

### Legal parenthood and parental responsibility

- 6.1** The centre should provide information to people seeking treatment about legal parenthood. This information should include who will be the child’s legal parent(s) under the HFE Act 2008 and other relevant legislation. Nationals or residents of other countries, or individuals treated with gametes obtained from nationals or residents of other countries, should be informed that the law in other countries may be different from that in the United Kingdom.
- 6.2** The centre should explain that there is a difference in law between the legal status of ‘father’ or ‘parent’ and having ‘parental responsibility’ for a child. In any case in which people seeking treatment have doubts or concerns about legal parenthood or parental responsibility for a child born as a result of treatment services, the centre should advise them to seek their own legal advice.



See also:

- [Human Fertilisation and Embryology Act 2008 explanatory notes available at www.opsi.gov.uk](http://www.opsi.gov.uk)

### Legal parenthood when the woman has a husband



#### Interpretation of mandatory requirements

6A

Where a married woman is seeking treatment using her husband's sperm or embryos created using her husband's sperm, then the husband will automatically be the legal father of any child born as a result of the treatment.

Where a married woman is seeking treatment using sperm other than that of her husband, or an embryo created using sperm other than that of her husband, her husband will be treated as the father of any child born as a result of that treatment unless:

- at the time the sperm and eggs or embryos were placed in her, or she was inseminated, she and her husband were judicially separated, or
- it is shown that the husband did not consent to the placing in her of the sperm and eggs or embryos, or to her insemination.

**6.3** If a married woman is seeking treatment using donor sperm, or embryos created using donor sperm, the centre should take all practical steps to:

- ascertain whether the husband consents to the treatment (taking into account the duty of confidentiality to the woman, where applicable), and
- obtain a written record of the husband's consent. If the husband does not consent, the centre should take all practical steps to obtain written evidence of this.

**6.4** If the centre cannot obtain a written record of the husband's consent or refusal to consent, it should record the steps taken to establish whether he consents to the treatment in the medical records.

**6.5** If a married woman wishes to be treated with a new partner (with his sperm or with donor sperm or a donor embryo) and her husband does not consent to his wife's treatment, then the woman's new partner can be the father or parent of any child born as a result of this treatment, if the right consents are in place.

### Legal parenthood when the woman has a civil partner



#### Interpretation of mandatory requirements

6B

Where a woman in a civil partnership is seeking treatment using donor sperm, or embryos created using donor sperm, the woman's civil partner will be treated as the legal parent of any resulting child unless, at the time of placing the embryo or sperm and eggs in the woman, or of her insemination:

- a separation order was in force, or
- it is shown that the civil partner did not consent to the placing in her of the sperm and eggs, or embryos, or to the insemination.

**6.6** If a woman in a civil partnership is seeking treatment using donor sperm, or embryos created using donor sperm, the centre should take all practical steps to:

- ascertain whether the civil partner consents to the treatment (taking into account the duty of confidentiality to the woman seeking treatment, where applicable), and



### 6.6 (cont)

- (b) obtain a written record of the civil partner's consent – if the civil partner does not consent, the centre should take all practical steps to obtain written evidence of this.

6.7 If the centre cannot obtain a written record of the civil partner's consent or refusal to consent, it should record the steps taken to establish whether the civil partner consents to the treatment in the medical records.

### Legal parenthood: male partner



#### Interpretation of mandatory requirements

6C

'Male partner' is the term used throughout this guidance note to refer to any man who intends to be the legal father of any child born from treatment, who is not married to and is not within a prohibited degree of relationship to the woman being treated (as defined in section 58(2), part 2, HFE Act 2008).

Where a woman is seeking treatment using her partner's sperm, or embryos created using her partner's sperm, the partner will automatically be the legal father of any child born as a result of the treatment.

Where a woman who is not married or in a civil partnership (or a woman who is separated from her husband or civil partner or whose husband or civil partner does not consent to the treatment) is to be treated with a male partner using donor sperm, or embryos created with donor sperm, the male partner can be treated as the legal father of any resulting child if, at the time the eggs and sperm or embryos are placed in the woman or she is inseminated:

- (a) both the woman and the male partner have given written, signed notice (subject to the exemption for illness, injury or physical disability) to the centre consenting to the male partner being treated as the father of any resulting child
- (b) neither of these consents has been withdrawn
- (c) the woman has not given any subsequent consent to any other man or woman being treated as the legal parent of any resulting child, and
- (d) the patient and male partner are not within prohibited degrees of relationship to each other (as defined in section 58(2), HFE Act 2008).

### Legal parenthood: female partner



#### Interpretation of mandatory requirements

6D

'Female partner' is the term used throughout this guidance note to refer to any woman who intends to be the legal parent of any child born from treatment, who is not in a civil partnership with or within a prohibited degree of relationship to the woman being treated (as defined in section 58(2), part 2, HFE Act 2008).

Where a woman who is not married or in a civil partnership (or a woman who is separated from her husband or civil partner or whose husband or civil partner does not consent to the treatment) is to be treated together with a female partner using donor sperm, or embryos created with donor sperm, the female partner can be treated as the legal parent of any resulting child if, at the time the eggs and sperm or embryos are placed in the woman or she is inseminated:

- (a) both the woman and the female partner have given written, signed notice (subject to the exemption for illness, injury or physical disability) to the centre consenting to the female partner being treated as the parent of any resulting child
- (b) neither of these consents has been withdrawn
- (c) the woman has not given any subsequent consent to any other man or woman being treated as the legal parent of any resulting child, and
- (d) the patient and female partner are not within prohibited degrees of relationship to each other (as defined in section 58(2), part 2, HFE Act 2008).



### Parenthood after death of a man providing sperm



#### Interpretation of mandatory requirements

6E

A husband or male partner who has provided sperm for the treatment of their wife or female partner can be registered as the father of any child born as a result of treatment after their death, if the following conditions are met:

- (a) the man had given written consent for his sperm, or embryos created using his sperm, to be used after his death in the treatment of his wife or partner
- (b) the man had given written consent to being registered as the father of any resulting child
- (c) the woman elected in writing, within 42 days (21 days in Scotland) after the child's birth for the man's details to be entered in the relevant register of births, and
- (d) no-one else is to be treated as the father or parent of the child.

The treatment can involve insemination of sperm, transfer of sperm and eggs, or transfer of embryos created before or after the man's death. The centre must ensure that partners are given an opportunity to consent to this.

### Parenthood after death of a partner who has not provided sperm



#### Interpretation of mandatory requirements

6F

A partner (husband, civil partner or other partner) who has not provided sperm for the treatment of their wife or female partner can be registered as the father or parent of any child born as a result of treatment after their death, if the following conditions are met:

- (a) the treatment involved the transfer to the woman of an embryo after the death of the partner
- (b) the embryo was created when the partner was alive
- (c) the partner had given written consent for the embryo to be placed in the woman after their death
- (d) the partner had given written consent to being registered as the father or parent of any resulting child
- (e) the woman elected in writing, within 42 days (21 days in Scotland) after the child's birth, for the partner's details to be entered in the relevant register of births, and
- (f) no-one else is to be treated as the father or parent of the child.

The centre must ensure that partners are given an opportunity to consent to this.

### Legal parenthood: surrogacy



#### Interpretation of mandatory requirements

6G

##### Surrogate mother

The woman who gives birth to the child (in this case the surrogate) is the legal mother when the child is born.

##### Intended parents

The intended parents (whether they are husband and wife, civil partners or two persons who are living as partners) will not be the parents upon birth of the child. Parenthood will need to be obtained by parental order or adoption.



### Interpretation of mandatory requirements (cont)

6G

#### Partner of the surrogate mother

If the surrogate is married or in a civil partnership, her husband or civil partner will be the legal father or parent of any child born as a result of her treatment, unless it is shown that the husband/partner does not consent to the treatment.

If the surrogate has a partner whom she is not married to or in a civil partnership with, the partner must have consented to being the father or parent of any child born as a result of treatment in order to be legally recognised as such. The surrogate must have also consented to her partner being recognised as the father or parent.

#### Intended father and sperm provider

If the intended father in a surrogacy arrangement has provided sperm for the treatment of the surrogate, he will need to register as a donor and therefore cannot be the father upon birth of the child. Fatherhood will need to be obtained by parental order or adoption.

See also guidance note:

- [14 – Surrogacy](#)

### General procedures for obtaining consent

- 6.8** The centre should establish documented procedures to obtain written informed consent. The centre should retain the signed consent forms and ensure that a copy is available for those who have given consent.
- 6.9** When anyone gives, withdraws or varies consent, the centre should check their identity against identifying information held in the medical records. If there is doubt about a patient's identity, the centre should take steps to verify this, including examining photo identification such as a photocard driving licence or passport. The centre should record this evidence in the medical records.
- 6.10** The centre should ensure that there is a written record in the medical records that information has been provided to the person giving consent in each case.
- 6.11** The centre should ensure that consent is:
- given voluntarily
  - given by a person who has the capacity to do so, and
  - taken by a person authorised by the centre to do so.
- 6.12** The centre should ensure that any person giving consent declares that:
- they were given enough information to understand the nature, purpose and implications of receiving treatment (or their partner receiving treatment) following consent
  - they were given a suitable opportunity to receive proper counselling about the implications of receiving treatment (or their partner receiving treatment) following consent
  - they were given information about the procedure for varying or withdrawing consent, and
  - the information they have given in writing is correct and complete.
- 6.13** When obtaining consent to register the partner as the parent after their death, the centre should ensure that the partner consents to their details and identifying information about treatment being disclosed to the Registrar General.



### People not to be treated as parents



#### Mandatory requirements

##### Human Fertilisation and Embryology (HFE) Act 2008

###### Part 2

###### 41 Persons not to be treated as father

- (1) Where the sperm of a man who had given such consent as is required by paragraph 5 of Schedule 3 to the 1990 Act (consent to use of gametes for purposes of treatment services or non-medical fertility services) was used for a purpose for which such consent was required, he is not to be treated as the father of the child.
- (2) Where the sperm of a man, or an embryo the creation of which was brought about with his sperm, was used after his death, he is not, subject to section 39, to be treated as the father of the child.
- (3) Subsection (2) applies whether W was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or of the sperm and eggs or of her artificial insemination.

###### 47 Woman not to be other parent merely because of egg donation

A woman is not to be treated as the parent of a child whom she is not carrying and has not carried, except where she is so treated—

- (a) by virtue of section 42 or 43, or
- (b) by virtue of section 46 (for the purpose mentioned in subsection (4) of that section), or
- (c) by virtue of adoption.

###### 34 Application of sections 35 to 47

- (1) Sections 35 to 47 apply, in the case of a child who is being or has been carried by a woman (referred to in those sections as “W”) as a result of the placing in her of an embryo or of sperm and eggs or her artificial insemination, to determine who is to be treated as the other parent of the child.



#### Interpretation of mandatory requirements

6H

A sperm donor is not to be treated as the father of any child resulting from the use of his sperm in the treatment of others.

An egg donor is not to be treated as the parent of any child resulting from the use of her egg(s) unless her egg(s), or embryos created from her egg(s), are used in treating a civil partner or other female partner (subject to the requirements in sections 42, 43 or 46 of the HFE Act 2008, where relevant) or the resulting child is adopted by the egg donor.



### Information provision and counselling

#### Mandatory requirements

##### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

##### Section 13

##### Conditions of licences for treatment

- (6) A woman shall not be provided with treatment services of a kind specified in Part 1 of Schedule 3ZA unless she and any man or woman who is to be treated together with her have been given a suitable opportunity to receive proper counselling about the implications of her being provided with treatment services of that kind, and have been provided with such relevant information as is proper.
- (6A) A woman shall not be provided with treatment services after the happening of any event falling within any paragraph of Part 2 of Schedule 3ZA unless (before or after the event) she and the intended second parent have been given a suitable opportunity to receive proper counselling about the implications of the woman being provided with treatment services after the happening of that event, and have been provided with such relevant information as is proper.
- (6B) The reference in subsection (6A) to the intended second parent is a reference to–
- (a) any man as respects whom the agreed fatherhood conditions in section 37 of the Human Fertilisation and Embryology Act 2008 (“the 2008 Act”) are for the time being satisfied in relation to treatment provided to the woman being treated, and
  - (b) any woman as respects whom the agreed female parenthood conditions in section 44 of the 2008 Act are for the time being satisfied in relation to treatment provided to the woman to be treated.
- (6C) In the case of treatment services falling within paragraph 1 of Schedule 3ZA (use of gametes of a person not receiving those services) or paragraph 3 of that Schedule (use of embryo taken from a woman not receiving those services), the information provided by virtue of subsection (6) or (6A) must include such information as is proper about–
- (a) the importance of informing any resulting child at an early age that the child results from the gametes of a person who is not a parent of the child, and
  - (b) suitable methods of informing such a child of that fact.

##### Schedule 3ZA: circumstances in which offer of counselling required as condition of licence for treatment

##### Part 2: events in connection with which counselling must be offered

- 4 A man gives the person responsible a notice under paragraph (a) of subsection (1) of section 37 of the Human Fertilisation and Embryology Act 2008 (agreed fatherhood conditions) in a case where the woman for whom the treatment services are provided has previously given a notice under paragraph (b) of that subsection referring to the man.
- 5 The woman for whom the treatment services are provided gives the person responsible a notice under paragraph (b) of that subsection in a case where the man to whom the notice relates has previously given a notice under paragraph (a) of that subsection.
- 6 A woman gives the person responsible notice under paragraph (a) of subsection (1) of section 44 of that Act (agreed female parenthood conditions) in a case where the woman for whom the treatment services are provided has previously given a notice under paragraph (b) of that subsection referring to her.
- 7 The woman for whom the treatment services are provided gives the person responsible a notice under paragraph (b) of that subsection in a case where the other woman to whom the notice relates has previously given a notice under paragraph (a) of that subsection.



### Information provision and counselling (cont)



#### Interpretation of mandatory requirements

61

The law states that, where a woman who has consented to her male or female partner being treated as the legal parent of any child born as a result of her treatment, and the partner has consented to being the legal parent, treatment may continue after the point at which consent is given only if the woman and her partner:

- (a) have had a suitable opportunity to receive proper counselling about the implications of treatment in these circumstances, and
- (b) have been given proper information.

When people seek treatment using donor gametes or embryos, they must be given information about:

- (a) the importance of informing any resulting child, at an early age, that they were conceived using the gametes of a person who is not their parent, and
- (b) suitable methods of telling the child this.

See also guidance note:

- [3 – Counselling](#)
- [4 – Information to be provided prior to consent](#)

### Notification of withdrawal of consent to parenthood



#### Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Schedule 13

Conditions of licences for treatment

- (6D) Where the person responsible receives from a person (“X”) notice under section 37(1)(c) or 44(1)(c) of the 2008 Act of X’s withdrawal of consent to X being treated as the parent of any child resulting from the provision of treatment services to a woman (“W”), the person responsible–
- (a) must notify W in writing of the receipt of the notice from X, and
  - (b) no person to whom the licence applies may place an embryo or sperm and eggs in W, or artificially inseminate W, until W has been so notified.
- (6E) Where the person responsible receives from a woman (“W”) who has previously given notice under section 37(1)(b) or 44(1)(b) of the 2008 Act that she consents to another person (“X”) being treated as a parent of any child resulting from the provision of treatment services to W–
- (a) notice under section 37(1)(c) or 44(1)(c) of the 2008 Act of the withdrawal of W’s consent, or
  - (b) a notice under section 37(1)(b) or 44(1)(b) of the 2008 Act in respect of a person other than X,
- the person responsible must take reasonable steps to notify X in writing of the receipt of the notice mentioned in paragraph (a) or (b).



### Notification of withdrawal of consent to parenthood (cont)



#### Interpretation of mandatory requirements

6J

If a person withdraws their consent to being treated as the legal parent of any child resulting from the treatment of their partner, the person responsible (PR) must notify the partner in writing of this. The partner must not be treated with sperm and eggs, or with embryos, or be inseminated, until she has been notified in this way.

If a woman withdraws her consent to her partner being treated as the legal parent of any child resulting from the woman's treatment, or notifies the centre that she wishes a different person to be treated as the legal parent of any child resulting from her treatment, the PR must notify the partner in writing of this.

Consent can be withdrawn only before sperm and egg or embryo transfer, or insemination.

- 6.14** The PR should ensure that the written notification they issue explains and refers to the relevant parts of the legislation regarding legal parenthood and withdrawal of consent.

See also:

- [HFEA consent forms available at www.hfea.gov.uk](http://www.hfea.gov.uk)

# 7. Multiple births

## This guidance note contains:


### Mandatory requirements

- Reference to relevant HFEA Directions

### HFEA guidance

- Strategy to minimise multiple births ■
- Limits on egg and embryo transfer ■
- Consent and provision of information

### Other legislation, professional guidelines and information

 Refer to principles 5, 6, 7, 10 and 13

■ Section includes interpretation of mandatory requirements



## Mandatory requirements

### Licence conditions

T123 The centre must not exceed the maximum multiple birth rate specified by Directions.

### Directions

0003 – Multiple births

For a copy of the relevant Directions visit [www.hfea.gov.uk](http://www.hfea.gov.uk)



## HFEA guidance

### Strategy to minimise multiple births



#### Interpretation of mandatory requirements

7A

HFEA Directions require centres to have a documented strategy to minimise multiple births. Its purpose is to reduce the annual rate of multiple births resulting from treatments at the centre.

The strategy must set out:

- (a) how the centre aims to reduce the annual multiple birth rate following treatment at that centre, and to ensure the rate does not exceed the maximum rate specified by the Authority as set out in Directions,
- (b) the circumstances in which the person responsible would consider it appropriate to recommend single embryo transfer (SET) to a patient (in setting out such circumstances, the centre should give proper consideration to relevant professional guidance), and
- (c) the criteria for transferring eggs during gamete intrafallopian transfer (GIFT).

The centre must document regular audits that:

- (a) assess progress in reducing its multiple birth rate, and
- (b) help evaluate the effectiveness of its strategy.



### Interpretation of mandatory requirements (cont)

7A

If more than one embryo is transferred to a patient who fulfilled the SET criteria outlined in the centre's strategy, this should be recorded in the patient's medical records, with:

- (a) an explanation of why the patient did not have SET, and
- (b) evidence that the risks of a multiple pregnancy were fully discussed with the patient before the procedure.

The centre must keep a summary log of all cases where more than one embryo was transferred to a patient who met the SET criteria outlined in the centre's strategy.

See also guidance note:

- [4 – Information to be provided prior to consent](#)
- [5 – Consent to treatment, storage, donation and disclosure of information](#)

## Limits on egg and embryo transfer



### Interpretation of mandatory requirements

7B

HFEA Directions require centres to:

- (a) detail in patients' medical records each time during a treatment cycle that four eggs or three embryos are placed in a woman, including the reasons, and
- (b) keep a summary log of every treatment cycle that involves the placing in a woman of four eggs or three embryos.

- 7.1 The person responsible should ensure that the centre's annual multiple birth rate does not exceed the figure specified by Directions.
- 7.2 When implementing the centre's strategy to minimise multiple births, the person responsible should consider the higher rate of multiple births from blastocyst transfers.
- 7.3 Where appropriate, the centre should have documented standard operating procedures for egg and embryo transfer.
- 7.4 The centre should not transfer more than three eggs or two embryos in any treatment cycle if:
  - (a) the woman is to receive treatment using her own eggs, or embryos created using her own eggs (fresh or cryopreserved), and
  - (b) the woman is aged under 40 at the time of transfer.
- 7.5 The centre should not transfer more than four eggs or three embryos in any treatment cycle if:
  - (a) the woman is to receive treatment using her own eggs, or embryos created using her own eggs (fresh or cryopreserved), and
  - (b) the woman is aged 40 or over at the time of transfer.
- 7.6 If a woman is to receive treatment using donated eggs or embryos, or embryos created with donated eggs, the centre should not transfer more than three eggs or two embryos in a treatment cycle. This is regardless of the procedure used and the woman's age at the time of transfer.



See also guidance note:

- [4 – Information to be provided prior to consent](#)
- [5 – Consent to treatment, storage, donation and disclosure of information](#)

### Consent and provision of information

- 7.7** If the treatment involves the use of superovulatory drugs or the transfer of multiple eggs or embryos in any one cycle (whether fresh or cryopreserved), the centre should give people seeking treatment information about the risks of multiple pregnancy for the woman, the fetus and any resulting child(ren), including:
- (a) the higher risk of miscarriage and complications during pregnancy
  - (b) the higher rate of premature birth and the problems arising from low birth weight, the higher rate of still birth, and the higher rate of perinatal mortality
  - (c) the higher rate of disability and other health problems, plus the potential need for extended stays in hospital before and after birth, and
  - (d) the possible practical, financial and emotional impact on the family and any children.
- 7.8** The centre should give the woman the opportunity to discuss the number of eggs or embryos to be transferred before egg collection and just before embryo transfer.
- 7.9** If a woman is to undergo an egg or embryo transfer, the centre should:
- (a) obtain her consent to the proposed number of eggs or embryos to be transferred and the reasons for this (including her acceptance of the risk of multiple births), and
  - (b) record her consent in her medical records.



### Other legislation, professional guidelines and information

- 'Elective Single Embryo Transfer: Guidelines for Practice', British Fertility Society and Association of Clinical Embryologists, *Human Fertility*, Volume 11, Issue 3 September 2008, pages 131–146 – [www.informahealthcare.com/doi/pdf/10.1080/14647270802302629](http://www.informahealthcare.com/doi/pdf/10.1080/14647270802302629)
- One at a time – better outcomes for fertility treatment (a web-resource for professionals and the public aimed at reducing the rate of multiple births) – [www.oneatatime.org.uk](http://www.oneatatime.org.uk)

# 8. Welfare of the child

## This guidance note contains:

### Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Extracts from licence conditions

### HFEA guidance

- Scope of the welfare of the child provision ■
- The welfare of the child assessment process
- Factors to take into account during the assessment process
- Obtaining further information during the assessment process
- Refusing treatment
- Record keeping

### Other legislation, professional guidelines and information

➔ Refer to principles 1, 4, 6, 7 and 10

■ Section includes interpretation of mandatory requirements



## Mandatory requirements

### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Section 13 (5): A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth.

Section 2 (1) ... “treatment services” means medical, surgical or obstetric services provided to the public or a section of the public for the purpose of assisting women to carry children.

### Licence conditions

T56 A woman must not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth.



## HFEA guidance

### Scope of the welfare of the child provision



#### Interpretation of mandatory requirements

8A

No treatment services regulated by the HFEA (including intrauterine insemination – IUI) may be provided unless account has been taken of the welfare of any child who may be born as a result (including the need of that child for supportive parenting) and of any other child who may be affected by the birth.

**8.1** This guidance note applies to all fertility treatments regulated by the HFEA, including IUI. Centres providing treatments that are not regulated by the HFEA but that fall within the definition of ‘treatment services’ (see above) may also find this guidance note helpful.



### The welfare of the child assessment process

- 8.2** The centre should have documented procedures to ensure that proper account is taken of the welfare of any child who may be born as a result of treatment services, and any other child who may be affected by the birth.
- 8.3** The centre should assess each patient and their partner (if they have one) before providing any treatment, and should use this assessment to decide whether there is a risk of significant harm or neglect to any child referred to in 8.2.
- 8.4** If the child is not to be raised by the carrying mother (ie, in a surrogacy arrangement), the centre should assess both those commissioning the surrogacy arrangement and the surrogate (and the surrogate's partner, if she has one) in case there is a breakdown in the surrogacy arrangement.

See also guidance note:

- [14 – Surrogacy](#)

- 8.5** Assessments do not need to be done on gamete or embryo donors (except those commissioning a surrogacy arrangement), or in cases where gametes are being stored for later use.
- 8.6** The centre should repeat the assessment if:
- (a) the centre has been out of contact with the patient for two years or more
  - (b) the patient has a new partner
  - (c) a child has been born to the patient since the previous assessment, or
  - (d) the centre has reason to believe that the patient's medical or social circumstances have changed significantly.
- 8.7** Those seeking treatment are entitled to a fair assessment. The centre is expected to consider the wishes of all those involved, and the assessment must be done in a non-discriminatory way. In particular, patients should not be discriminated against on grounds of gender, race, disability, sexual orientation, religious belief or age.

See also guidance note:

- [29 – Treating people fairly](#)

- 8.8** If patients have referred themselves for treatment, the centre should take all reasonable steps to verify the identity of those seeking treatment with appropriate evidence (eg, passport or photocard driving licence).
- 8.9** The centre should take a medical and social history from each patient and their partner (if they have one). Where appropriate, the patient and their partner may be interviewed separately. The information gathered should relate to the factors in paragraphs 8.10–8.12 below.

### Factors to take into account during the assessment process

- 8.10** The centre should consider factors that are likely to cause a risk of significant harm or neglect to any child who may be born or to any existing child of the family. These factors include any aspects of the patient's or (if they have one) their partner's:
- (a) past or current circumstances that may lead to any child mentioned above experiencing serious physical or psychological harm or neglect, for example:
    - (i) previous convictions relating to harming children



### 8.10 (cont)

- (ii) child protection measures taken regarding existing children, or
- (iii) violence or serious discord in the family environment
- (b) past or current circumstances that are likely to lead to an inability to care throughout childhood for any child who may be born, or that are already seriously impairing the care of any existing child of the family, for example:
  - (i) mental or physical conditions
  - (ii) drug or alcohol abuse
  - (iii) medical history, where the medical history indicates that any child who may be born is likely to suffer from a serious medical condition, or
  - (iv) circumstances that the centre considers likely to cause serious harm to any child mentioned above.

### 8.11 When considering a child's need for supportive parenting, centres should consider the following definition:

'Supportive parenting is a commitment to the health, well being and development of the child. It is presumed that all prospective parents will be supportive parents, in the absence of any reasonable cause for concern that any child who may be born, or any other child, may be at risk of significant harm or neglect. Where centres have concern as to whether this commitment exists, they may wish to take account of wider family and social networks within which the child will be raised.'

### 8.12 If the child will not be raised by the carrying mother, the centre should take into account the possibility of a breakdown in the surrogacy arrangement and whether this is likely to cause a risk of significant harm or neglect to any child who may be born or any existing children in the surrogate's family.

## Obtaining further information during the assessment process

### 8.13 The centre should obtain consent from the prospective patient (and their partner if they have one) to approach any individuals, agencies or authorities for any factual information required for further investigation if:

- (a) information provided by the patient (and their partner if they have one) suggests a risk of significant harm or neglect to any child
- (b) the patient (and their partner if they have one) has failed to provide any of the information requested
- (c) the information the patient (and their partner if they have one) has provided is inconsistent, or
- (d) there is evidence of deception.

A refusal to provide consent to disclosure of information should not, in itself, be grounds for denying treatment but the centre should take this into account in deciding whether to provide treatment. The centre should discuss with the patient (and their partner if they have one) the reason for refusing to provide consent.

### 8.14 If information has been provided in confidence to a member of staff, the staff member should seek consent from the information provider to discuss it with other staff. If such consent is refused and the member of staff considers the matter to be crucial to a decision, they should use their discretion, based on good professional practice, in deciding whether to break that confidence. In line with professional guidance, patients should normally be informed of the decision to break confidence and the reasons for it, before the information is shared with other members of staff.



### Refusing treatment

- 8.15** The centre should refuse treatment if it:
- (a) concludes that any child who may be born or any existing child of the family is likely to be at risk of significant harm or neglect, or
  - (b) cannot obtain enough information to conclude that there is no significant risk.
- 8.16** In deciding whether to refuse treatment, the centre should:
- (a) take into account the views of all staff who have been involved with caring for the patient (and their partner if they have one), and
  - (b) give the patient (and their partner if they have one) the opportunity to respond to the reason or reasons for refusal before the centre makes a final decision.
- 8.17** If treatment is refused, the centre should explain, in writing, to the patient (and their partner if they have one):
- (a) why treatment has been refused
  - (b) any circumstances that may enable the centre to reconsider its decision
  - (c) any remaining options, and
  - (d) opportunities for obtaining appropriate counselling.

### Record keeping

- 8.18** In all cases, the centre should record in the patient's medical records the information it has considered during the assessment. If further information has been sought or discussion has taken place, the record should reflect the views of those consulted in reaching the decision and the views of the patient (and their partner if they have one).



## Other legislation, professional guidelines and information

- Welfare of the Child patient history form can be found at – [www.hfea.gov.uk/docs/Welfare\\_of\\_the\\_child\\_patient\\_history\\_form.pdf](http://www.hfea.gov.uk/docs/Welfare_of_the_child_patient_history_form.pdf)

# 9. Preimplantation genetic screening (PGS)

## This guidance note contains:

 Refer to principles 5, 7 and 9

### Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Extracts from licence conditions

### HFEA guidance

- The use of PGS ■
- Prohibitions on embryo selection ■

■ Section includes interpretation of mandatory requirements

### Other legislation, professional guidelines and information



## Mandatory requirements

### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

#### Schedule 2

#### *Licences for treatment*

- 1 (1) A licence under this paragraph may authorise any of the following in the course of providing treatment services –
- ...(b) procuring, keeping, testing, processing or distributing embryos...

#### *Embryo testing*

- 1ZA (1) A licence under paragraph 1 cannot authorise the testing of an embryo, except for one or more of the following purposes –
- (a) establishing whether the embryo has a gene, chromosome or mitochondrion abnormality that may affect its capacity to result in a live birth,
  - (b) in a case where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality, establishing whether it has that abnormality or any other gene, chromosome or mitochondrion abnormality,

### Licence conditions

- T88 With respect to any embryo testing programme involving biopsy the centre must ensure that:
- a. no embryo is transferred to a woman where that embryo or any material removed from it or from the gametes that produced it, has been subject to a test that supplies genetic information about the embryo, unless the test has been expressly authorised by the Authority, and
  - b. any information derived from tests on an embryo, or any material removed from it or from the gametes that produced it, is not used to select embryos of a particular sex for social reasons.
- T89 With respect to any embryo testing programme the centre must ensure that embryo testing is only being carried out for those genetic conditions that are expressly authorised by the Authority.



## The use of PGS



### Interpretation of mandatory requirements

9A

An embryo may be tested to establish whether it has a particular chromosomal abnormality only if:

- (a) that abnormality may affect its capacity to result in a live birth, or
- (b) there is a particular risk that it has that abnormality, and where the Authority is satisfied that there is a significant risk that a person with that abnormality will have or develop a serious medical condition.

**9.1** The centre should ensure that before people seeking treatment give consent to PGS for aneuploidy, they are given information explaining:

- (a) the risks associated with the procedure
- (b) the unproven nature of the procedure, in particular that:
  - (i) more robust clinical and laboratory trials are needed to assess whether or not PGS can significantly increase live birth rates
  - (ii) the method of fluorescent in situ hybridisation (FISH) on embryos, using a limited number of chromosomes, is not effective at increasing live birth rates
- (c) that embryos biopsied may not be available for cryopreservation and for use in subsequent treatment cycles
- (d) the misdiagnosis rates associated with PGS for aneuploidy, including the fact that false results can be positive or negative
- (e) that the more chromosome tests are carried out the higher the possibility of the test not working, and the lower the chance of finding suitable embryos for transfer
- (f) that there is no guarantee against a miscarriage occurring, despite PGS for aneuploidy being performed, and
- (g) the financial and emotional costs where treatment fails and there is no live birth following PGS for aneuploidy.

**9.2** Embryos from which biopsies have been taken, or resulting from gametes from which biopsies have been taken, should not be transferred with any other (non-biopsied) embryos in the same treatment cycle.

**9.3** Centres should ensure that they keep up to date with relevant literature and professional guidance in order to validate the use of PGS for each category of patient to which they offer it. Validation should also be based on data from previously published studies and retrospective evaluation of the clinic's own data.

## Prohibitions on embryo selection



### Interpretation of mandatory requirements

9B

The law requires that the centre should not select embryos of a particular sex for social reasons.

NOTE: Guidance note 10 (Embryo testing and sex selection) contains all the guidance and mandatory requirements relevant to embryo testing in general. Centres offering PGS should familiarise themselves with this guidance note as well.



## HFEA guidance (cont)

See also guidance note:

- [10 – Embryo testing and sex selection](#)



## Other legislation, professional guidelines and information

- British Fertility Society guidelines on PGS: Anderson, R A and Pickering, S (2008). – [www.britishfertilitysociety.org.uk/public/factsheets/PGS.html](http://www.britishfertilitysociety.org.uk/public/factsheets/PGS.html)

# 10. Embryo testing and sex selection

## This guidance note contains:

 Refer to principles 5, 7 and 9

### Mandatory requirements

- Extracts from HFE Act 1990 (as amended)
- Extracts from licence conditions
- Reference to relevant HFEA Directions

### HFEA guidance

- Staff to be involved in embryo testing
- Embryo transfer using biopsied embryos
- Preimplantation genetic diagnosis for heritable conditions ■
- Preimplantation genetic diagnosis to establish the identity of gamete providers ■
- Genetic consultation and counselling
- Information for those seeking preimplantation genetic diagnosis
- Prohibitions in connection with embryo selection ●■
- Sex selection for social reasons ■
- Sex selection: sperm sorting for medical reasons
- Preimplantation genetic diagnosis for histocompatibility (tissue typing) ●■
- Information for those seeking preimplantation genetic diagnosis for histocompatibility
- Follow-up arrangements for preimplantation tissue typing

● Section includes mandatory requirements

■ Section includes interpretation of mandatory requirements

### Other legislation, professional guidelines and information



## Mandatory requirements

### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Schedule 2 – Activities that may be licensed under the 1990 Act

Licences for treatment

Embryo testing

- 1ZA (1) A licence ... cannot authorise the testing of an embryo, except for one or more of the following purposes–
- (a) establishing whether the embryo has a gene, chromosome or mitochondrial abnormality that may affect its capacity to result in a live birth,
  - (b) in a case where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality, establishing whether it has that abnormality or any other gene, chromosome or mitochondrion abnormality,
  - (c) in a case where there is a particular risk that any resulting child will have or develop –
    - (i) a gender-related serious physical or mental disability,
    - (ii) a gender-related serious illness, or

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## Mandatory requirements (cont)

- (c) (cont)
    - (iii) any other gender-related serious medical condition, establishing the sex of the embryo,  
...
  - (e) in a case where uncertainty has arisen as to whether the embryo is one of those whose creation was brought about by using the gametes of particular persons, establishing whether it is.
- (2) A licence... cannot authorise the testing of embryos for the purpose mentioned in sub-paragraph (1)(b) unless the Authority is satisfied–
- (a) in relation to the abnormality of which there is a particular risk, and
  - (b) in relation to any other abnormality for which testing is to be authorised under sub-paragraph (1)(b), that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition.
- (3) For the purposes of sub-paragraph (1)(c), a physical or mental disability, illness or other medical condition is gender-related if the Authority is satisfied that –
- (a) it affects only one sex, or
  - (b) it affects one sex significantly more than the other.

### Licence conditions

- T86 Embryos that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop:
- a. a serious physical or mental disability
  - b. a serious illness, or
  - c. any other serious medical condition,
- must not be preferred to those that are not known to have such an abnormality.
- T87 Embryos that are known to be of a particular sex and are known to carry a particular risk, compared with embryos of that sex in general, that any resulting child will have or develop:
- a. a gender-related serious physical or mental disability
  - b. a gender-related serious illness, or
  - c. any other gender-related serious medical condition,
- must not be preferred to those that are not known to carry such a risk.
- T88 With respect to any embryo testing programme involving biopsy the centre must ensure that:
- a. no embryo is transferred to a woman where that embryo or any material removed from it or from the gametes that produced it, has been subject to a test that supplies genetic information about the embryo, unless the test has been expressly authorised by the Authority, and
  - b. any information derived from tests on an embryo, or any material removed from it or from the gametes that produced it, is not used to select embryos of a particular sex for social reasons.
- T89 With respect to any embryo testing programme the centre must ensure that embryo testing is only being carried out for those genetic conditions that are expressly authorised by the Authority.
- T91 Centres may use non-invasive procedures, for example metabolomics, to test and select for the viability of embryos. However, centres must not use these procedures to test for specific gene, chromosome or mitochondrion abnormality without prior authorisation from the Authority.



## Mandatory requirements (cont)

### Directions

**0008** – Information to be submitted to the HFEA as part of the licensing process

**0012** – Retention of records

For a copy of the relevant Directions visit [www.hfea.gov.uk](http://www.hfea.gov.uk)



## HFEA guidance

### Staff to be involved in embryo testing

- 10.1** A senior clinical geneticist should be involved in deciding whether a particular patient should receive treatment involving embryo testing.
- 10.2** The centre should ensure that a multidisciplinary team is involved in providing the embryo testing service. The team should include reproductive specialists, embryologists, clinical geneticists, genetic counsellors, cytogeneticists and molecular geneticists. It should maintain close contact with the primary care physician or the referring clinician.
- 10.3** Treatment should include patient support following embryo testing.

### Embryo transfer using biopsied embryos

- 10.4** Embryos from which biopsies have been taken, or resulting from gametes from which biopsies have been taken, should not be transferred with any other (non-biopsied) embryos in the same treatment cycle.

### Preimplantation genetic diagnosis for heritable conditions



#### Interpretation of mandatory requirements

10A

Preimplantation genetic diagnosis (PGD) can be carried out for a heritable condition only in two circumstances:

- (a) where there is a particular risk that the embryo to be tested may have a genetic, mitochondrial or chromosomal abnormality, and the Authority is satisfied that a person with the abnormality will have or develop a serious disability, illness or medical condition, or
- (b) where there is a particular risk that any resulting child will have or develop a gender related serious disability, illness or medical condition. A condition is gender related if the Authority is satisfied that it affects only one sex, or affects one sex significantly more than the other.

In the first situation, PGD may be carried out to establish whether the embryo has the suspected abnormality; in the second, PGD may be carried out to establish the sex of the embryo.

- 10.5** When deciding if it is appropriate to provide PGD in particular cases, the centre should consider the circumstances of those seeking treatment rather than the particular heritable condition.
- 10.6** The use of PGD should be considered only where there is a significant risk of a serious genetic condition being present in the embryo. When deciding if it is appropriate to provide PGD in particular cases, the seriousness of the condition in that case should be discussed between the people seeking treatment and the clinical team. The perception of the level of risk for those seeking treatment will also be an important factor for the centre to consider.



- 10.7** The centre should consider the following factors when deciding if PGD is appropriate in particular cases:
- (a) the views of the people seeking treatment in relation to the condition to be avoided, including their previous reproductive experience
  - (b) the likely degree of suffering associated with the condition
  - (c) the availability of effective therapy, now and in the future
  - (d) the speed of degeneration in progressive disorders
  - (e) the extent of any intellectual impairment
  - (f) the social support available, and
  - (g) the family circumstances of the people seeking treatment.
- 10.8** Concerns have been raised about the ethical implications of directly testing embryos for a genetic condition without disclosing the test results to the patients (PGD with non-disclosure).
- Where patients seek PGD, but do not wish to discover their own genetic status, centres should, where possible, only offer PGD with exclusion testing.
- 10.9** In exceptional circumstances the centre may offer PGD, but withhold the patient's test results (PGD with non-disclosure). However, this should only be offered under the following conditions:
- (a) that patients are given the opportunity to receive genetic counselling on the implications prior to giving consent,
  - (b) that protocols are established to limit, as far as possible, the risk of unwanted disclosure to the patients. Centres should consider using a different embryology laboratory from their own, in order to minimise the number of centre staff who know the patient's genetic status, and
  - (c) that no dummy embryo transfers are to be performed.
- 10.10** The centre should document its reasons for offering PGD with non-disclosure to a patient. This record should include:
- (a) written informed consent from the patient to perform PGD with non-disclosure,
  - (b) a statement from the people seeking treatment confirming that they have been given the opportunity to receive genetic counselling and that they have, prior to giving consent, received information:
    - (i) on the risks of inadvertent disclosure,
    - (ii) that where all embryos are suitable for transfer this is not evidence of the patient's genetic status,
    - (iii) that where no embryos are suitable for transfer this is not evidence of the patient's genetic status,
    - (iv) that therefore dummy embryo transfers are not necessary or permissible, and
    - (v) that treatment may go ahead which is not medically necessary in cases where the patient (or partner) does not have the genetic condition. This includes information about the potential costs and risks of any medically unnecessary treatments.

### Preimplantation genetic diagnosis to establish the identity of gamete providers



#### Interpretation of mandatory requirements

10B

An embryo may be tested to establish whether it was brought about using the gametes of particular people, where this is uncertain.



### Genetic consultation and counselling

**10.11** The centre should ensure that people seeking treatment have access to clinical geneticists, genetic counsellors and, where appropriate, infertility counsellors.

**10.12** The centre should work closely with the local genetics team of those seeking treatment.

### Information for those seeking preimplantation genetic diagnosis

**10.13** The centre should ensure that people seeking PGD are given the appropriate information about the treatment. This should include:

- (a) the process, procedures and possible risks involved in IVF and biopsy procedures when providing a sophisticated genetic test
- (b) the experience of the centre in carrying out the procedure.

**10.14** The centre should also provide information to those seeking treatment to help them make decisions about their treatment, including:

- (a) genetic and clinical information about the condition being tested for
- (b) the likely impact of the condition on those affected and their families
- (c) information about treatment and social support available, and
- (d) information from a relevant patient support group or the testimony of people living with the condition, if those seeking treatment have no direct experience of it themselves.

**10.15** If the person seeking treatment has already been given information about the particular genetic disorder, for example from a regional genetics centre, the centre need not provide this information again. However, the centre should ensure that the information has been provided to a satisfactory standard of breadth and clarity.

**10.16** Before providing PGD, the centre should ensure that those seeking treatment have had sufficient opportunity to fully consider the possible outcomes of genetic testing and their implications.

### Prohibitions in connection with embryo selection



#### Mandatory requirements

##### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

##### Section 14

- (8) Subsections (9) and (10) apply in determining any of the following –
- (a) the persons who are to provide gametes for use in pursuance of the licence in a case where consent is required under paragraph 5 of Schedule 3 for the use in question;
  - (b) the woman from whom an embryo is to be taken for use in pursuance of the licence, in a case where her consent is required under paragraph 7 of Schedule 3 for the use of the embryo;
  - (c) which of two or more embryos to place in a woman.
- (9) Persons or embryos that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop–
- (a) a serious physical or mental disability,
  - (b) a serious illness, or



### Mandatory requirements (cont)

(c) any other serious medical condition,

must not be preferred to those that are not known to have such an abnormality.

(10) Embryos that are known to be of a particular sex and to carry a particular risk, compared with embryos of that sex in general, that any resulting child will have or develop–

(a) a gender-related serious physical or mental disability,

(b) a gender-related serious illness, or

(c) any other gender-related serious medical condition,

must not be preferred to those that are not known to carry such a risk.

(11) For the purposes of subsection (10), a physical or mental disability, illness or other medical condition is gender-related if–

(a) it affects only one sex, or

(b) it affects one sex significantly more than the other.

Schedule 2 – Activities that may be licensed under the 1990 Act

Sex selection

1ZB (1) A licence under paragraph 1 cannot authorise any practice designed to secure that any resulting child will be of one sex rather than the other.

(2) Sub-paragraph (1) does not prevent the authorisation of any testing of embryos that is capable of being authorised under paragraph 1ZA.

(3) Sub-paragraph (1) does not prevent the authorisation of any other practices designed to secure that any resulting child will be of one sex rather than the other in a case where there is a particular risk that a woman will give birth to a child who will have or develop –

(a) a gender-related serious physical or mental disability,

(b) a gender-related serious illness, or

(c) any other gender-related serious medical condition.

(4) For the purposes of sub-paragraph (3), a physical or mental disability, illness or other medical condition is gender-related if the Authority is satisfied that –

(a) it affects only one sex, or

(b) it affects one sex significantly more than the other.

Licence conditions

T86 Embryos that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop:

a. a serious physical or mental disability

b. a serious illness, or

c. any other serious medical condition,

must not be preferred to those that are not known to have such an abnormality.



### Mandatory requirements (cont)

- T87 Embryos that are known to be of a particular sex and are known to carry a particular risk, compared with embryos of that sex in general, that any resulting child will have or develop:
- a gender-related serious physical or mental disability
  - a gender-related serious illness, or
  - any other gender-related serious medical condition,
- must not be preferred to those that are not known to carry such a risk.
- T88 With respect to any embryo testing programme involving biopsy the centre must ensure that:
- ...
- any information derived from tests on an embryo, or any material removed from it or from the gametes that produced it, is not used to select embryos of a particular sex for social reasons.



### Interpretation of mandatory requirements

10C

The law prohibits the selection of an embryo for treatment if it is known to:

- have a gene, chromosome or mitochondrial abnormality involving a significant risk that the person with the abnormality will develop a serious physical or mental disability, a serious illness, or a serious medical condition, or
- be of a sex that carries a particular risk that any resulting child will have or develop a gender-related serious physical or mental disability, serious illness, or serious medical condition

This applies only where there is at least one other embryo suitable for transfer that is not known to have the characteristics. Where there is no other embryo suitable for transfer, an embryo with these characteristics may be transferred.

**10.17** The use of an embryo known to have an abnormality as described above should be subject to consideration of the welfare of any resulting child and should normally have approval from a clinical ethics committee.

**10.18** If a centre decides that it is appropriate to provide treatment services to a woman using an embryo known to have an abnormality as described above, it should document the reason for the use of that embryo.

NOTE: An example of an embryo not suitable for transfer in this context is one that has no realistic prospect of resulting in a live birth.

See also guidance note:

- [8 – Welfare of the child](#)



### Sex selection for social reasons



#### Interpretation of mandatory requirements

10D

The law requires that the centre should not, for social reasons:

- (a) select embryos of a particular sex
- (b) separate sperm samples, or use sperm samples that have been separated, for the purpose of sex selection, or
- (c) participate in any other practices designed to ensure that a resulting child will be of a particular sex.

### Sex selection: sperm sorting for medical reasons

- 10.19** If sperm is sorted for medical reasons to create (or maximise the chance of creating) embryos of a particular sex for medical reasons, patients should be given information about the process, procedures, possible risks and the experience of the clinic in doing the procedure.
- 10.20** Due to concerns about the reliability of the technique, sperm that has been sorted for sex selection using gradient methods should not be used for medical reasons.

### Preimplantation genetic diagnosis for histocompatibility (tissue typing)



#### Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Schedule 2 – Activities that may be licensed under the 1990 Act

Licences for treatment

Embryo testing

- 1ZA (1) A licence ... cannot authorise the testing of an embryo, except for one or more of the following purposes–
- ...
- (d) in a case where a person (“the sibling”) who is the child of the persons whose gametes are used to bring about the creation of the embryo (or of either of those persons) suffers from a serious medical condition which could be treated by umbilical cord blood stem cells, bone marrow or other tissue of any resulting child, establishing whether the tissue of any resulting child would be compatible with that of the sibling
- ...
- 1ZA (4) In sub-paragraph (1)(d) the reference to “other tissue” of the resulting child does not include a reference to any whole organ of the child.



### Interpretation of mandatory requirements

10E

The law requires that the intended recipient of any donated tissue from a child born following tissue typing must:

- (a) be a sibling of any child born as a result of treatment, and
- (b) suffer from a serious medical condition that could be treated by umbilical cord blood stem cells, bone marrow or other tissue (excluding whole organs) of any resulting child.

The law also permits tissue typing if the embryo will not, in addition to the histocompatibility test, be tested for a particular genetic or mitochondrial abnormality.

- 10.21** Where preimplantation tissue typing is to be used with PGD for a heritable condition, the centre should follow the requirements and guidance applicable to a PGD service.
- 10.22** When deciding whether to use preimplantation tissue typing, the centre should consider the circumstances of each case individually, rather than the fact that the procedure is sought to provide tissue to treat a particular condition.
- 10.23** When deciding on the appropriateness of preimplantation tissue typing in a particular situation, the centre should consider the condition of the affected child, including:
- (a) the degree of suffering associated with their condition
  - (b) the speed of degeneration in progressive disorders
  - (c) the extent of any intellectual impairment
  - (d) their prognosis, considering all treatment options available
  - (e) the availability of alternative sources of tissue for treating them, now and in the future, and
  - (f) the availability of effective therapy for them, now and in the future.
- 10.24** The centre should also consider the possible consequences for any child who may be born as a result, including:
- (a) any possible risks associated with embryo biopsy
  - (b) the likely long-term emotional and psychological implications
  - (c) whether they are likely to require intrusive surgery as a result of the treatment of the affected child (and whether this is likely to be repeated), and
  - (d) any complications or predispositions associated with the tissue type to be selected.
- 10.25** The centre should also consider the family circumstances of the people seeking treatment, including:
- (a) their previous reproductive experience
  - (b) their views and the affected child's views of the condition
  - (c) the likelihood of a successful outcome, taking into account:
    - (vi) their reproductive circumstances (ie, the number of embryos likely to be available for testing in each treatment cycle, the number likely to be suitable for transfer, whether carrier embryos may be transferred, and the likely number of cycles)
    - (vii) the likely outcome of treatment for the affected child
  - (d) the consequences of an unsuccessful outcome
  - (e) the demands of IVF/preimplantation testing treatment on them while caring for an affected child, and
  - (f) the extent of social support available.



### Information for those seeking preimplantation genetic diagnosis for histocompatibility

**10.26** Information given to patients considering preimplantation tissue typing should include:

- (a) information about the tissue typing tests to be done
- (b) an explanation of the latest evidence about any risk associated with the biopsy procedure for any child who may be born
- (c) the overall likelihood of a successful outcome for the affected child, including:
  - (i) the likelihood of an embryo with appropriate tissue type being available for transfer following the IVF, biopsy and genetic testing
  - (ii) the likelihood of a child being born as a result, taking into account the circumstances of the people seeking treatment and their previous reproductive experience
  - (iii) the likelihood of tissue from that child providing a successful treatment
  - (iv) the limitations of the treatment for the affected child
- (d) the likely impact of the proposed procedure on all family members involved, and
- (e) information about other sources of treatment, counselling and social support available.

**10.27** If information about the disorder affecting the existing child has already been provided, for example by a regional genetics centre or by the clinical team responsible for that child's care, it will not be necessary to provide this information again. However, the centre should:

- (a) ensure that this information is satisfactorily broad and clear, and
- (b) obtain a statement to that effect from those providing it

### Follow-up arrangements for preimplantation tissue typing

**10.28** Centres offering preimplantation tissue typing should be able to demonstrate that they have arrangements for inviting patients and their families to take part in long-term follow-up studies. These should include long-term medical and psychosocial follow-up studies of children born as a result. Centres should strongly encourage patients and their families to participate in such studies.

See also guidance note:

- [5 – Consent to treatment, storage, donation and disclosure of information](#)

See also:

- [HFEA consent forms at www.hfea.gov.uk](http://www.hfea.gov.uk)



## Other legislation, professional guidelines and information

- Association of Clinical Embryologists – Accreditation Standards and Guidelines for IVF Laboratories – [www.embryologists.org.uk](http://www.embryologists.org.uk)

# 11. Donor recruitment, assessment and screening

## This guidance note contains:

 Refer to principles 1, 2, 4, 5, 6, 7 and 8

### Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Extracts from licence conditions
- Reference to relevant HFEA Directions
- Reference to relevant Regulations

### HFEA guidance

- Advertising
- Age of prospective donors
- General enquiries to be made
- Family and other relevant history
- Suitability as a donor ■
- Medical and laboratory tests
- People considered unsuitable as donors
- Unsuspected heritable conditions in donors
- Information for prospective donors
- Giving donors information about children born as a result of their donation ■
- Informing donors about information available to donor-conceived people
- Provision of counselling to those considering donation ■
- Consent ■
- Monitoring and complying with the 10 family limit
- Sperm donation for benefits in kind

■ Section includes interpretation of mandatory requirements

### Other legislation, professional guidelines and information



## Mandatory requirements

### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

#### Schedule 3

Consent to use or storage of gametes, embryos or human admixed embryos etc.

#### Use of gametes for treatment of others

- 5 (1) A person's gametes must not be used for the purposes of treatment services or non-medical fertility services unless there is an effective consent by that person to their being so used and they are used in accordance with the terms of the consent.
- (2) A person's gametes must not be received for use for those purposes unless there is an effective consent by that person to their being so used.
- (3) This paragraph does not apply to the use of a person's gametes for the purpose of that person, or that person and another together, receiving treatment services.

#### 31ZD Provision to donor of information about resulting children

- (1) This section applies where a person ("the donor") has consented under Schedule 3 (whether before or after the coming into force of this section) to—

Human Fertilisation and Embryology Authority



## Mandatory requirements (cont)

(1)(cont)

- (a) the use of the donor's gametes, or an embryo the creation of which was brought about using the donor's gametes, for the purposes of treatment services provided under a licence, or
- (b) the use of the donor's gametes for the purposes of non-medical fertility services provided under a licence.

(2) In subsection (1)–

- (a) “treatment services” do not include treatment services provided to the donor, or to the donor and another person together, and
- (b) “non-medical fertility services” do not include any services involving partner-donated sperm.

(3) The donor may by notice request the appropriate person to give the donor notice stating–

- (a) the number of persons of whom the donor is not a parent but would or might, but for the relevant statutory provisions, be a parent by virtue of the use of the gametes or embryos to which the consent relates,
- (b) the sex of each of those persons, and
- (c) the year of birth of each of those persons.

(4) Subject to subsections (5) and (7), the appropriate person shall notify the donor whether the appropriate person holds the information mentioned in subsection (3) and, if the appropriate person does so, shall comply with the request.

(5) The appropriate person need not comply with a request under subsection (3) if the appropriate person considers that special circumstances exist which increase the likelihood that compliance with the request would enable the donor to identify any of the persons falling within paragraphs (a) to (c) of subsection (3).

(6) In the case of a donor who consented as described in subsection (1)(a), the Authority need not comply with a request made to it under subsection (3) where the person who held the licence referred to in subsection (1)(a) continues to hold a licence under paragraph 1 of Schedule 2, unless the donor has previously made a request under subsection (3) to the person responsible and the person responsible–

- (a) has notified the donor that the information concerned is not held, or
- (b) has failed to comply with the request within a reasonable period.

(7) In the case of a donor who consented as described in subsection (1)(b), the Authority need not comply with a request made to it under subsection (3) where the person who held the licence referred to in subsection (1)(b) continues to hold a licence under paragraph 1A of Schedule 2, unless the donor has previously made a request under subsection (3) to the person responsible and the person responsible–

- (a) has notified the donor that the information concerned is not held, or
- (b) has failed to comply with the request within a reasonable period.

(8) In this section “the appropriate person” means–

(a) in the case of a donor who consented as described in paragraph (a) of subsection (1)–

- (i) where the person who held the licence referred to in that paragraph continues to hold a licence under paragraph 1 of Schedule 2, the person responsible, or
- (ii) the Authority, and

(b) in the case of a donor who consented as described in paragraph (b) of subsection (1)–

- (i) where the person who held the licence referred to in that paragraph continues to hold a licence under paragraph 1A of Schedule 2, the person responsible, or
- (ii) the Authority.



## Mandatory requirements (cont)

(9) In this section “the relevant statutory provisions” has the same meaning as in section 31ZA.

### Conditions of licences for treatment

- 13 (9) Persons or embryos that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop–
- (a) a serious physical or mental disability,
  - (b) a serious illness, or
  - (c) any other serious medical condition,
- must not be preferred to those that are not known to have such an abnormality.

### Licence conditions

- T52 Prior to the use and/or storage of donor gametes and/or embryos created with donor gametes the centre must comply with the selection criteria for donors and the requirements for laboratory tests and storage set out below, namely
- a. donors must be selected on the basis of their age, health and medical history, provided on a questionnaire and through a personal interview performed by a qualified and trained healthcare professional. This assessment must include relevant factors that may assist in identifying and screening out persons whose donations could present a health risk to others, such as the possibility of transmitting diseases, (such as sexually transmitted infections) or health risks to themselves (eg, superovulation, sedation or the risks associated with the egg collection procedure or the psychological consequences of being a donor)
  - b. the donors must be negative for HIV1 and 2, HCV, HBV and syphilis on a serum or plasma sample tested as follows, namely:
    - HIV 1 and 2: Anti-HIV – 1, 2
    - Hepatitis B: HBsAg/Anti-HBc
    - Hepatitis C: Anti-HCV-Ab
    - Syphilis: see (d) below
  - c. the centre must devise a system of storage which clearly separates:
    - quarantined/unscreened gametes and embryos,
    - gametes and embryos which have tested negative, and
    - gametes and embryos which have tested positive.
  - d. a validated testing algorithm must be applied to exclude the presence of active infection with *Treponema pallidum*. The non-reactive test, specific or non-specific, can allow gametes to be released. When a non-specific test is performed, a reactive result will not prevent procurement or release if a specific *Treponema* confirmatory test is non-reactive. The donor whose specimen test reacted on a *Treponema*-specific test will require a thorough risk assessment to determine eligibility for clinical use
  - e. in addition to the requirements in (b) and (d) above, sperm donors must be negative for chlamydia on a urine sample tested by the nucleic acid amplification technique (NAT)
  - f. This requirement has been removed.**
  - g. HTLV-1 antibody testing must be performed for donors living in or originating from high incidence areas or with sexual partners originating from those areas or where the donor’s parents originate from those areas, and
  - h. in certain circumstances, additional testing may be required depending on the donor’s history and the characteristics of the gametes donated (eg, RhD, Malaria, T.cruzi).



## Mandatory requirements (cont)

- T53 The centre must ensure that the laboratory tests required by licence condition T52 meet the following requirements, namely:
- the test must be carried out by a qualified laboratory, which has suitable accreditation (for example by CPA (UK) Ltd or another body accrediting to an equivalent standard), using CE marked testing kits where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge,
  - blood samples must be obtained within a timeframe specified by the Authority, and
  - donor sperm must be quarantined for a minimum of 180 days, after which repeat testing is required. If the blood donation sample is additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV, quarantining of the gametes and re-testing of a repeat blood sample is not required. Quarantine and re-testing is also not required if the processing includes an inactivation step that has been validated for the viruses concerned.
- T55 Potential donors that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop:
- a serious physical or mental disability,
  - a serious illness, or
  - any other serious medical condition,
- must not be preferred to those that are not known to have such an abnormality.

### Directions

**0001** – Gametes and embryos

**0005** – Collecting and recording information for the HFEA

For a copy of the relevant Directions visit [www.hfea.gov.uk](http://www.hfea.gov.uk)

### Regulations

Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004



## HFEA guidance

### Advertising

- 11.1** Advertising and publicity materials should be designed and written with regard to the sensitive issues involved in recruiting donors.

See also guidance note:

- **13 – Payments for donors**

### Age of prospective donors

- 11.2** Unless there are exceptional reasons, sperm for the treatment of others should not be taken from donors aged 46 or over. If there are exceptional reasons, the centre should record them in the patient records.



- 11.3** Unless there are exceptional reasons, eggs for the treatment of others should not be taken from donors aged 36 or over. If there are exceptional reasons, the centre should record them in the patient's medical records.
- 11.4** Gametes for the treatment of others should not be taken from anyone under the age of 18.
- 11.5** Unless there are exceptional reasons, the centre should follow the age limits for gamete donors if:
- (a) gametes are used to produce embryos specifically for donation, or
  - (b) embryos are donated following licensed fertility treatment.
- If there are exceptional reasons, the centre should record them in the patient's medical records.

### General enquiries to be made

- 11.6** The recruiting centre should take reasonable steps to verify the identity of the prospective donor by asking for appropriate identification (eg, passport or photocard driving licence). Failure to obtain satisfactory evidence of identity should be taken into account in deciding whether to accept their gametes or embryos for treatment.
- 11.7** When obtaining gametes or embryos for the treatment of others (whether directly from a donor, from another licensed centre or from a foreign supplier), the centre should take appropriate steps to discover whether gametes from that donor have been obtained for use in licensed treatment before and, if so:
- (a) establish which centre is the primary centre for that donor
  - (b) notify that centre that it proposes to use that donor's gametes
  - (c) seek authorisation to do so, if appropriate, and
  - (d) ensure that the limit of 10 families per donor will not be exceeded.

### Family and other relevant history

- 11.8** Before a prospective donor provides gametes, the recruiting centre should take their medical and family histories, and details of previous donations. The centre should encourage prospective donors to provide as much other non-identifying biographical information as possible, so that it may be available to prospective recipients, parents and resulting children. If a prospective donor cannot give a full and accurate family history, the centre should record this fact and take it into account in deciding whether or not to accept their gametes or embryos for treatment.
- 11.9** The centre should seek the prospective donor's consent to approach their GP for further factual information if it suspects the donor might be unsuitable. The centre should always seek further information if:
- (a) information provided by the patient suggests there are risk factors that may affect anyone treated using their gametes or any child born as a result
  - (b) the prospective donor has failed to provide any information requested
  - (c) the information provided by the prospective donor is inconsistent, or
  - (d) there is evidence of deception.
- 11.10** If the prospective donor refuses to give such consent, the centre should take this into consideration when deciding whether to accept that donor. Such refusal should not in itself be grounds for not accepting the donor. The centre should discuss with the prospective donor their reason for refusing.

See also:

- [HFEA consent form available at www.hfea.gov.uk](http://www.hfea.gov.uk)



### Suitability as a donor



#### Interpretation of mandatory requirements

11A

A donor must not be selected because they are known to have a particular gene, chromosome or mitochondrial abnormality that, if inherited by any child born as a result of the donation, may result in that child having or developing:

- (a) a serious physical or mental disability
- (b) a serious illness, or
- (c) any other serious medical condition.

**11.11** The use of gametes from a donor known to have an abnormality as described above, should be subject to consideration of the welfare of any resulting child and should normally have approval from a clinical ethics committee.

**11.12** If a centre determines that it is appropriate to provide treatment services for a woman using a donor known to have an abnormality as described above, it should document the reason for the use of that donor.

See also guidance note:

- [10 – Embryo testing and sex selection](#)

**11.13** Before accepting gametes for the treatment of others, the recruiting centre should consider the suitability of the prospective donor. In particular, the centre should consider:

- (a) personal or family history of heritable disorders
- (b) personal history of transmissible infection
- (c) the level of potential fertility indicated by semen analysis (where appropriate)
- (d) the implications of the donation for the prospective donor and their family, especially for any children they may have at the time of donation or in the future, and
- (e) the implications for any children born as a result of the donation, in the short and long term.

See also guidance notes:

- [8 – Welfare of the child](#)
- [20 – Donor assisted conception](#)

**11.14** The centre should ensure that its procedures for recruiting donors are fair and non-discriminatory.

See also guidance note:

- [29 – Treating people fairly](#)



### Medical and laboratory tests

- 11.15** In addition to meeting the requirements set out in licence conditions, donors of gametes and embryos should be screened in accordance with current professional guidance produced by the relevant professional bodies.
- 11.16** In addition to meeting the mandatory requirements outlined in this guidance note, the centre should quarantine donated gametes and embryos in line with guidance from the relevant professional bodies.

### People considered unsuitable as donors

- 11.17** A prospective donor should not be accepted if the centre:
- concludes that a recipient or any child born as a result of treatment using the donor's gametes is likely to experience serious physical, psychological or medical harm, or
  - cannot get enough further information to conclude there is no significant risk.

See also guidance note:

- [8 – Welfare of the child](#)

- 11.18** When the centre decides that a prospective donor is unsuitable to donate, it should record the reasons and explain them to the prospective donor. The centre should present the reasons for the decision sensitively and answer any questions in a straightforward and comprehensive way.
- 11.19** The centre should offer counselling to all prospective donors who are considered unsuitable for any reason. When the centre refuses to accept a prospective gamete donor because of physical or psychological problems that require separate treatment or specialist counselling, the centre should provide reasonable assistance to the individual to obtain relevant treatment or counselling.
- 11.20** If information affecting the suitability of a prospective donor becomes known after the selection process, the centre should review the prospective donor's suitability and take appropriate action.

### Unsuspected heritable conditions in donors

- 11.21** At registration, donors should indicate whether or not they wish to be notified if the centre learns (eg, through the birth of an affected child) that they have a previously unsuspected genetic disease or they are a carrier of a harmful inherited condition. They should also be asked whether or not they would like their primary care physician to be informed. Their wishes should be recorded in the donors' medical records.
- 11.22** If a centre learns that a donor has a previously unsuspected genetic disease or is a carrier of a harmful inherited condition, the centre should:
- notify the primary centre (where there is one) and the HFEA immediately (the primary centre should immediately notify other centres who have received gametes obtained from that donor)
  - inform patients who have had a live birth as a result of treatment with gametes from that donor, and offer these patients appropriate counselling
  - carefully consider when and how a woman who is pregnant, as a result of treatment with gametes from that donor, is given this information
  - refer to the donor's medical records to establish whether, and in what way, they would like to be given the information. If the donor has indicated that they would like to be given such information, the centre should notify their primary care physician, so that the donor can be referred for the appropriate medical care and counselling. If the donor has indicated that they would not like their primary care physician to be informed, the centre should contact the donor directly.



- 11.23** The centre should tell gamete donors that they should inform the centre if, after the donation:
- they discover they are affected by an unsuspected genetic disease, or
  - they find they are a carrier of a harmful recessively inherited condition (eg, through the birth of an affected child).

The centre should then proceed as indicated above.

See also guidance note:

- **15 – Procuring, processing and transporting gametes and embryos**

### Information for prospective donors

**11.24** Before any consents or samples are obtained from a prospective donor, the recruiting centre should provide information about:

- the screening that will be done, and why it is necessary
- the possibility that the screening may reveal unsuspected conditions (eg, low sperm count, genetic anomalies or HIV infection) and the practical implications
- the scope and limitations of the genetic testing that will be done and the implications for the donor and their family
- the importance of informing the recruiting centre of any medical information that may come to light after donation that may have health implications for any woman who receives treatment with those gametes or for any child born as a result of such treatment
- the procedure used to collect gametes, including any discomfort, pain and risk to the donor (eg, from the use of superovulatory drugs)
- the legal parenthood of any child born as a result of their donation
- the restriction on using gametes and embryos from an individual donor when the number of families that have already had children as a result of treatment using such gametes or embryos has reached 10 (or any lower figure specified by the donor)
- what information about the donor must be collected by the centre and held on the HFEA Register
- the fact that the centre or the HFEA (or both) may disclose non-identifying information about the donor, for example to prospective recipients or to the parents of donor-conceived children
- the HFEA's obligation to disclose non-identifying information (and identifying information if donation took place after 31 March 2005), to someone who applies for such information if:
  - the applicant is aged over 16 (to access non-identifying information) or 18 (to access identifying information), and
  - the applicant appears to have been conceived using the donor's gametes, or embryos created using the donor's gametes
- the importance of supplying up-to-date contact information so that the donor can be informed if and when disclosure of identifiable information will be made
- the importance of the information provided at 11.29 and 11.30 to people born as a result of their donation
- the possibility that a donor-conceived person who is disabled as a result of an inherited condition that the donor knew about, or ought reasonably to have known about, but failed to disclose, may be able to sue the donor for damages



### 11.24 (cont)

- (n) the procedure for donors to withdraw consent for the use of their gametes, or embryos created with their gametes, and
- (o) the fact that if the donor is an egg donor who is not a patient, she is free to withdraw from the donation process after preparation for egg recovery has begun without incurring a financial or other penalty.

### 11.25 Men who wish to donate embryos originally created for the treatment of their partner and themselves, and those people considering treatment with such embryos, should be:

- (a) informed of the uncertain legal status of men donating embryos created originally for the treatment of their partner and themselves, when the embryos are used in the treatment of a single woman
- (b) referred to information on the HFEA's website on this issue, and
- (c) advised to seek independent legal advice before consenting to donate their embryos or being treated with the embryos.

See also guidance notes:

- [4 – Information to be provided prior to consent](#)
- [5 – Consent to treatment, storage, donation and disclosure of information](#)
- [12 – Egg sharing arrangements](#)
- [20 – Donor assisted conception](#)

## Giving donors information about children born as a result of their donation



### Interpretation of mandatory requirements

11B

If donors of gametes and embryos ask, centres must provide the following information about any children born as a result of their donation:

- (a) number
- (b) sex, and
- (c) year of birth.

If the centre is unable to provide this information, it should direct donors to the Authority.

**11.26** The centre should inform donors and potential donors that they may ask at any time how many children have been born as a result of their donation.

**11.27** The centre should inform donors seeking information about children born as a result of their donation that they may find counselling, or similar support services, helpful in considering the implications of receiving such information.

**11.28** The centre should inform anonymous donors seeking information about children resulting from their donation that they have the right to re-register as identifiable, if they wish.



### Informing donors about information available to donor-conceived people

**11.29** The centre should inform donors that anyone born as a result of their donation will have access to the following non-identifying information provided by them, from the age of 16:

- (a) physical description (height, weight, and eye, hair and skin colours)
- (b) year and country of birth
- (c) ethnic group
- (d) whether the donor had any genetic children when they registered, and the number and sex of those children
- (e) other details the donor may have chosen to supply (eg, occupation, religion and interests)
- (f) the ethnic group(s) of the donor's parents
- (g) whether the donor was adopted or donor conceived (if they are aware of this)
- (h) marital status (at the time of donation)
- (i) details of any screening tests and medical history
- (j) skills
- (k) reason for donating
- (l) a goodwill message, and
- (m) a description of themselves as a person (pen portrait).

**11.30** The centre should also inform donors who register or re-register after 31 March 2005 that anyone born as a result of their donation will have access to the following identifying information, from the age of 18:

- (a) full names (and any previous names)
- (b) date of birth, and town or district where born, and
- (c) last known postal address (or address at time of registration).

**11.31** The centre should inform identifiable donors that it will make a reasonable attempt to contact and forewarn them before disclosing identifiable details to anyone born as a result of their donation. The centre should encourage donors to provide up-to-date contact details to facilitate this.

See also guidance note:

- [20 – Donor assisted conception](#)

### Provision of counselling to those considering donation



#### Interpretation of mandatory requirements

11C

All prospective donors must be given a suitable opportunity to receive proper counselling. Where embryos are to be donated, the recruiting centre must offer counselling to each person whose gametes were used to create the embryos.

**11.32** If the possibility of donating gametes or embryos for the treatment of others, or for research or training, arises during the course of treatment, the centre should allow potential donors enough time to consider the implications and to receive counselling before giving consent.



### Consent



#### Interpretation of mandatory requirements

11D

The law requires the centre to obtain written informed consent from a person before it uses:

- (a) their gametes for the treatment of others or for non-medical fertility services, or
- (b) embryos created with their gametes for the treatment of others.

Those giving consent can specify conditions for the use of their gametes and embryos.

**11.33** Where someone intends to donate gametes or embryos for the treatment of others, the centre should ensure it obtains written consent to do so from that person. Such consent should include the number of families that may have children using the donated gametes or embryos.

**11.34** The centre is not required to obtain the consent of the donor's partner or spouse. However, if the donor is married, in a civil partnership or in a long-term relationship, the centre should encourage them to seek their partner's support for the donation of their gametes.

See also guidance note:

- [5 – Consent to treatment, storage, donation and disclosure of information](#)

### Monitoring and complying with the 10 family limit

**11.35** The centre should establish documented procedures to ensure that if the number of families created using gametes (or embryos created using donated gametes) from a particular donor has reached 10 (or any lower figure specified by the donor), that those gametes or embryos are not used or distributed for use in further treatment.

**11.36** Before authorising a secondary centre to use gametes (or embryos created using gametes) from a particular donor, the primary centre should ensure that no more than 10 families (or any lower figure specified by the donor) at any time:

- (a) have had live births as a result of treatment using that donor's gametes
- (b) have embryos created using that donor's gametes and placed in storage so they are available for subsequent transfer, or
- (c) are being treated using that donor's gametes (or embryos created using gametes).

**11.37** If a centre uses gametes (or embryos created using gametes) from a particular donor who was recruited by another centre, it should notify that primary centre each time a new patient has:

- (a) a live birth as a result of treatment using that donor's gametes, or
- (b) embryos created using that donor's gametes and placed in storage so they are available for subsequent transfer.

**11.38** The primary centre for a particular donor should notify any secondary centres having or using gametes (or embryos created using gametes) from that donor, within two working days, when it becomes aware that six families<sup>1</sup> have had:

- (a) a live birth as a result of treatment using that donor's gametes, or
- (b) embryos created using that donor's gametes and placed in storage so they are available for subsequent transfer.

<sup>1</sup> The six-family alert applies where the donor has not specified a family limit lower than 10.



### 11.38 (cont)

After this, gametes (or embryos created using gametes) from that donor should not be used without authorisation from the primary centre, unless they are used to treat a family who already has a child using that donor. However, if recipients have already begun or had medical, surgical or obstetric treatment (such as ovarian stimulation or egg collection) when the notification is given, this should be allowed to continue.

**11.39** When using gametes (or embryos created using gametes) from a particular donor authorised in this way by a primary centre, a secondary centre should notify the primary centre each time a woman starts or ends relevant treatment.

**11.40** Relevant treatment situations are where the woman has:

See also guidance note:

- **17 – Storage of gametes and embryos**

- (a) begun, but not completed, a treatment cycle (eg, ovarian stimulation)
- (b) received treatment (insemination or embryo transfer) and is awaiting confirmation of pregnancy
- (c) a confirmed ongoing pregnancy
- (d) embryos created that have not yet been transferred (eg, placed in storage), or
- (e) received treatment but has not reported the outcome.

### Sperm donation for benefits in kind

**11.41** Centres may offer benefits in kind (in line with those for egg sharing arrangements) if a man donates sperm. The centre should, as appropriate, treat sperm providers donating for benefits in kind in the same way as other potential gamete donors.



## Other legislation, professional guidelines and information

- Association of Biomedical Andrologists/Association of Clinical Embryologists/British Andrology Society/ British Fertility Society/Royal College of Obstetricians and Gynaecologists – UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors (2008) – [www.ncbi.nlm.nih.gov/pubmed/19085256](http://www.ncbi.nlm.nih.gov/pubmed/19085256)
- British Infertility Counselling Association - Guidelines for Good Practice in Infertility Counselling (2008) – [www.bica.net/books/guidelines-good-practice-infertility-counselling](http://www.bica.net/books/guidelines-good-practice-infertility-counselling)

# 12. Egg sharing arrangements


## This guidance note contains:

### Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Reference to relevant HFEA Directions

### HFEA guidance

- Selection of egg providers
- Benefits
- Information
- Consent
- Counselling ■
- Confidentiality
- Egg sharing agreements
- Agreement between a licensed centre and an egg provider
- Agreement between a licensed centre and an egg recipient
- Egg sharing for research

 Refer to principles 2, 5, 6, 10 and 12

### Other legislation, professional guidelines and information

■ Section includes interpretation of mandatory requirements



## Mandatory requirements

### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

- 12 (e) that no money or other benefit shall be given or received in respect of any supply of gametes, embryos or human admixed embryos unless authorised by Directions.

### Directions

#### 0001 – Gametes and embryos

- ...5. There is no restriction on the value of other benefits which may be given to the donor, but the only benefits which may be offered for this purpose are treatment services. These services should be provided to the donor in the course of the donation cycle unless there is a medical reason why they cannot be provided at that time...

For a copy of the relevant Directions visit [www.hfea.gov.uk](http://www.hfea.gov.uk)



## HFEA guidance

### Selection of egg providers

- 12.1** Where relevant, the possibility of donating gametes should be raised before a potential donor's treatment cycle begins. Patients should not be put under pressure or unduly influenced to donate gametes or embryos.



- 12.2** The centre should, as appropriate, treat egg providers involved in egg sharing arrangements in the same way as other potential gamete donors.
- 12.3** The centre should ensure that:
- care is taken when selecting egg providers in egg sharing arrangements
  - egg providers are fully assessed and medically suitable, and
  - the treatment offered is the most suitable for the egg provider and recipient(s).

See also guidance notes:

- [8 – Welfare of the child](#)
- [11 – Donor recruitment, assessment and screening](#)

### Benefits

- 12.4** If benefits in the form of treatment services are offered to an egg provider, they should be given in connection with the cycle in which eggs are supplied for a recipient's treatment unless there is a clinical reason to defer those benefits. In the latter circumstances only, the egg provider may choose to donate all the eggs collected in the initial cycle and take advantage of the benefits in a subsequent cycle.
- 12.5** Centres may offer benefits in kind (in line with those for egg sharing arrangements) if a man donates sperm. The centre should, as appropriate, treat sperm providers donating for benefits in kind in the same way as other potential gamete donors.

See also guidance note:

- [11 – Donor recruitment, assessment and screening](#)

### Information

- 12.6** The centre should provide women receiving eggs with the same information as other people seeking treatment with donated gametes. Also, before the egg sharing cycle begins, the centre should give the egg provider and the egg recipient the following written information setting out:
- the criteria for selecting women providing and receiving eggs in egg sharing arrangements
  - how the centre proposes to distribute the eggs between the provider and the recipient(s)
  - the screening that a woman providing eggs in an egg sharing arrangement will undergo
  - the terms of the agreement to be made
  - the law relating to consent, in particular the rights of a woman providing eggs to vary or withdraw her consent and the implications of her doing so, and
  - available alternative treatment options.

See also guidance notes:

- [4 – Information to be provided prior to consent](#)
- [5 – Consent to treatment, storage, donation and disclosure of information](#)
- [11 – Donor recruitment, assessment and screening](#)



### Consent

- 12.7** The person obtaining consent should ensure that an egg provider's consent is recorded so that different conditions can be placed on:
- the use of eggs and the use and storage of embryos created for the egg provider's own treatment, and
  - the use of eggs and the use and storage of embryos created for the treatment of the recipient(s).

These conditions should be able to be varied independently of each other.

- 12.8** The person obtaining consent should tell the egg provider and recipient(s) that the egg provider may withdraw or vary her consent up to when an egg, or an embryo created using her eggs, is:
- transferred to a woman
  - used in a research project (defined as being under the control of the researchers and being cultured for use in research)
  - used for training, or
  - allowed to perish.

The possible consequences of this should:

- be made clear to the egg provider and the recipient(s) before the egg sharing cycle begins, and
  - be set out in the written patient information included with the egg sharing agreement.
- 12.9** The egg provider should be given enough time to consider the implications of donating, before her donation is used.
- 12.10** If either the egg provider or the recipient in an egg sharing arrangement withdraws their consent after preparation has begun, the centre should bear any financial loss it sustains as a result.

See also guidance note:

- 5 – Consent to treatment, storage, donation and disclosure of information**

See also:

- HFEA consent forms available at [www.hfea.gov.uk](http://www.hfea.gov.uk)**

### Counselling



#### Interpretation of mandatory requirements

12A

The centre must offer anyone intending to participate in an egg sharing arrangement the opportunity for counselling.

- 12.11** The counselling of those intending to participate in an egg sharing arrangement should accord with the guidance from the British Infertility Counselling Association.

See also guidance note:

- 3 – Counselling**



### Confidentiality

**12.12** In addition to following standard procedures for protecting patient and donor confidentiality, the centre should ensure it keeps all notes, facilities and procedures for the egg provider separate from those for the recipient(s). Care should be taken to ensure that confidentiality is not compromised, for example, if the egg provider and recipient(s) are treated at the same centre at the same time.

See also guidance note:

- [30 – Confidentiality and privacy](#)

### Egg sharing agreements

**12.13** The centre should draw up separate agreements with the egg provider and with the egg recipient(s). These agreements should be consistent with each other. The centre should abide by the terms of egg sharing agreements it has made.

### Agreement between a licensed centre and an egg provider

**12.14** When drawing up agreements between the centre and egg providers, centres should seek legal advice.

**12.15** The agreement between the centre and the egg provider should set out all the terms of the arrangement. It should identify clearly the egg provider and the centre, and be signed by both parties.

**12.16** The agreement should include a statement confirming:

- that any patient who has consented to providing eggs for the treatment of others in licensed treatment under the HFE Act 1990 (as amended) will not be the legal parent of any resulting child(ren)
- what information will be available to the egg provider about the recipient and the outcome of her treatment, for example the number and sex of any resulting children, and
- what information will be available to the egg recipient about the egg provider and the outcome of her treatment, for example the number and sex of any resulting children.

**12.17** The agreement should include a full description of what the treatment is expected to involve, including:

- the number of treatment cycles covered by the agreement, and
- the expected waiting time for treatment.

**12.18** The agreement should include a statement from the egg provider confirming that she has:

- had an opportunity to talk with a member of staff qualified to explain the procedures involved in providing her eggs as part of an egg sharing arrangement
- received verbal and written information about her treatment
- received all the appropriate information listed in the relevant parts of this Code of Practice
- been offered counselling about the implications of the treatment, and
- been made aware of the screening that will be done before treatment begins.

See also guidance notes:

- [4 – Information to be provided prior to consent](#)
- [11 – Donor recruitment, assessment and screening](#)



**12.19** The agreement should include a statement confirming:

- (a) that the centre has obtained the patient's consent to the treatment
- (b) that the centre has recorded appropriately the egg provider's consent to the use of her eggs and the creation, use and storage of embryos from her eggs
- (c) that the agreement does not override the terms of paragraph 4A of Schedule 3 to the HFE Act 1990 (as amended). This states that the egg provider may withdraw or vary her consent about any embryo created using her egg at any time, until that embryo is:
  - (i) transferred to a woman
  - (ii) used in a research project
  - (iii) used in training, or
  - (iv) allowed to perish.
- (d) the consequences of any variation or withdrawal of consent, and the liability of the parties involved to pay any resulting extra charges.

**12.20** The agreement should include a statement setting out:

- (a) what charges (if any) the egg provider is expected to pay to the treatment centre, and
- (b) if the egg provider's treatment is provided at a discount, the circumstances under which she would be liable for the full cost of her treatment and the amount she would have to pay.

NOTE: If too few eggs are collected for sharing, the woman should be given the option of using all the eggs for her own treatment, at the agreed discount.

**12.21** The agreement should include full details of the proposed arrangements for distributing the eggs between the provider and recipient(s), including:

- (a) the minimum number of eggs required for sharing
- (b) the number of recipients among whom eggs will be shared (this should be no more than two, excluding the egg provider), and
- (c) how these eggs will be distributed between the provider and recipient(s).

### Agreement between a licensed centre and an egg recipient

**12.22** When drawing up agreements between the centre and egg recipients, centres should seek legal advice.

**12.23** The agreement between the centre and the egg recipient should set out all the terms of the arrangement. It should identify clearly the egg recipient and the centre, and be signed by both parties.

**12.24** The agreement should include a statement confirming:

- (a) that anyone who has consented to providing eggs for the treatment of others in licensed treatment under the HFE Act 1990 (as amended) will not be the legal parent of any resulting child(ren)
- (b) the information that will be available to the egg provider about the recipient and the outcome of her treatment, for example the number and sex of any resulting children, and
- (c) the information that will be available to the egg recipient about the egg provider and the outcome of her treatment, for example the number and sex of any resulting children, and the information that will be available to any children of the egg recipient about the egg provider, including:
  - (i) information recorded on the HFEA Register that the children are entitled to receive, and
  - (ii) the circumstances under which they may receive such information.



- 12.25** The agreement should set out what the treatment is expected to involve, including:
- the number of treatment cycles
  - the expected waiting time for treatment, and
  - that a proportion of the eggs collected from the egg provider will be used for the provider's own treatment.
- 12.26** The agreement should include a statement from the recipient confirming that she has:
- had an opportunity to discuss with an experienced member of the centre's staff the procedures involved in receiving eggs as part of an egg sharing arrangement
  - received verbal and written information about her treatment
  - received all the appropriate information listed in the relevant parts of the HFEA's Code of Practice (written information should be attached to the agreement)
  - been offered counselling about the implications of the treatment, and
  - been informed about the screening that the egg provider has undergone and the limitations of that screening in avoiding transmissible conditions.

See also guidance notes:

- [4 – Information to be provided prior to consent](#)
- [11 – Donor recruitment, assessment and screening](#)
- [20 – Donor assisted conception](#)

- 12.27** The agreement should include a statement confirming that the agreement does not override the terms of paragraph 4A of Schedule 3 to the HFE Act 1990 (as amended). This states that the egg provider may withdraw or vary her consent about any embryo created using her eggs at any time until that embryo is:
- transferred to a woman
  - used in a research project
  - used in training, or
  - allowed to perish.
- 12.28** The agreement should include a statement describing:
- what charges the egg recipient is expected to pay to the centre, and
  - what treatment these charges will cover.
- 12.29** The agreement should set out the proposed arrangements for distributing the eggs between the provider and recipient(s), including:
- the minimum number of eggs required for sharing
  - the number of recipients among whom eggs will be shared (this should be no more than two, excluding the egg provider), and
  - how these eggs will be allocated between the provider and recipient(s).

### Egg sharing for research

- 12.30** As outlined in the previous sections, the centre should draw up agreements between the centre and the egg provider, and the centre and the egg recipient (in this case, the research group), including all relevant information.



## HFEA guidance (cont)

- 12.31** If eggs are being donated to research through an egg sharing agreement, the centre must ensure that the eggs are divided between the egg donor and the recipient (the research project) by someone not directly involved in the research project.
- 12.32** If a centre offers egg sharing for treatment and research, equal benefits in kind should be available for both. This ensures that there is no advantage in donating to one recipient rather than the other.

See also guidance notes:

- [22 – Research and training](#)



## Other legislation, professional guidelines and information

- BICA Guidelines for Good Practice in Infertility Counselling (2008)

# 13. Payments for donors


## This guidance note contains:

### Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Extracts from licence conditions
- Reference to relevant HFEA Directions

### HFEA guidance

- Payments for donors ■
- Recording payments for donors

 Refer to principles 1, 2, 10, and 13

■ Section includes interpretation of mandatory requirements



## Mandatory requirements

### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

#### 12 General conditions

(1) The following shall be conditions of any licence granted under this Act –

... (e) that no money or other benefit shall be given or received in respect of any supply of gametes, embryos or human admixed embryos unless authorised by Directions...

#### 41 Offences

...(8) Where a person to whom a licence applies or the holder of the licence gives or receives any money or other benefit, not authorised by Directions, in respect of any supply of gametes, embryos or human admixed embryos, he is guilty of an offence.

(9) A person guilty of an offence under subsection (8) above is liable on summary conviction to imprisonment for a term not exceeding six months or a fine not exceeding level five on the standard scale or both.

### Licence conditions

T69 No money or other benefit must be given or received in respect to any supply of gametes, embryos or human admixed embryos unless authorised by Directions.

### Directions

#### 0001 – Gametes and embryos

For a copy of the relevant Directions visit [www.hfea.gov.uk](http://www.hfea.gov.uk)



## HFEA guidance

### Payments for donors



#### Interpretation of mandatory requirements

13A

If the person responsible or the licence holder gives or receives any money or benefit for the supply of gametes, embryos or human admixed embryos that is not authorised by the applicable HFEA Directions, they have committed a criminal offence. Conviction may result in a prison term, a fine or both.



- 13.1** HFEA Directions do not allow payment of a ‘flat rate’ to all donors (for example, £20 to all sperm donors).
- 13.2** Donors may be reimbursed all reasonable expenses incurred in the UK in connection with donating gametes or embryos (for example a standard-class rail ticket by the most direct route), but not excessive expenses if these would be benefits in themselves.
- 13.3** Expenses claimed by donors should be directly linked to the process of donation (for example, the cost of travel to the centre, or the cost of childcare during donation when the donor would normally be caring for the child). They should not be expenses which the donor would have incurred irrespective of their donation.
- 13.4** Donors may be compensated for loss of earnings (wherever they live) up to a daily maximum of £61.28 but with an overall limit of £250 for each course or cycle of donation.
- 13.5** When gametes have been donated overseas and import to the UK is being considered, centres should ensure that the donor has not received compensation for loss of earnings that exceeds the amounts specified above (local currency equivalent).
- 13.6** Advertising or publicity aimed at recruiting gamete or embryo donors, or encouraging donation, should not refer to the possibility of financial gain or similar advantage, although it may refer to reimbursement or compensation permitted under relevant HFEA Directions.
- 13.7** The person responsible has a duty to assure themselves that no payments or benefits have been given or promised to the donor by another agency or intermediary, including introductory agencies, except those that are in line with relevant HFEA Directions.
- 13.8** The centre should ensure that donors understand that donating gametes and embryos is voluntary and unpaid and that they may be reimbursed only for expenses and compensated for loss of earnings.
- 13.9** If an egg donor becomes ill as a direct result of donating, the centre may also reimburse their reasonable expenses arising from the illness.

See also guidance note:

- [12 – Egg sharing arrangements](#)

### Recording payments for donors

- 13.10** The HFEA expects centres to keep a central log of all expenses and reimbursement for loss of earnings paid to donors. This log should be made available to HFEA inspectors, and should contain the following information:
- date of payment
  - amount of payment
  - donor (name or unique identifier)
  - reason for payment (nature of expense or loss of earnings)
  - total amount paid to the donor to date for this course (of sperm donation) or cycle (of egg donation), and
  - receipts that show expenses incurred, or evidence that demonstrates the loss of earnings.

# 14. Surrogacy

## This guidance note contains:


### Mandatory requirements

- Extracts from the HFE Act 1990
- Reference to relevant Regulations
- Reference to relevant HFEA Directions

### HFEA guidance

- Patients providing gametes in surrogacy arrangements ■
- Additional information for those involved in surrogacy arrangements

### Other legislation, professional guidelines and information

 Refer to principle 5

■ Section includes interpretation of mandatory requirements



## Mandatory requirements

### Human Fertilisation and Embryology Act 2008

#### PART 2 – Parenthood in cases involving assisted reproduction

##### Parental orders

- 54 (1) On an application made by two people (“the applicants”), the court may make an order providing for a child to be treated in law as the child of the applicants if—
- (a) the child has been carried by a woman who is not one of the applicants, as a result of the placing in her of an embryo or sperm and eggs or her artificial insemination,
  - (b) the gametes of at least one of the applicants were used to bring about the creation of the embryo, and
  - (c) the conditions in subsections (2) to (8) are satisfied.
- (2) The applicants must be—
- (a) husband and wife,
  - (b) civil partners of each other, or
  - (c) two persons who are living as partners in an enduring family relationship and are not within prohibited degrees of relationship in relation to each other.
- (3) Except in a case falling within subsection (11), the applicants must apply for the order during the period of 6 months beginning with the day on which the child is born.
- (4) At the time of the application and the making of the order—
- (a) the child’s home must be with the applicants, and
  - (b) either or both of the applicants must be domiciled in the United Kingdom or in the Channel Islands or the Isle of Man.
- (5) At the time of the making of the order both the applicants must have attained the age of 18.
- (6) The court must be satisfied that both—
- (a) the woman who carried the child, and



## Mandatory requirements (cont)

(b) any other person who is a parent of the child but is not one of the applicants (including any man who is the father by virtue of section 35 or 36 or any woman who is a parent by virtue of section 42 or 43),

have freely, and with full understanding of what is involved, agreed unconditionally to the making of the order.

(7) Subsection (6) does not require the agreement of a person who cannot be found or is incapable of giving agreement; and the agreement of the woman who carried the child is ineffective for the purpose of that subsection if given by her less than six weeks after the child's birth.

(8) The court must be satisfied that no money or other benefit (other than for expenses reasonably incurred) has been given or received by either of the applicants for or in consideration of—

(a) the making of the order,

(b) any agreement required by subsection (6),

(c) the handing over of the child to the applicants, or

(d) the making of arrangements with a view to the making of the order,

unless authorised by the court.

(9) For the purposes of an application under this section—

(a) in relation to England and Wales, section 92(7) to (10) of, and Part 1 of Schedule 11 to, the Children Act 1989 (c. 41) (jurisdiction of courts) apply for the purposes of this section to determine the meaning of “the court” as they apply for the purposes of that Act and proceedings on the application are to be “family proceedings” for the purposes of that Act,

(b) in relation to Scotland, “the court” means the Court of Session or the sheriff court of the sheriffdom within which the child is, and

(c) in relation to Northern Ireland, “the court” means the High Court or any county court within whose division the child is.

(10) Subsection (1)(a) applies whether the woman was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or the sperm and eggs or her artificial insemination.

(11) An application which—

(a) relates to a child born before the coming into force of this section, and

(b) is made by two persons who, throughout the period applicable under subsection (2) of section 30 of the 1990 Act, were not eligible to apply for an order under that section in relation to the child as husband and wife,

may be made within the period of six months beginning with the day on which this section comes into force.

### Interpretation of Part 2

58 (1) In this Part “enactment” means an enactment contained in, or in an instrument made under—

(a) an Act of Parliament,

(b) an Act of the Scottish Parliament,

(c) a Measure or Act of the National Assembly for Wales, or

(d) Northern Ireland legislation.

(2) For the purposes of this Part, two persons are within prohibited degrees of relationship if one is the other's parent, grandparent, sister, brother, aunt or uncle; and in this subsection references to relationships—

(a) are to relationships of the full blood or half blood or, in the case of an adopted person, such of those relationships as would subsist but for adoption, and



## Mandatory requirements (cont)

(b) include the relationship of a child with his adoptive, or former adoptive, parents, but do not include any other adoptive relationships.

(3) Other expressions used in this Part and in the 1990 Act have the same meaning in this Part as in that Act.

### Regulations

The Parental Orders (Human Fertilisation and Embryology) Regulations 2010

The Parental Orders (Human Fertilisation and Embryology) (Scotland) Regulations 2010

Copies of this legislation can be found at [www.opsi.gov.uk](http://www.opsi.gov.uk)

### Directions

**0005** – Directions on collecting and recording information for the HFEA

For a copy of the relevant Directions visit [www.hfea.gov.uk](http://www.hfea.gov.uk)



## HFEA guidance

### Patients providing gametes in surrogacy arrangements



#### Interpretation of mandatory requirements

14A

Patients providing gametes in surrogacy arrangements must be registered as donors and therefore:

- (a) screened as donors, in accordance with screening requirements for donors of gametes, and
- (b) be subject to all other requirements (eg, consent, counselling and provision of information) applicable to donors.

See also guidance notes:

- **11 – Donor recruitment, assessment and screening**

### Additional information for those involved in surrogacy arrangements

- 14.1** In addition to providing relevant information about gamete donation, the centre should give those involved in surrogacy arrangements information about the effect of the Parental Orders provisions in the HFE Act 2008. These state that parental rights and obligations in respect of surrogacy arrangements may be transferred from the birth parents to those who commissioned the surrogacy arrangement, as long as certain conditions are met.
- 14.2** The centre should advise patients that surrogacy arrangements are unenforceable and that they should seek legal advice about this.
- 14.3** The centre should advise patients intending to travel to another country for the purpose of entering into a surrogacy arrangement not to do so until they have sought legal advice about:
- (a) legal parenthood of the prospective child, and
  - (b) the adoption or parental orders procedures for that country.



## HFEA guidance (cont)

See also guidance notes:

- [4 – Information to be provided prior to consent](#)
- [6 – Legal parenthood](#)



## Other legislation, professional guidelines and information

- Surrogacy Arrangements Act 1985
- Home Office UK Border Agency – [www.bia.homeoffice.gov.uk](http://www.bia.homeoffice.gov.uk)

# 15. Procuring, processing and transporting gametes and embryos

This guidance note contains:

## Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Extracts from licence conditions
- Reference to relevant HFEA Directions

## HFEA guidance

- Documented procedures: general ●
- Patient selection and procurement ●
- Home insemination ■
- Home procurement ●
- Reception at the centre ●
- Processing and disposal of gametes and embryos ●
- Packaging, distribution and recall of gametes and embryos ●■
- Quality and safety of gametes and embryos

➔ Refer to principles 3, 6, 7, 8, 10 and 11

● Section includes mandatory requirements

■ Section includes interpretation of mandatory requirements

## Other legislation, professional guidelines and information



## Mandatory requirements

### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Requirements for holding a licence for gametes and embryo preparation processes

- 11 In respect of gametes and embryos preparation processes, licence conditions shall require compliance with—
- (a) the requirements of Article 20(2) and (3) (tissue and cell processing) and Article 21(2) to (4) of the first Directive, and
  - (b) the requirements laid down in the provisions of the third Directive listed in the right-hand column, the subject-matter of which are described in the left-hand column in respect of those provisions.

Relevant provisions of the third Directive	
Reception of gametes and embryos at the tissue establishment	Annex II, Part A
Processing of gametes and embryos (validation, documentation and evaluation of critical procedures)	Annex II, Part B
Storage and release of gametes and embryos (criteria to be complied with, including standard operating procedures)	Annex II, Part C
Distribution and recall of gametes and embryos (criteria to be complied with, including procedures to be adopted)	Annex II, Part D
Final labelling of gametes and embryo containers for distribution (information to be shown on container label or in accompanying documentation)	Annex II, Part E
External labelling of the shipping container (information to be shown on label on shipping container)	Annex II, Part F



## Mandatory requirements (cont)

NOTE: Directive 2006/86/EC (the third Directive) implements Directive 2004/23/EC as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.

### Directions

**0001** – Gamete and embryo donation.

**0009** – Keeping gametes and embryos in the course of carriage between premises

For a copy of the relevant Directions visit [www.hfea.gov.uk](http://www.hfea.gov.uk)



## HFEA guidance

### Documented procedures: general



#### Mandatory requirements

##### Licence conditions

- T70 There must be a documented system in place that ensures the identification of all gametes and embryos from procurement to use or disposal.
- T74 There must be a documented system in place for ratifying that gametes and/or embryos meet appropriate specifications of safety and quality for use and for their transportation/distribution.

**15.1** The centre should, where appropriate, have documented procedures that cover:

- (a) superovulation
- (b) egg retrieval
- (c) sedation
- (d) resuscitation
- (e) sperm aspiration
- (f) gamete and embryo transfer
- (g) insemination
- (h) follow-up after treatment, including management of complications, and
- (i) management of ovarian hyper-stimulation syndrome.

See also guidance note:

- **31 – Record keeping and document control**



See also references to specific documented procedures in the following sections of this guidance note:

- [Home procurement](#)
- [Reception at the centre](#)
- [Processing and disposal of gametes and embryos](#)
- [Packaging, distribution and recall of gametes and embryos](#)
- [Quality and safety of gametes and embryos.](#)

### Patient selection and procurement



#### Mandatory requirements

##### Licence conditions

- T49 The clinician responsible for the patient must document the justification for the use of their gametes or embryos created with their gametes in treatment, based on the patient's medical history and therapeutic indications.



#### Interpretation of mandatory requirements

15A

Procurement of gametes is a licensable activity which must be undertaken at licensed premises or in accordance with a third party agreement.

- 15.2** In addition to meeting the requirements in licence conditions, the centre should, at the time of procurement, label each package containing gametes and embryos in a way that is not susceptible to unauthorised or undetectable alteration. If the size of the packaging permits, the identity of the patient, patient's partner or donor should also be noted.

- 15.3** The centre should not obtain gametes for treatment from anyone under the age of 18 unless:
- (a) those gametes are intended for the patient's own treatment or that of their partner
  - (b) the centre can satisfy itself that the patient is capable of giving effective consent to the use of the gametes for that purpose, and
  - (c) the patient has given effective consent to the use of their gametes for that purpose.

### Home insemination



#### Interpretation of mandatory requirements

15B

The centre may supply cryopreserved sperm only to a person covered by a licence. Sperm supplied for home insemination must therefore be thawed or thawing. The use of a dry shipper or any other container that would preserve the sperm in a frozen or preserved state when it leaves the treatment centre is prohibited.

- 15.4** Sperm should be supplied for insemination at home (or another unlicensed site) only in exceptional circumstances. When this occurs, the treatment centre should:
- (a) record this fact and explain the relevant exceptional circumstances in the medical records, and



### 15.4 (cont)

- (b) complete the relevant DI (Donor Insemination) treatment form in the usual way, except that the date of supply or posting should be entered as the date of insemination and a note made that the sperm was supplied for home insemination.

**15.5** Provided that the woman has attended the treatment centre for assessment, sperm for insemination at home (or another unlicensed site) may be either handed to her in person or sent to her by courier.

See also:

- [DI Treatment Forms – available at www.hfea.gov.uk](http://www.hfea.gov.uk)

## Home procurement



### Mandatory requirements

#### Licence conditions

**T68** Where the sperm is procured at home, the centre must record this in the gamete provider's records.

**15.6** A centre should normally store or use only sperm that has been obtained directly from the provider, another licensed clinic or a centre with which the licensed centre has a transport arrangement, or that has been imported in line with HFEA Directions.

**15.7** The centre may use sperm produced by a man at home (or another unlicensed site). The centre should follow protocols to ensure, as far as possible, that:

- (a) the identity of the sperm provider is confirmed
- (b) the sperm provider confirms he produced the sperm
- (c) the date and time of the sperm production is confirmed (and is no more than two hours before the centre received the sperm)
- (d) the sperm has not been interfered with, and
- (e) the sperm receptacle is clearly labelled with the sperm provider's full name and unique identifier.

The centre's documented procedures should ensure that this information is recorded in the patient's medical records.

**15.8** If embryos have been created using partner sperm produced at home (or another unlicensed site) and donation is being considered, the centre should consider the fact that the sperm was not produced at a licensed treatment centre and tell prospective recipients.

**15.9** The requirements for receipt from another centre also apply to sperm procured at home or another unlicensed site (see 'Reception at the centre' below).

See also guidance note:

- [16 – Imports and exports](#)



### Reception at the centre

#### Mandatory requirements (cont)

##### Licence conditions

**T109** The centre must put in place, maintain and implement a procedure for the receipt of gametes and/or embryos from another centre or third party premises to ensure that:

- a. the consignment of gametes and/or embryos is verified against SOPs and specifications. These must include information relating to the transport conditions, packaging, labelling, patient/donor documentation, and any other associated documentation and samples. These must also include the technical requirements and other criteria considered by the establishment to be essential for the maintenance of acceptable quality, and
- b. the gametes and embryos received are quarantined until they, along with associated documentation, have been inspected or otherwise verified as conforming to requirements. The review of relevant patient/donor and procurement information and thus acceptance of the donation needs to be carried out by specified/authorised persons.

**T110** The following data must be registered at the centre:

- a. consent including the purpose(s) for which the gametes and/or embryos may be used and any specific instructions for disposal if the gametes or embryos are not used for the consented purpose
- b. patient/donor identification and characteristics: age, sex and presence of risk
- c. all required records relating to the procurement and the taking of the patient/donor history
- d. gametes and embryos obtained and relevant characteristics
- e. the results of laboratory tests and of other tests, and
- f. a properly documented review of the complete patient/donor evaluation against the selection criteria by an authorised and trained person.

**15.10** In addition to the requirements in licence conditions, the documented procedures against which each consignment of gametes and embryos is verified should include requirements for:

- (a) patient, patient's partner and donor verification
- (b) packaging and transport
- (c) labelling of containers for procured gametes, and
- (d) labelling of shipping containers and any associated documents.

**15.11** The documented procedure for the receipt of gametes or embryos from another centre should also ensure that records are kept to demonstrate that before gametes or embryos are released, all appropriate specifications have been met.

**15.12** The centre's documented procedures should ensure that the relevant legal requirements are met for registering patients, patients' partners and donors.



### Processing and disposal of gametes and embryos



#### Mandatory requirements

##### Licence conditions

- T72 The critical processing procedures must be validated and must not render the gametes or embryos clinically ineffective or harmful to the recipient. This validation may be based on studies performed by the establishment itself, or on data from published studies or from well-established processing procedures, by retrospective evaluation of the clinical results of tissues provided by the establishment.
- T73 Before implementing any significant change in processing, the modified process must be validated and documented.

**15.13** The centre should take account of the special status of the human embryo when the development of an embryo is to be brought to an end. Terminating the development of embryos and disposing of the remaining material should be approached with appropriate sensitivity, having regard to the interests of the gamete providers and anyone for whose treatment the embryos were being kept.

See also guidance note:

- **10 – Embryo testing and sex selection**

### Packaging, distribution and recall of gametes and embryos



#### Mandatory requirements

##### Licence conditions

- T105 All gametes and embryos must be packaged and transported in a manner that minimises the risk of contamination and preserves the required characteristics and biological functions of the gametes or embryos. The packaging must also prevent contamination of those responsible for packaging and transportation.
- T106 The packaged gametes/embryos must be shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos.
- T107 The transport conditions, including temperature and time limit, must be specified and the labelling of every shipping container must include as a minimum:
- a label marked “TISSUES AND CELLS” and “HANDLE WITH CARE”
  - the identification of the establishment from which the package is being transported (address and telephone number) and a contact person in the event of problems
  - the identification of the tissue establishment of destination (address and telephone number) and the person to be contacted to take delivery of the package
  - the date and time of the start of transportation.
  - the type of gametes/embryos plus their identification code
  - specifications concerning conditions of transport relevant to the quality and safety of the gametes or embryos
  - specifications concerning storage conditions such as “DO NOT FREEZE”



### Mandatory requirements

T107 (cont)

- h. in the case of all gametes and embryos, the following indication: “DO NOT IRRADIATE”, and
- i. when a product is known to be positive for a relevant infectious disease marker, the following indication: “BIOLOGICAL HAZARD”.

If any of the information under the points above cannot be included on the primary container label, it must be provided on a separate sheet accompanying the primary container. The sheet must be packaged with the primary container in a manner that ensures that they remain together.

T108 The container/package must be secure and ensure that the gametes or embryos are maintained in the specified conditions. All containers and packages need to be validated as fit for purpose.



### Interpretation of mandatory requirements

15C

When a third party transports gametes or embryos, they must be subject to a third party agreement, and a documented agreement must be in place to ensure that the required conditions are fulfilled.

The centre originating the distribution must have a recall procedure that defines the responsibilities and actions required when a distribution is recalled. Such a recall should be investigated using the procedure for investigating adverse incidents. There must be a procedure for handling returned gametes and embryos that includes their reacceptance into the inventory, if applicable.

**15.14** If a container used to ship packaged gametes or embryos has not been validated by the manufacturer or supplier for specified transport conditions, these conditions should be monitored during transport, or validated by the centre or third party responsible for transport.

**15.15** The centre's documented procedures should ensure that the following are recorded:

- (a) packaging and labelling procured gametes for distribution
- (b) transporting gametes and embryos
- (c) labelling shipping containers, and
- (d) recalling gametes and embryos.

See also guidance notes:

- [24 – Third party agreements](#)
- [27 – Adverse incidents](#)

### Quality and safety of gametes and embryos

**15.16** The centre should establish and use documented procedures to ensure that:

- (a) procedures involving the manipulation of gametes or embryos (for example, sperm preparation, separation of eggs from cumulus cells, and fertilisation of eggs) are performed in a controlled environment with appropriate air quality
- (b) the risk of bacterial or other contamination is minimised
- (c) appropriate measures are in place for handling contaminated samples



### 15.16 (cont)

- (d) gametes or embryos are handled in a way that protects those properties that are required for their ultimate clinical use
- (e) where permitted, the mixture of gametes or embryos that have been subject to different laboratory procedures before transfer (eg, IVF and ICSI) is recorded and the reasons for their mixture are clearly set out, and
- (f) all blood products with which gametes or embryos may come into contact, except those of the woman receiving treatment, are pre-tested for HIV, hepatitis B and hepatitis C.

**15.17** If it is impractical to carry out a procedure involving the manipulation of gametes or embryos in a Grade C environment, it should be done in an environment of at least Grade D air quality. If the environmental air quality drops below Grade D during a procedure involving the manipulation of gametes or embryos, those gametes or embryos should be used in treatment only if the centre can assure itself that this poses no extra risk to the woman to be treated or to any resulting child.

**15.18** Air quality monitoring should be used as a routine measure of quality assurance (for example, through particle counts or the use of settle plates, recording any cultures observed). The process of validating air quality should include:

- (a) documenting culture conditions, and
- (b) mapping temperature and using control charts to predict the effects of any change in procedures.

**15.19** Where possible, cryopreserved gametes should be accompanied by documents that indicate their expected post-thaw quality.

**15.20** The centre should not use for treatment gametes or embryos exposed to a material risk of contamination or damage that may harm recipients or resulting children. If in any doubt about these risks, the centre should seek expert advice.

See also:

- [HFEA Summary of air quality information, 2006](#)  
You can find these forms at [www.hfea.gov.uk](http://www.hfea.gov.uk)



## Other legislation, professional guidelines and information

- Rules and Guidance for Pharmaceutical Manufacturers and Distributors (2002).

# 16. Imports and exports

## This guidance note contains:

### Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Reference to relevant HFEA Directions

 Refer to principles 7, 10 and 13

### HFEA guidance

- Registering patients and donors ■
- Information for patients and donors
- Imports and exports decision tree
- General Directions: evidence of compliance ■
- Special Directions: imports or exports within the EEA and Gibraltar
- Special Directions: imports or exports outside the EEA and Gibraltar
- Notifying the HFEA about transfers ■

■ Section includes interpretation of mandatory requirements

### Other legislation, professional guidelines and information



## Mandatory requirements

### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

24 Directions as to particular matters

- (3) In relation to gametes or embryos that are not intended for human application, directions may authorise, in such circumstances and subject to such conditions as may be specified in the directions, the keeping, by or on behalf of a person to whom a licence applies, of gametes or embryos in the course of their carriage to or from any premises.
- (3A) In relation to gametes and embryos that are intended for human application, directions may authorise the keeping of gametes or embryos by or on behalf of a person to whom a licence applies, in the course of their carriage –
- (a) between premises to which licences relate,
  - (b) between such premises and relevant third party premises,
  - (c) between premises referred to in paragraphs (a) and (b) and tissue establishments accredited, designated, authorised or licensed under the laws, or other measures, of an EEA state other than the United Kingdom or of Gibraltar which implement the first, second and third Directives, or
  - (d) between premises referred to in paragraphs (a) and (b) and tissue establishments in a country which is not an EEA state, pursuant to directions given under subsection (4), in such circumstances and subject to such conditions as may be specified in directions.
- (3B) Directions may authorise, in such circumstances and subject to such conditions as may be specified in the directions, the keeping, by or on behalf of a person to whom a licence applies, of human admixed embryos in the course of their carriage to or from any premises.



## Mandatory requirements (cont)

- (4) Directions may authorise any person to whom a licence applies to receive gametes, embryos or human admixed embryos from outside the United Kingdom or to send gametes, embryos or human admixed embryos outside the United Kingdom in such circumstances and subject to such conditions as may be specified in the directions, and directions made by virtue of this subsection may provide for sections 12 to 14 of this Act to have effect with such modifications as may be specified in the directions.
- (4A) In giving any directions under subsection (4) authorising any person to whom a licence applies to import into the United Kingdom from a country which is not an EEA state, or to export from the United Kingdom to such a country, gametes or embryos intended for human application, the Authority shall—
- include directions specifying the measures that persons to whom a licence applies shall take to ensure that all such imports or exports meet standards of quality and safety equivalent to those laid down in the Act, and
  - have regard to ensuring traceability.

### Directions

**0005** – Collecting and recording information for the HFEA

**0006** – Import and export of gametes and embryos

For a copy of the relevant Directions visit [www.hfea.gov.uk](http://www.hfea.gov.uk)



## HFEA guidance

### Registering patients and donors



#### Interpretation of mandatory requirements

16A

Where a centre wishes to import gametes or embryos into the UK, or export them from the UK, the person responsible must ensure that:

- a donor information form is completed in respect of any donated gametes, and
- where the gametes are exported or imported for the use of a patient, that the patient is registered with the HFEA, and the relevant registration forms are completed.

### Information for patients and donors

**16.1** Before a patient or donor considers obtaining gametes or embryos from outside the UK, the centre should inform them that special criteria relating to UK standards must be met.

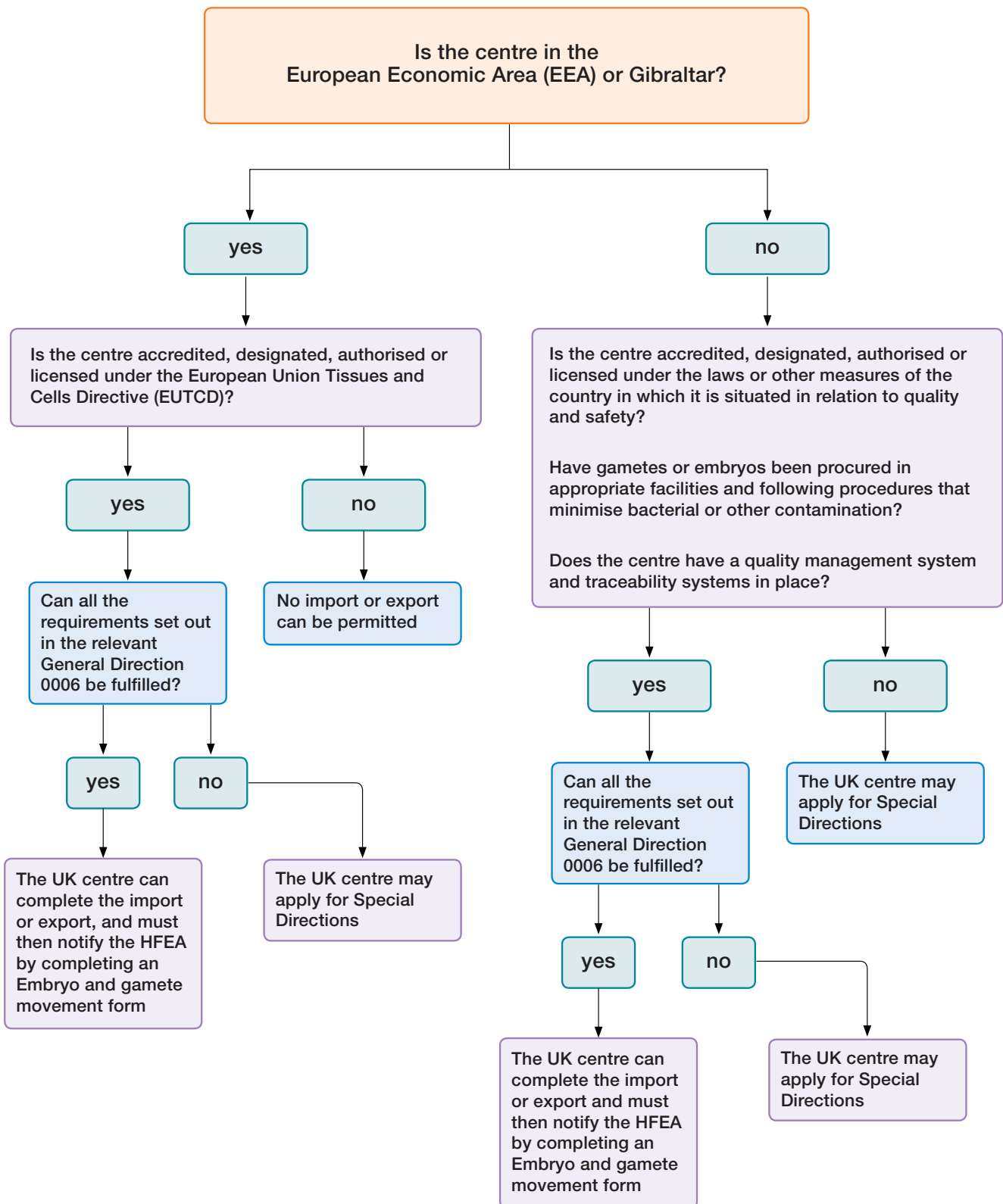
### Imports and exports decision tree

**16.2** The decision tree on the following page summarises what centres must consider when transferring gametes and embryos:

- within the European Economic Area (EEA) and Gibraltar, or
- outside the EEA and Gibraltar.



Imports and exports decision tree





### General Directions: evidence of compliance



#### Interpretation of mandatory requirements

16B

##### a) Within the EEA and Gibraltar

Where a centre wants to export or import gametes or embryos to or from another EEA state or Gibraltar, the person responsible must obtain and retain (for three years) written evidence that the receiving or sending centre is accredited, designated, authorised or licensed in accordance with the requirements of the European Tissues and Cells Directive (EUTCD).

##### b) Outside the EEA and Gibraltar

Where a centre wants to export or import gametes or embryos to or from a country outside the EEA or Gibraltar, the person responsible must obtain and retain (for three years) written evidence that:

- (i) the receiving or sending centre is accredited, designated, authorised or licensed under the laws or other measures of the country in which it is situated in relation to quality and safety
- (ii) the centre has appropriate quality management and traceability systems, and
- (iii) the gametes or embryos have been procured and processed in appropriate facilities, and following procedures that minimise bacterial or other contamination.

In each case, a copy of the information retained must be provided to the Authority on request.

In all cases, all the remaining requirements in the relevant HFEA Directions on import and export of gametes and embryos relating to identification, consent, parenthood, payment of the donor, use of the gametes and embryos, and screening must be met.

- 16.3** The systems referred to in the interpretation box above should include the traceability of all materials and equipment that could affect the quality and safety of the gametes or embryos. For transfers to or from centres within the EEA and Gibraltar, this evidence may include documented certification from the competent authority that the centre complies with the requirements of the EUTCD, is included in a national database of registered tissue establishments, or both.

See also guidance note:

- [19 - Traceability](#)
- [31 - Record keeping and document control](#)

### Special Directions: imports or exports within the EEA and Gibraltar

- 16.4** An application to the HFEA for Special Directions should be made when patients wish to transfer gametes or embryos to or from an EEA centre that is accredited, designated, authorised or licensed in line with the EUTCD, but compliance with the other conditions in the relevant General Directions cannot be assured.
- 16.5** The HFEA has no power to issue Special Directions to allow imports to or exports from unaccredited tissue establishments within the EEA. Centres should tell patients that imports or exports of gametes or embryos are permitted only if the EEA centre has been accredited and licensed as complying with the requirements of the EUTCD.

### Special Directions: imports or exports outside the EEA and Gibraltar

- 16.6** If compliance with all conditions in the relevant General Directions cannot be assured, then an application to the HFEA for Special Directions should be made.



See also:

- [Special Direction – Export of Embryos form](#)
- [Special Direction – Export of Gametes form](#)
- [Special Direction – Import of Embryos form](#)
- [Special Direction – Import of Gametes form](#)

You can find these forms at: [www.hfea.gov.uk](http://www.hfea.gov.uk)

### Notifying the HFEA about transfers



#### Interpretation of mandatory requirements

16C

When transferring gametes or embryos to or from the UK under General Directions, the centre must complete the relevant transfer notification form. In this form, the person responsible must declare that they are satisfied that the centre to or from which the transfer is being made meets the requirements listed in the Directions. Completed forms must be returned to the HFEA no later than five working days after the transfer has taken place.

When transferring gametes or embryos under Special Directions, the person responsible must notify the HFEA within two working days.

See also:

- [Embryo and gamete movement – Out \(GO\) form](#)
- [Embryo and gamete movement – In \(GI\) form](#)
- Found on the Electronic Data Interchange (EDI) system



### Other legislation, professional guidelines and information

For information on EEA countries and the relevant competent authorities there, you may find the following links useful:

- EEA countries – [www.ec.europa.eu/external\\_relations/eea/](http://www.ec.europa.eu/external_relations/eea/)
- list of EEA countries and competent authorities – [www.ec.europa.eu/health/ph\\_threats/human\\_substance/documents/tissues\\_responses\\_en.pdf](http://www.ec.europa.eu/health/ph_threats/human_substance/documents/tissues_responses_en.pdf)
- list of competent bodies for EUTCD – [www.iss.it/ecet/scie/cont.php?id=85&lang=2&tipo=23](http://www.iss.it/ecet/scie/cont.php?id=85&lang=2&tipo=23)

# 17. Storage of gametes and embryos

## This guidance note contains:

 Refer to principles 5, 6, 7, 8 and 10

### Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Extracts from licence conditions
- Reference to relevant HFEA Directions
- Reference to relevant Regulations

### HFEA guidance

- Facilities and documented procedures
- Safety of equipment used to store cryopreserved gametes and embryos
- Screening and storage of samples to prevent cross-contamination
- Storing ovarian and testicular tissue ■
- Information for those seeking storage of gametes or embryos
- Treatment using cryopreserved eggs or embryos
- Consent to storage and cases where consent is not required for storage ■
- Extension of storage
- Disputes involving the withdrawal of consent to storage ●■
- Storage review
- The end of storage ■

● Section includes mandatory requirements

■ Section includes interpretation of mandatory requirements

### Other legislation, professional guidelines and information



## Mandatory requirements

### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

- 1 Meaning of “embryo”, “gamete” and associated expressions
  - (4) In this Act (except in section 4A) –
    - (a) references to eggs are to live human eggs, including cells of the female germ line at any stage of maturity, but (except in subsection (1)(b)) not including eggs that are in the process of fertilisation or are undergoing any other process capable of resulting in an embryo,
    - (b) references to sperm are to live human sperm, including cells of the male germ line at any stage of maturity, and
    - (c) references to gametes are to be read accordingly.
- 3 Prohibitions in connection with embryos
  - (1) No person shall bring about the creation of an embryo except in pursuance of a licence.
  - (1A) No person shall keep or use an embryo except–
    - (a) in pursuance of a licence, or
    - (b) in the case of–

Human Fertilisation and Embryology Authority



## Mandatory requirements (cont)

(1A) (cont)

- (i) the keeping, without storage, of an embryo intended for human application, or
- (ii) the processing, without storage, of such an embryo in pursuance of a third party agreement.

(3) A licence cannot authorise –

... (c) keeping or using an embryo in any circumstances in which regulations prohibit its keeping or use

4 Prohibitions in connection with gametes

(1) No person shall–

- (a) store any gametes...  
except in pursuance of a licence.

(2) A licence cannot authorise storing or using gametes in any circumstances in which regulations prohibit their storage or use.

14 Conditions of storage licences

(1) The following shall be conditions of every licence authorising the storage of gametes, embryos or human admixed embryos

- (a) that gametes of a person shall be placed in storage only if–
  - (i) received from that person,
  - (ii) acquired in circumstances in which by virtue of paragraph 9 or 10 of Schedule 3 that person's consent to the storage is not required, or
  - (iii) acquired from a person to whom a licence or third party agreement applies,
- (aa) that an embryo taken from a woman shall be placed in storage only if–
  - (i) received from that woman, or
  - (ii) acquired from a person to whom a licence or third party agreement applies,
- (ab) that an embryo the creation of which has been brought about in vitro otherwise than in pursuance of that licence shall be placed in storage only if acquired from a person to whom a licence or third party agreement applies,
- (ac) that a human admixed embryo the creation of which has been brought about in vitro otherwise than in pursuance of that licence shall be placed in storage only if acquired from a person to whom a licence under paragraph 2 or 3 of Schedule 2 applies,
- (b) that gametes or embryos which are or have been stored shall not be supplied to a person otherwise than in the course of providing treatment services unless that person is a person to whom a licence applies,
- (ba) that human admixed embryos shall not be supplied to a person unless that person is a person to whom a licence applies,
- (c) that no gametes, embryos or human admixed embryo shall be kept in storage for longer than the statutory storage period and, if stored at the end of the period, should be allowed to perish, and
- (d) that such information as the Authority may specify in directions as to the persons whose consent is required under Schedule 3 to this Act, the terms of their consent and the circumstances of the storage and as to such other matters as the Authority may specify in directions shall be included in the records maintained in pursuance of the licence.



## Mandatory requirements (cont)

- (2) No information should be removed from any records maintained in pursuance of such a licence before the expiry of such period as may be specified in directions for records of the class in question.
- (3) The statutory storage period in respect of gametes is such period not exceeding ten years as the licence may specify.
- (4) The statutory storage period in respect of embryos is such period not exceeding ten years as the licence may specify.
- (4A) The statutory storage period in respect of human admixed embryos is such period not exceeding ten years as the licence may specify.
- (5) Regulations may provide that subsection (3), (4) or (4A) above should have effect as if for ten years there were substituted–
  - (a) such shorter period, or
  - (b) in such circumstances as may be specified in the regulations, such longer period,as may be specified in the regulations.

### 14A Conditions of licences: human application

- (1) This section applies to–
  - (a) every licence under paragraph 1 or 1A of Schedule 2,
  - (b) every licence under paragraph 2 of that Schedule, so far as authorising storage of gametes or embryos intended for human application, and
  - (c) every licence under paragraph 3 of that Schedule, so far as authorising activities in connection with the derivation from embryos of stem cells that are intended for human application.
- (2) A licence to which this section applies may not authorise the storage, procurement, testing, processing or distribution of gametes or embryos unless it contains the conditions required by Schedule 3A.
- (3) In relation to any gametes or embryos imported into the United Kingdom from an EEA state other than the United Kingdom or from Gibraltar, compliance with the requirements of the laws or other measures adopted in the relevant state or territory for the purpose of implementing the first, second and third Directives shall be taken to be compliance with the conditions required by Schedule 3A.
- (4) Subsection (3) shall not apply to any licence conditions imposed by the Authority which amount to more stringent protective measures for the purposes of Article 4(2) of the first Directive.

### 41 Offences

- (1) A person who –
  - (b) does anything which, by virtue of section 3(3) of this Act, cannot be authorised by a licence,is guilty of an offence and liable on conviction on indictment to imprisonment for a term not exceeding ten years or a fine or both.
- (2) A person who–
  - (a) contravenes section 3(1) or (1A) of this Act, otherwise than by doing something which, by virtue of section 3(3) of this Act, cannot be authorised by a licence,...
  - (b) keeps any gametes in contravention of section 4(1)(a) of this Act,...is guilty of an offence.



## Mandatory requirements (cont)

### Schedule 3

Consent to use or storage of gametes, embryos or human admixed embryos etc

#### Storage of gametes and embryos

- 8
- (1) A person's gametes must not be kept in storage unless there is an effective consent by that person to their storage and they are stored in accordance with the consent.
  - (2) An embryo the creation of which was brought about in vitro must not be kept in storage unless there is an effective consent, by each relevant person in relation to the embryo, to the storage of the embryo and the embryo is stored in accordance with those consents.

#### Cases where consent not required for storage

- 9
- (1) The gametes of a person ("C") may be kept in storage without C's consent if the following conditions are met.
  - (2) Condition A is that the gametes are lawfully taken from or provided by C before C attains the age of 18 years.
  - (3) Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that C is expected to undergo medical treatment and that in the opinion of the registered medical practitioner—
    - (a) the treatment is likely to cause a significant impairment of C's fertility, and
    - (b) the storage of the gametes is in C's best interests.
  - (4) Condition C is that, at the time when the gametes are first stored, either—
    - (a) C has not attained the age of 16 years and is not competent to deal with the issue of consent to the storage of the gametes, or
    - (b) C has attained that age but, although not lacking capacity to consent to the storage of the gametes, is not competent to deal with the issue of consent to their storage.
  - (5) Condition D is that C has not, since becoming competent to deal with the issue of consent to the storage of the gametes—
    - (a) given consent under this Schedule to the storage of the gametes, or
    - (b) given written notice to the person keeping the gametes that C does not wish them to continue to be stored.
  - (6) In relation to Scotland, sub-paragraphs (1) to (5) are to be read with the following modifications—
    - (a) for sub-paragraph (4), substitute—

“(4) Condition C is that, at the time when the gametes are first stored, C does not have capacity (within the meaning of section 2(4) of the Age of Legal Capacity (Scotland) Act 1991) to consent to the storage of the gametes.”, and
    - (b) in sub-paragraph (5), for “becoming competent to deal with the issue of consent to the storage of the gametes” substitute “acquiring such capacity”.
- 10
- (1) The gametes of a person ("P") may be kept in storage without P's consent if the following conditions are met.
  - (2) Condition A is that the gametes are lawfully taken from or provided by P after P has attained the age of 16 years.
  - (3) Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that P is expected to undergo medical treatment and that in the opinion of the registered medical practitioner—
    - (a) the treatment is likely to cause a significant impairment of P's fertility,



## Mandatory requirements (cont)

(3)(cont)

- (b) P lacks capacity to consent to the storage of the gametes,
- (c) P is likely at some time to have that capacity, and
- (d) the storage of the gametes is in P's best interests.

(4) Condition C is that, at the time when the gametes are first stored, P lacks capacity to consent to their storage.

(5) Condition D is that P has not subsequently, at a time when P has capacity to give a consent under this Schedule—

- (a) given consent to the storage of the gametes, or
- (b) given written notice to the person keeping the gametes that P does not wish them to continue to be stored.

(6) In relation to Scotland—

- (a) references in sub-paragraphs (3) and (4) to P lacking capacity to consent are to be read as references to P being incapable, within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000, of giving such consent,
- (b) the references in sub-paragraphs (3) and (5) to P having capacity are to be read as references to P not being so incapable, and
- (c) that Act applies to the storage of gametes under this paragraph to the extent specified in section 84A of that Act.

11 A person's gametes must not be kept in storage by virtue of paragraph 9 or 10 after the person's death.

### Licence conditions

T50 Prior to the processing of patient gametes or embryos, intended for use in treatment or storage, the centre must:

- a. Carry out the following biological tests to assess the risk of cross contamination
  - HIV 1 and 2: Anti-HIV – 1, 2
  - Hepatitis B: HBsAg/Anti-HBc
  - Hepatitis C: Anti-HCV-Ab
- b. Devise a system of storage which clearly separates:
  - quarantined/unscreened gametes and embryos,
  - gametes and embryos which have tested negative, and
  - gametes and embryos which have tested positive.
- c. Perform HTLV- 1 antibody testing for patients living in or originating from high incidence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas
- d. In certain circumstances, carry out additional testing depending on the patient's travel and exposure history and the characteristics of the tissue or cells donated (eg, Rh D, Malaria, CMV, T.cruzi)

Positive results will not necessarily prevent the use of the partners' gametes.



## Mandatory requirements (cont)

- T51 The centre must ensure that the laboratory tests required by licence condition T50 meet the following requirements, namely:
- the test must be carried out by a qualified laboratory, which has suitable accreditation (for example by CPA (UK) Ltd or another body accrediting to an equivalent standard), using CE marked testing kits where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge, and
  - blood samples must be obtained at the time of donation.
- T75 Centres must ensure that all storage processes are carried out under controlled conditions.
- T76 Gametes of a person must be placed in storage only if –
- received from that person,
  - acquired in circumstances in which by virtue of paragraph 9 and 10 of Schedule 3 to the Human Fertilisation and Embryology Act 1990 (as amended) that person's consent to the storage is not required, or
  - acquired from a person to whom a licence or third party agreement applies.
- T77 Embryos taken from a woman must be placed in storage only if –
- received from that woman, or
  - acquired from a person to whom a licence or third party agreement applies.
- T78 Embryos which have been created in vitro otherwise than in pursuance of this licence must be placed in storage only if acquired from a person to whom a licence or third party agreement applies.
- T79 No gametes or embryos must be kept in storage for longer than the statutory storage period and, if stored at the end of the period, must be allowed to perish.
- T80 The statutory storage period in respect of gametes is such period not exceeding ten years as the licence may specify.
- T81 The statutory storage period in respect of embryos is such period not exceeding ten years as the licence may specify.
- T82 Regulations may provide that licence conditions T80 and T81 must have effect as if for ten years there were substituted –
- such shorter period, or
  - in such circumstances as may be specified in the relevant Regulations, such longer period, as may be specified in the relevant Regulations.
- T83 Gametes or embryos which are or have been stored must not be supplied to a person otherwise than in the course of providing treatment services, unless that person is a person to whom a licence applies.
- T85 A documented risk assessment must be undertaken to determine the fate of all stored gametes and embryos following the introduction of any new donor/patient selection or testing criterion or any significantly modified processing step that enhances safety or quality.

### Directions

#### 0007 – Consent

For a copy of the relevant Directions visit [www.hfea.gov.uk](http://www.hfea.gov.uk)

### Regulations

The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009  
Copies of this legislation can be found at [www.opsi.gov.uk](http://www.opsi.gov.uk)



### Facilities and documented procedures

- 17.1** The centre should establish documented procedures to ensure that all storage and handling of gametes and embryos comply with licence conditions, regulations, and relevant patient and donor consent.
- 17.2** The centre should ensure that the storage facilities for gametes and embryos:
- (a) are dedicated for the purpose, and adequate for the volume and types of activities
  - (b) are designed to avoid proximity to ionising radiation (radioactive material), any known potential source of infection, or chemical or atmospheric contamination, and
  - (c) have a storage-location system that minimises the amount of handling required to retrieve gametes and embryos.
- 17.3** The centre should also have emergency procedures to deal with damage to storage vessels, failure of storage conditions or both.
- 17.4** The centre's documented procedures should also ensure that:
- (a) gametes and embryos are stored under controlled conditions that are validated and monitored
  - (b) gametes and embryos are packaged for storage in a way that:
    - (i) prevents any adverse effects on the material
    - (ii) minimises the risk of contamination
  - (c) records are kept indicating every occasion when gametes and embryos are handled during storage and release, and by whom
  - (d) records are kept indicating that gametes and embryos meet requirements for safety and quality before release, and
  - (e) risk assessments (approved by the person responsible) are done to determine the fate of all stored material whenever any of the following is introduced:
    - (i) a new donor selection criterion
    - (ii) a new criterion for testing donors, patients' partners or patients
    - (iii) a new processing step to enhance safety, quality or both
    - (iv) a new procedure for appropriate disposal of gametes and embryos.

### Safety of equipment used to store cryopreserved gametes and embryos

- 17.5** Centres should store gametes and embryos in a designated area. Access to this area should be limited to staff authorised under the terms of the centre's licence. Cryopreservation dewars should be fitted with local alarms and be linked to an auto-dial or similar facility, (eg, a link to a fire alarm board) to alert staff to non-conformities outside normal working hours.
- 17.6** The centre should have adequate staff and funding for an 'on-call' system for responding to alarms out of hours, and adequate spare storage capacity to enable transfer of samples if a dewar fails.
- 17.7** A centre storing gametes and/or embryos for patients whose future fertility may be impaired by a medical condition or procedure should divide individual patients' samples into separate storage vessels, in case of dewar failure.

See also guidance note:

- [26 – Equipment and materials](#)



### Screening and storage of samples to prevent cross-contamination

- 17.8** The centre should ensure that no gametes or embryos are placed in storage unless the people who provided the gametes have been screened in accordance with current recommended professional guidelines.
- 17.9** Centres should:
- assess the risks of cross-contamination during the quarantine period
  - put procedures in place to minimise these risks, and
  - document the rationale for the chosen quarantine procedures.

See also guidance note:

- [15 – Procuring, processing and transporting gametes and embryos](#)
- [19 – Traceability](#)
- [20 – Donor assisted conception](#)

### Storing ovarian and testicular tissue



#### Interpretation of mandatory requirements

17A

Ovarian and testicular tissue, as cells of the germ line, fall within the definition of gamete in the Human Fertilisation and Embryology Act 1990 (as amended) and so are subject to the same storage requirements as sperm and eggs.

- 17.10** In addition to an HFEA storage licence, a licence from the Human Tissue Authority will be required in order to store ovarian and testicular tissue. The centre wishing to store this tissue should also familiarise themselves with the requirements of the Human Tissue Act 2004.

### Information for those seeking storage of gametes or embryos

- 17.11** If the treatment involves the creation of embryos in vitro, the centre should give people seeking treatment information about the availability of facilities for freezing embryos, and about the implications of storing and then using stored embryos.
- 17.12** If there is an intention to store gametes or embryos, or where this possibility arises during treatment, in addition to relevant information about treatment and donation, the centre should give those providing the gametes or embryos relevant information about:
- the possible deterioration or loss of viability of gametes or embryos as a result of storage, and the potential risk of cross-contamination between samples
  - regulations for statutory storage periods for gametes and embryos, and regulations for extending storage periods including, in the case of embryos, the requirement for both gamete providers to consent to any extension of storage
  - the likelihood of a live birth resulting from previously cryopreserved embryos or gametes, and
  - screening tests to be done, the cost of these, the reason for them and the implications of the tests for the gamete providers.
- 17.13** The centre should provide specific information tailored to the needs and circumstances of oncology patients and other patients requiring long-term storage. Where relevant, this should include information appropriate to minors.



- 17.14** The centre should ensure that, before someone consents to gametes or embryos being stored, they are told:
- the options available if a person providing gametes or resulting embryos dies or becomes mentally incapacitated
  - that it may be possible to register a deceased partner as the parent of a child resulting from treatment, and the conditions for doing so, and
  - that it is unlawful to store embryos and gametes beyond the period of consent, the centre having a legal obligation to dispose of them once consent has expired.

See also guidance note:

- [4 – Information to be provided prior to consent](#)
- [5 – Consent to treatment, storage, donation and disclosure of information](#)

See also:

- [HFEA consent forms available at www.hfea.gov.uk](http://www.hfea.gov.uk)

### Treatment using cryopreserved eggs or embryos

- 17.15** The centre should ensure that the following sets of eggs or embryos are only transferred during the same treatment cycle in exceptional circumstances, with an upper limit of 2% of all cases:
- fresh eggs and eggs that have been cryopreserved, or
  - embryos that have been created using cryopreserved eggs, and embryos created using fresh eggs, or
  - cryopreserved embryos that have been created using cryopreserved eggs and cryopreserved embryos that have been created using fresh eggs.

The circumstances justifying such a transfer should be specified in the patient's notes.

### Consent to storage and cases where consent is not required for storage



#### Interpretation of mandatory requirements

17B

The law requires the centre to obtain written informed consent from a person before it stores their gametes or embryos created with their gametes.

The law allows gametes to be stored without consent if the conditions met in paragraph 9 or 10, and 11 of Schedule 3 of the HFE Act 1990 (as amended) are met.

Gametes stored following the application of these paragraphs may be used only if the person from whom they were collected gives written effective consent to their use (and has sufficient capacity and competence to do so).

If sperm was in storage on 1 August 1991, storage may legally continue without the written consent of the individual who provided the sperm. However, the centre is not obliged to continue to store sperm in the absence of a written agreement to do so.

For guidance about steps to take when consent is not required, see guidance note 5 – Consent to treatment, storage, donation, and disclosure of information.



See also guidance note:

- [5 – Consent to treatment, storage, donation and disclosure of information](#)

See also:

- [HFEA consent forms available at www.hfea.gov.uk](http://www.hfea.gov.uk)

### Extension of storage

**17.16** Before the centre obtains consent from anyone wishing to store gametes or embryos for more than 10 years, it should ensure that the conditions for extended storage in the relevant regulations are satisfied.

### Disputes involving the withdrawal of consent to storage



#### Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Schedule 3 Consent to use or storage of gametes, embryos or human admixed embryos etc

4A (1) This paragraph applies where –

- (a) a permitted embryo, the creation of which was brought about in vitro, is in storage,
- (b) it was created for use in providing treatment services,
- (c) before it is used in providing treatment services, one of the persons whose gametes were used to bring about its creation (“P”) gives the person keeping the embryo notice withdrawing P’s consent to the storage of the embryo, and
- (d) the embryo was not to be used in providing treatment services to P alone.

(2) The person keeping the embryo must as soon as possible take all reasonable steps to notify each interested person in relation to the embryo of P’s withdrawal of consent.

(3) For the purposes of sub-paragraph (2), a person is an interested person in relation to an embryo if the embryo was to be used in providing treatment services to that person.

(4) Storage of the embryo remains lawful until–

- (a) the end of the period of 12 months beginning with the day on which the notice mentioned in sub-paragraph (1) was received from P, or
- (b) if, before the end of that period, the person keeping the embryo receives a notice from each person notified of P’s withdrawal under sub-paragraph (2) stating that the person consents to the destruction of the embryo, the time at which the last of those notices is received.

(5) The reference in sub-paragraph (1)(a) to a permitted embryo is to be read in accordance with section 3ZA.



### Interpretation of mandatory requirements

17C

If one of the gamete providers withdraws consent to the continued storage of embryos intended for treatment (created from their gametes), the law requires the centre to take all reasonable steps to notify the intended recipient(s).

The law allows embryos to be stored for 12 months from the date that the centre receives written withdrawal of consent, or less if the centre receives written signed consent from all intended recipients for the embryos to be destroyed. This 12 month 'cooling off' period must not extend beyond the end of the statutory storage period.

For guidance about the withdrawal of consent see guidance note 5 – Consent to treatment, storage, donation, and disclosure of information.

See also guidance note:

- [5 – Consent to treatment, storage, donation and disclosure of information](#)

See also:

- [HFEA consent forms available at www.hfea.gov.uk](http://www.hfea.gov.uk)

## Storage review

**17.17** The centre should establish documented procedures to ensure that:

- (a) reviews of stored gametes and embryos are done at least once every two years to:
  - (i) reconcile the centre's records with material in storage
  - (ii) review the purpose and duration of storage, and
  - (iii) identify any action needed
- (b) if the number of families created using gametes (or embryos created using donated gametes) from a particular donor has reached 10, those gametes or embryos are not used or distributed for use in further treatment.

See also guidance note:

- [11 – Donor recruitment, assessment and screening](#)
- [20 – Donor assisted conception](#)

**17.18** The centre should operate a bring-forward system in order to ensure sufficient advance notice of the end of the statutory storage period (or such shorter period as specified by a person who provided the gametes) for gametes or embryos in storage.

## The end of storage



### Interpretation of mandatory requirements

17D

No centre may keep embryos or store gametes after the expiry of the legal maximum storage period, or the period specified when the embryos or gametes were stored if shorter. Storing embryos or gametes beyond the relevant period is a criminal offence, punishable by a prison sentence, fine or both.



## HFEA guidance (cont)

- 17.19** The centre should make efforts to stay in contact with patients who have gametes or embryos in storage for their own treatment, and with any woman to be treated with stored gametes or embryos (where she is not a gamete provider.) The centre should also explain to gamete providers and current patients the importance of informing the centre of any change in their contact details.
- 17.20** Centres should inform patients who have gametes or embryos in storage for their own treatment when the end of the permitted storage period is approaching. Patients should be provided with information about the options available to them as the end of their permitted storage period approaches. They should be given enough notice to enable them to consider those options, and to access appropriate advice. Options could include the donation of the gametes or embryos for research or treatment.



## Other legislation, professional guidelines and information


- Association of Biomedical Andrologists/Association of Clinical Embryologists/British Andrology Society/ British Fertility Society/Royal College of Obstetricians and Gynaecologists – UK Guidelines for the medical and laboratory screening of sperm, egg and embryo donors (2008) – [www.ncbi.nlm.nih.gov/pubmed/19085256](http://www.ncbi.nlm.nih.gov/pubmed/19085256)
- The Human Tissue Authority – [www.hta.gov.uk](http://www.hta.gov.uk)
- Department of Health – A Code of Practice for Tissue Banks Providing Tissues of Human Origin For Therapeutic Purposes – [www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4006116](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4006116)
- Department of Health – Guidance on the Microbiological Safety of Human Organs (2011) – [www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_121497](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_121497)

# 18. Witnessing and assuring patient and donor identification

## This guidance note contains:

### Mandatory requirements

- Extracts from licence conditions

 Refer to principles 7, 8, 9 and 10

### HFEA guidance

- Witnessing clinical and laboratory procedures
- Keeping a record of witnessing
- Witnessing training
- Appropriate person to witness
- Interruptions and distractions in the clinic and laboratory
- Patient and donor identification
- Risk assessment
- Risk assessment: electronic witnessing systems
- Risk assessment: barcoding
- Risk assessment: radio frequency identification systems



## Mandatory requirements

### Licence conditions

- T71 Centres must have in place robust and effective processes to ensure that no mismatches of gametes or embryos or identification errors occur. Centres must double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process. These checks must be completed and recorded at the time the relevant clinical or laboratory process/procedure takes place. A record must be kept in each patient's/donor's medical record.



## HFEA guidance

### Witnessing clinical and laboratory procedures

- 18.1** Witnessing protocols should ensure that every sample of gametes or embryos can be identified at all stages of the laboratory and treatment process to prevent any mismatches of gametes or embryos.
- 18.2** Centres should have witnessing protocols relevant to their local systems and conditions, based on HFEA model protocols. Where appropriate, clinics may adapt HFEA model protocols to take into account their local systems.

See also:

- **Relevant HFEA model protocols at:**  
[www.hfea.gov.uk/docs/witnessing-protocols.pdf](http://www.hfea.gov.uk/docs/witnessing-protocols.pdf)

- 18.3** Electronic systems such as barcoding and radio frequency identification (RFID) for assisted conception are appropriate, subject to a risk assessment as set out at 18.31–18.38.



**18.4** Witnessing protocols should be followed when any of the following clinical or laboratory procedures take place:

**(a) Collecting eggs**

- Cross-check identifying information that the egg provider gives against records and laboratory data sheets, or cross-check information entered into the electronic system and the allocation of the barcode or RFID tag.
- Cross-check information marked on egg collection dishes and lids against the patient's medical records. This step does not need to be manually witnessed if an electronic system (barcoding or RFID) is being used.

**(b) Collecting sperm**

- Cross-check identifying information that the sperm provider gives against records, the laboratory data sheet and sperm receptacle, or cross-check information entered into the system and the allocation of the barcode or RFID tag.

**(c) Preparing sperm**

- Cross-check information on tubes against the documents and information on the sperm receptacle (when the sperm sample is transferred onto a preparation column). This step does not need to be manually witnessed if an electronic system (barcoding or RFID) is being used.

**(d) Mixing sperm and eggs or injecting sperm into eggs**

- Verify identifying information on the dishes and tubes and confirm that the sperm and eggs should be mixed or the sperm injected into eggs.

**(e) Transferring gametes or embryos between tubes or dishes**

- Cross-check information marked on dishes and tubes against the patient's or donor's records, and the information marked on the dishes and tubes that the gametes or embryos are being transferred from.

**(f) Transferring embryos into a woman**

- Cross-check identifying information that the patient provides against the patient's medical records or the electronic system (or both) and the laboratory data sheet, and confirm that these are the correct embryos to transfer.

**(g) Inseminating a woman with sperm prepared in the laboratory**

- Cross-check identifying information that the patient provides against the patient's medical records, or cross-check information entered into the electronic system and the allocation of a barcode or RFID tag.
- Verify the sperm provider's identifying information in their records, the electronic system and on the sperm container, and confirm that this is the correct sperm provider.

**(h) Placing gametes or embryos into cryopreservation**

- Cross-check identifying information on the storage container against the patient's or donor's records and the information on the tube or dish that the gametes or embryos are being transferred from.
- Cross-check where in the dewar the gametes or embryos are placed.

**(i) Removing gametes or embryos from cryopreservation**

- Cross-check information on the storage container against information in the patient or donor records to confirm they are the correct gametes or embryos to remove.
- Cross-check information from the storage container and the patient or donor records or their information on the electronic system against the thaw dish or tube (and, if applicable, attach a barcode or RFID tag to the thaw dish or tube).



### 18.4 (cont)

#### (j) Disposing of gametes or embryos

- Cross-check information on the storage container against information in the patient or donor records to confirm they are the correct gametes or embryos to dispose of.

#### (k) Transporting gametes or embryos

- Cross-check information on the storage container against information in the patient's medical records to check that these are the correct gametes or embryos to transport.
- Check that information on the storage container is correct.

### 18.5 Each stage of the witnessing trail should check the patient's or donor's full name and their unique identifying code. Whenever it is not possible to label the dishes or tubes with the donor's name:

- (a) the donor code should uniquely identify that donor, and
- (b) the dishes or tubes should be labelled with the female patient's name and unique identifying code as soon as possible.

## Keeping a record of witnessing

**18.6** The checking of identifying samples, patients and donors, and the witnessing of these checks, should be recorded when the clinical and laboratory procedures take place. This means that embryologists performing procedures that need to be witnessed cannot work alone. This will ensure that the witnessing protocol has the maximum potential to identify errors in the treatment process at the time the procedures take place.

**18.7** When the procedure takes place, a record should be made in the patient or donor notes stating:

- (a) the procedure
- (b) the date and time of the procedure
- (c) the signature of the person doing the procedure, and
- (d) the signature of the witness.

A hard copy of electronic witnessing should be retained.

**18.8** There should be a separate record of the name, job title and signature of everyone who carries out or witnesses laboratory and clinical procedures.

## Witnessing training

**18.9** Centres should have an induction programme for new staff to ensure they understand the principles of witnessing and follow the centre's protocols.

**18.10** Staff should receive appropriate training if a new system for witnessing is introduced.

See also guidance note:

- [2 – Staff](#)

## Appropriate person to witness

**18.11** Centres should consider who is the most appropriate person to witness clinical and laboratory procedures. This will usually be someone who has completed the centre's training programme for new staff, and refresher training (as appropriate), to ensure they fully understand the principles of witnessing procedures and follow the centre's protocols. For exceptions to this, refer to paragraphs 18.13 and 18.14.

**18.12** At egg collection and embryo transfer, the appropriate person to witness is another embryologist, clinician or nurse.



- 18.13** At sperm collection, centres may consider the patient or donor to be the appropriate person to witness the cross-checking of their identifying information against their records, the laboratory data sheet and the sperm receptacle.
- 18.14** Insemination centres performing intrauterine insemination (IUI) with partner sperm may consider the patient to be the appropriate person to verify the sperm provider's details.

### Interruptions and distractions in the clinic and laboratory

- 18.15** The centre should consider the implications of distractions in the clinic and laboratory, such as from phones and external noise, and ensure they are minimised.
- 18.16** When considering the protocol it uses for witnessing procedures, and the most appropriate person to witness checks, the centre may wish to take into account the implications of interruptions to the work of laboratory and clinical staff, particularly embryologists performing critical procedures. Interrupting and returning to a task is a common source of human error.

### Patient and donor identification

- 18.17** Centres should establish procedures to ensure patients, donors, and their gametes and embryos are accurately identified.
- At the assessment stage, centres should use appropriate evidence to verify the identity of donors and self-referred patients seeking treatment (eg, passport or photocard driving licence).
- 18.18** When collecting eggs or sperm, transferring embryos and carrying out insemination, staff should ask patients and donors to give their own identifying information (full name and date of birth), rather than asking the donor or patient to confirm or reject information read out to them.
- 18.19** Centres should consider how patients and donors with disabilities or whose first language is not English will be asked to identify themselves. If possible, centres should provide an independent interpreter for patients and donors whose first language is not English.
- 18.20** All samples of gametes and embryos should be labelled with at least the patient's or donor's full name and a unique identifier. If at some stages (eg, labelling donor sperm) it is not possible to label the dishes or tubes with the donor name:
- the donor code should uniquely identify that donor, and
  - the dishes or tubes should be labelled with the female patient's name and unique identifier as soon as possible.
- 18.21** Centres should allocate a unique identifier to each sample of gametes or embryos to ensure it can be accurately identified at all stages of the laboratory and treatment process. This identifier could, for example, comprise two or more of the following:
- the patient's or donor's date of birth
  - hospital number
  - NHS number/CHI (Community Health Index) number, or
  - a donor code.
- 18.22** Centres should consider the most appropriate way to label dishes or tubes when they are likely to be seen by the patient.
- 18.23** Centres should consider when to change the labelling from showing the donor's or male partner's identifying information to the female patient's identifying information. Centres may consider it appropriate to label all dishes and tubes with both partners' names and identifying codes throughout.



**18.24** Centres should ensure that other patients' or donors' gametes or embryos are not introduced into the critical working area until the procedure is complete. In particular, during sperm preparation, no more than one sample should be processed in the critical working area at any one time. However, it is acceptable for centres to cryopreserve gametes or embryos from more than one patient at one time, provided that procedures are in place to keep the samples separate.

See also guidance note:

- [19 – Traceability](#)

### Risk assessment

- 18.25** Centres should do a risk assessment before introducing or changing witnessing protocols. Centres should consider integrating protocols into the whole laboratory and clinical process and risk-reduction procedures. Centres may wish to identify and specify key points when mismatching of gametes and embryos is most likely to occur.
- 18.26** Centres should be aware of the risks associated with staff doing repetitive activities. The risk of mismatching gametes and embryos is higher when repetitive activities are taking place. Centres should bear this in mind when selecting the most appropriate person to witness procedures. Similarly, when using witnesses, centres should consider staff workload and hours, and should ensure staff take regular breaks.
- 18.27** Centres should have formal risk control measures to minimise the risk of writing incorrect or incomplete identifying data on patient's medical records. There is a risk of error when copying details from sample containers and patient's records to other records. The risk is particularly high when a record sheet becomes separated from the patient's records and is relied on during a witnessed step.
- 18.28** As part of a quality review, audits of the patient's medical records should include checking for transcription errors (or omissions) in patient identifiers, such as the misspelling of names and the absence of unique identifiers on a record sheet, particularly in laboratory records.
- 18.29** Centres should check their compliance with witnessing protocols regularly, including during the audit of their quality management system.
- 18.30** As part of their risk assessment for sperm preparation, centres may consider witnessing the cross-checking of information on tubes only at the start and end of the procedure, not at every stage in it.

See also guidance note:

- [23 – The quality management system](#)

### Risk assessment: electronic witnessing systems

- 18.31** Before introducing new electronic systems or protocols for witnessing, centres should do a risk assessment covering the following:
- (a) Centres should ensure that any system will not harm gametes and embryos. In establishing that this is the case, centres should consider what the supplier or manufacturer has done to satisfy itself that the system will not harm gametes and embryos (eg, commissioned independent reports or carried out irradiance readings).
  - (b) Centres should be aware that the reliability and safety of different electronic systems may vary.
  - (c) Centres should evaluate the evidence that the supplier or manufacturer provides to support the safety and reliability of its system (eg, false positive and negative matches and breakdown), plus any other relevant studies.



### 18.31 (cont)

- (d) Any software should be fully tested, quality assured and risk assessed.
- (e) Centres should consider what the manufacturer has done to ensure that any labels and tags will continue to be effective when placed in long-term cryostorage.

**18.32** Centres should be aware that although they cannot completely eliminate the potential for human error in any electronic witnessing system, effective risk assessment should mitigate this.

**18.33** If centres use an electronic system (barcode or RFID) with ‘forcing functions’ (which prevent the user omitting key matching tasks in the process by preventing them from proceeding with subsequent task steps), then as part of their risk assessment they may wish to consider that manually witnessing transfer steps are not necessary. This exemption should not apply however to mixing sperm and eggs; injecting sperm into eggs; and placing eggs and sperm into and removing them from cryopreservation.

**18.34** Centres should consider any potential loopholes in the system that could allow users to circumvent key steps, thus negating safeguards against error. Centres should consider implementing a system that allocates a unique identifier to each system user.

**18.35** Centres should not rely solely on electronic systems to check the identity of patients, donors and samples. Centres should follow protocols for witnessing in line with HFEA model protocols; these include several manual witnessing steps.

**18.36** Centres should have procedures to ensure that all witnessing steps can still be done if the electronic system fails, and that witnessing staff maintain their manual witnessing skills for all critical steps.

**18.37** In addition to using the electronic system of identification (information stored on barcodes or RFID tags), centres should continue to manually label all culture dishes, tubes, lids and straws with the patient’s full name and unique identifier. If the electronic identification fails (for example losing a barcode label or RFID tag from a sample), centres should revert to manual identification.

**18.38** Centres should consider whether the barcode or RFID tags are suitable for use on storage containers (ie, are able to withstand long periods of cryopreservation).

### Risk assessment: barcoding

**18.39** Centres considering installing a barcode system should consider as part of their risk assessment:

- (a) the type and power of light used in the barcode equipment
- (b) the length of time the gametes and embryos are likely to be exposed to it, and
- (c) whether exposure to this light is likely to harm the gametes and embryos.

**18.40** Although there is substantial evidence about using barcodes with human tissue, as far as the HFEA is aware no independent studies have yet been done on the effect of light on human gametes and embryos. So the HFEA does not have enough evidence to consider barcoding to be risk free.

**18.41** Barcoding equipment may use a range of light sources. The HFEA is aware of two types of barcoding systems marketed for use in assisted conception: those using white-light-emitting diodes and those using laser light.

**18.42** Considering the evidence of damage to human cells from some powers of laser light, centres must weigh up the degree of possible risk of using laser light barcoding systems. Centres should only consider using class 1 or 2 lasers.

**18.43** Barcode equipment that uses ultraviolet or infrared light should not be used. These sources of radiation are known to heat, and so potentially damage human cells.



### Risk assessment: radio frequency identification systems


- 18.44** Centres considering installing an RFID system should, as part of their risk assessment, consider the frequency of the radio waves used in the RFID system and whether exposure to them is likely to harm gametes and embryos. Centres should be aware that detectable changes in temperature may result in DNA damage. Centres should do this risk assessment in the context of other risk factors in the centre and the environment (eg, mobile phone signals).
- 18.45** Although there is evidence for the use of RFID in a medical setting, as far as the HFEA is aware no independent studies have yet been done on the effect of electromagnetic radiation on human gametes and embryos. So there is not yet a compelling evidence base to enable the HFEA to consider RFID systems to be risk free.

# 19. Traceability

## This guidance note contains:

### Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Extracts from licence conditions

 Refer to principles 7, 8 and 10

### HFEA guidance

- Traceability requirements



## Mandatory requirements

### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

#### 2 Other terms

(1) “traceability” means the ability—

- (a) to identify and locate gametes and embryos during any step from procurement to use for human application or disposal,
- (b) identify the donor and recipient of particular gametes or embryos,
- (c) to identify any person who has carried out any activity in relation to particular gametes or embryos, and
- (d) to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

#### 12 General conditions

(3) It shall be a condition of every licence to which this subsection applies that—

- (a) such information as is necessary to facilitate the traceability of gametes and embryos, and
- (b) any information relating to the quality or safety of gametes or embryos, shall be recorded and provided to the Authority upon request.

#### Schedule 3A

##### Traceability and coding system

1 Licence conditions shall require that all persons to whom a licence applies adopt such systems as the Authority considers appropriate to secure—

- (a) in relation to traceability, compliance with the requirements of Article 8 (traceability) of the first Directive and Article 9 (traceability) of the third Directive, and
- (b) in relation to the coding of information, compliance with the requirements of Article 25 (coding of information) of the first Directive and Article 10 (European coding system) of the third Directive.

2 Licence conditions imposed in accordance with paragraph 1 may specify the coding system which must be applied in relation to gametes and embryos intended for human application.

### Licence conditions

T99 The centre must establish, implement and comply with documented procedures to ensure that:

- a. all gametes and embryos, and



## Mandatory requirements (cont)

- T99 (cont)
- b. all relevant data relating to anything coming into contact with those gametes or embryos are traceable from procurement of gametes to patient treatment or disposal and vice versa.
- T100 The documented procedures referred to in licence condition T99 include the following information:
- a. the unique and accurate identification of each patient/donor
  - b. the unique and accurate identification of each set of gametes and embryos
  - c. date of procurement
  - d. place of procurement
  - e. type of treatment
  - f. description and origin of any and all products associated with the procurement, processing, use and storage of gametes and embryos, and
  - g. description of all processing steps applied to the procurement, use and storage of gametes and embryos.
- T101 The centre must ensure that all containers (dishes, vials, ampoules, tubes etc) used in the course of procurement, possessing, use and storage of gametes and embryos are labelled with the patient's/donor's full name and a further identifier. If at some stages (eg, labelling patient/donor sperm) it is not possible to label the dishes or tubes with the patient/donor name then it must be ensured that the patient/donor code used is uniquely identifying.
- T102 The centre must record such information as is necessary to facilitate the traceability of gametes and embryos and any information relating to the quality or safety of gametes and embryos. This information must be provided to the Authority upon request.
- T103 The centre must keep data necessary to ensure traceability for a minimum of thirty years (and for such longer period as may be specified in Directions) in an appropriate readable storage medium.
- T104 Records not covered by licence condition T103 and test results that impact on the safety and quality of the embryos and gametes, must be kept so as to ensure access to the data for at least 10 years after the expiry date, clinical use or disposal.



## HFEA guidance

### Traceability requirements

- 19.1** Procedures for ensuring traceability of gametes and embryos should be documented. Centres should ensure that:
- (a) they uniquely and accurately identify:
    - (i) the patient
    - (ii) the patient's partner, donor or both, as applicable
    - (iii) gametes and embryos, and
    - (iv) any containers used for the receipt and distribution of gametes and embryos.
  - (b) quarantined, non-quarantined and rejected material is clearly distinguishable at all processing stages.



### 19.1 (cont)

- (c) they keep records of the equipment and materials used to receive, process, store and discard gametes and embryos
- (d) they keep registers of received, processed, stored, distributed and discarded gametes or embryos. Registers should enable a centre to investigate adequately if a problem is identified after the gametes have been used. Registers should also enable the centre to identify:
  - (i) a patient, patient's partner or donor
  - (ii) processing steps applied to gametes or embryos (or both) and, if applicable, third parties involved in processing
  - (iii) individual procurement of gametes and embryos
  - (iv) the institution from which gametes and embryos have come
  - (v) distributed gametes or embryos, and
  - (vi) the institutions to which gametes or embryos have been sent (whether for a patient's use or for research).

### 19.2 For the system of identification, centres should use an identifying code that contains at least the following information:

- (a) for donors:
  - (i) their identity, and
  - (ii) the centre's identity.
- (b) for gametes and embryos:
  - (i) a unique code
  - (ii) split number (if applicable), and
  - (iii) end of statutory storage period.

### 19.3 The centre's traceability procedures should cover any materials or equipment that could affect the quality or safety of gametes and embryos, for example:

- (a) culture media
- (b) serial numbers or batch numbers of equipment and materials coming into contact with gametes and embryos, and
- (c) records of the monitoring and maintenance of the required conditions in incubators and storage tanks.

See also guidance note:

- [26 – Equipment and materials](#)

### 19.4 For gametes that have been stored at the centre (eg, for oncology or pre-vasectomy patients) and then supplied to another centre (eg, to be stored or used in treatment), the centre will not be expected to hold traceability data for subsequent processes involving those gametes outside the centre. However, the storing centre's record keeping procedures should show a link to the centre to which the gametes are supplied, so that the complete process from procurement to use or disposal can be traced if needed.

# 20. Donor-assisted conception

## This guidance note contains:

### Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Extracts from licence conditions

 Refer to principles 2, 4, 5 and 6

### HFEA guidance

- Information for people seeking treatment with donated gametes and embryos
- The importance of informing children of their donor origins ■
- Implications of donor conception and the provision of counselling
- Access to information for donors, donor-conceived people and parents ■

■ Section includes interpretation of mandatory requirements

### Other legislation, professional guidelines and information



## Mandatory requirements

### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

#### Conditions of licences for treatment

- 13 (6C) In the case of treatment services falling within paragraph 1 of Schedule 3ZA (use of gametes of a person not receiving those services) or paragraph 3 of that Schedule (use of embryo taken from a woman not receiving those services), the information provided by virtue of subsection (6) or (6A) must include such information as is proper about–
- (a) the importance of informing any resulting child at an early age that the child results from the gametes of a person who is not a parent of the child, and
  - (b) suitable methods of informing such a child of that fact.
- 13 (13) The person responsible shall comply with any requirement imposed on that person by section 31ZD.
- 31ZA Request for information as to genetic parentage etc.
- (1) A person who has attained the age of 16 (“the applicant”) may by notice to the Authority require the Authority to comply with a request under subsection (2).
  - (2) The applicant may request the Authority to give the applicant notice stating whether or not the information contained in the register shows that a person (“the donor”) other than a parent of the applicant would or might, but for the relevant statutory provisions, be the parent of the applicant, and if it does show that–
    - (a) giving the applicant so much of that information as relates to the donor as the Authority is required by regulations to give (but no other information), or
    - (b) stating whether or not that information shows that there are other persons of whom the donor is not the parent but would or might, but for the relevant statutory provisions, be the parent and if so–
      - (i) the number of those other persons,
      - (ii) the sex of each of them, and
      - (iii) the year of birth of each of them.



## Mandatory requirements (cont)

31ZB Request for information as to intended spouse etc.

- (1) Subject to subsection (4), a person (“the applicant”) may by notice to the Authority require the Authority to comply with a request under subsection (2).
- (2) The applicant may request the Authority to give the applicant notice stating whether or not information contained in the register shows that, but for the relevant statutory provisions, the applicant would or might be related to a person specified in the request (“the specified person”) as–
  - (a) a person whom the applicant proposes to marry,
  - (b) a person with whom the applicant proposes to enter into a civil partnership, or
  - (c) a person with whom the applicant is in an intimate physical relationship or with whom the applicant proposes to enter into an intimate physical relationship.
- (3) Subject to subsection (5), the Authority shall comply with a request under subsection (2) if–
  - (a) the information contained in the register shows that the applicant is a relevant individual,
  - (b) the Authority receives notice in writing from the specified person consenting to the request being made and that notice has not been withdrawn, and
  - (c) the applicant and the specified person have each been given a suitable opportunity to receive proper counselling about the implications of compliance with the request.
- (4) A request may not be made under subsection (2)(c) by a person who has not attained the age of 16.
- (5) Where a request is made under subsection (2)(c) and the specified person has not attained the age of 16 when the applicant gives notice to the Authority under subsection (1), the Authority must not comply with the request.

31ZD Provision to donor of information about resulting children

- (3) The donor may by notice request the appropriate person to give the donor notice stating–
  - (a) the number of persons of whom the donor is not a parent but would or might, but for the relevant statutory provisions, be a parent by virtue of the use of the gametes or embryos to which the consent relates,
  - (b) the sex of each of those persons, and
  - (c) the year of birth of each of those persons.
- (4) Subject to subsections (5) and (7), the appropriate person shall notify the donor whether the appropriate person holds the information mentioned in subsection (3) and, if the appropriate person does so, shall comply with the request.
- (5) The appropriate person need not comply with a request under subsection (3) if the appropriate person considers that special circumstances exist which increase the likelihood that compliance with the request would enable the donor to identify the persons falling within paragraphs (a) to (c) of subsection (3).

31ZE Provision of information about donor-conceived genetic siblings

- (1) For the purposes of this section two relevant individuals are donor-conceived genetic siblings of each other if a person (“the donor”) who is not the parent of either of them would or might, but for the relevant statutory provisions, be the parent of both of them.
- (2) Where–
  - (a) the information on the register shows that a relevant individual (“A”) is the donor-conceived genetic sibling of another relevant individual (“B”),



## Mandatory requirements (cont)

(2)(cont)

(b) A has provided information to the Authority (“the agreed information”) which consists of or includes information which enables A to be identified with the request that it should be disclosed to –

- (i) any donor-conceived genetic sibling of A, or
- (ii) such siblings of A of a specified description which includes B, and

(c) the conditions in subsection (3) are satisfied, then, subject to subsection (4), the Authority shall disclose the agreed information to B.

(3) The conditions referred to in subsection (2)(c) are –

- (a) that each of A and B has attained the age of 18,
- (b) that B had requested the disclosure to B of information about any donor-conceived genetic sibling of B, and
- (c) that each of A and B has been given a suitable opportunity to receive proper counselling about the implications of disclosure under subsection (2).

(4) The Authority need not disclose any information under subsection (2) if it considers that the disclosure of information will lead to A or B identifying the donor unless –

- (a) the donor has consented to the donor’s identity being disclosed to A or B, or
- (b) were A or B to make a request under section 31ZA(2)(a), the Authority would be required by regulations under that provision to give A or B information which would identify the donor.

The Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004

Information that the Authority is required to give

2 (1) Subject to paragraph (4), the information contained in the register which the Authority is required to give an applicant by virtue of section 31(4)(a) of the Act is any information to which paragraph (2) or (3) applies.

(2) This paragraph applies to information as to–

- (a) the sex, height, weight, ethnic group, eye colour, hair colour, skin colour, year of birth, country of birth and marital status of the donor;
- (b) whether the donor was adopted;
- (c) the ethnic group or groups of the donor’s parents;
- (d) the screening tests carried out on the donor and information on his personal and family medical history;
- (e) where the donor has a child, the sex of that child and where the donor has children, the number of those children and the sex of each of them;
- (f) the donor’s religion, occupation, interests and skills and why the donor provided sperm, eggs or embryos;
- (g) matters contained in any description of himself as a person which the donor has provided;
- (h) any additional matter which the donor has provided with the intention that it be made available to an applicant;

but does not include information which may identify the donor by itself or in combination with any other information which is in, or is likely to come into, the possession of the applicant.



## Mandatory requirements (cont)

(3) This paragraph applies to information from which the donor may be identified which he provides after 31st March 2005 to a person to whom a licence applies, being information as to–

- (a) any matter specified in sub-paragraphs (a) to (h) of paragraph (2);
- (b) the surname and each forename of the donor and, if different, the surname and each forename of the donor used for the registration of his birth;
- (c) the date of birth of the donor and the town or district in which he was born;
- (d) the appearance of the donor;
- (e) the last known postal address of the donor.

(4) The information which the Authority is required to give to the applicant does not include any information which at the time of his request the applicant indicates that he does not wish to receive.

### Licence conditions

T54 Gametes from non-identifiable donors must not be used in licensed treatment except in the following circumstances:

- a. The gametes were supplied to the centre before 1 April 2005; and
- b. The woman having treatment (or the person that she is having treatment with) has a child that was conceived from the gametes before 1 April 2006; and
- c. The gametes are to be used to create a genetically related sibling for that child

Embryos from non-identifiable donors must not be used in licensed treatment except in the following circumstances:

- a. The embryos were created before 1 April 2005; and
- b. The woman having treatment (or the person that she is having treatment with) has a child that was conceived from the embryos before 1 April 2006; and
- c. The embryo is to be used to create a genetically related sibling for that child

Embryos which were created before 1 April 2006, and which were created using the gametes of the woman to be treated (or the person that she is being treated with) and the gametes of a non-identifiable donor, may continue to be used in treatment (regardless of whether or not there are any existing genetically related siblings).



## HFEA guidance

### Information for people seeking treatment with donated gametes and embryos

**20.1** The centre should give people seeking treatment with donated gametes or embryos:

- (a) relevant non-identifying information about donors whose gametes are available to them, including the goodwill message and the pen-portrait (if available), and
- (b) relevant information about genetic inheritance and, in particular, the likelihood of inheriting physical characteristics from the donor.

See also guidance note:

- **4 – Information to be provided prior to consent**



- 20.2** The centre should provide information to people seeking treatment with donated gametes or embryos about legal parenthood, and the collection and provision of information, specifically:
- who will be the child's legal parent(s) under the HFE Act 2008 and other relevant legislation (nationals or residents of other countries, or anyone treated with gametes obtained from nationals or residents of other countries, should be informed that the law in other countries may be different from that in the UK)
  - information that centres must collect and register with the HFEA about the donors
  - what information may be disclosed to people born as a result of donation and in what circumstances, and
  - a donor-conceived person's right to access:
    - anonymous information about the donor and any donor-conceived genetic siblings, from the age of 16
    - identifying information about the donor (where applicable), from the age of 18
    - identifying information about donor-conceived genetic siblings, with mutual consent, from the age of 18
    - information about the possibility of being related to the person they intend to marry or enter into a civil partnership with, at any age, and
    - information about the possibility of being related to the person they intend to enter into an intimate physical relationship with, from the age of 16.
- 20.3** The centre should give people seeking treatment with donated gametes or embryos information about genetic and other screening of people providing gametes. This information should include details about:
- the sensitivity and suitability of the tests, and
  - the possibility that a screened provider of gametes may be a carrier of a genetic disease or infection.
- 20.4** The centre should provide information that explains the limitations of testing procedures and the risks of treatment to anyone seeking treatment with donated gametes or embryos. The centre should make available appropriate counselling.
- See also guidance note:
- 3 – Counselling**
- 20.5** If a woman is to receive donor insemination treatment, then, before treatment commences, the centre should discuss with her the number of treatment cycles to be attempted if she does not conceive initially. The centre and the woman should together review this situation regularly.
- 20.6** Women should not be treated with gametes, or with embryos derived from gametes, of more than one man or more than one woman during any treatment cycle.

### The importance of informing children of their donor origins



#### Interpretation of mandatory requirements

20A

The centre must give patients seeking treatment with donor gametes and embryos information about the importance of telling any resultant children, at an early age, of their donor-conceived origins. The centre must also give patients information on suitable methods of informing children of their donor-conceived origins.



- 20.7** The centre should tell people who seek treatment with donated gametes or embryos that it is best for any resulting child to be told about their origin early in childhood. There is evidence that finding out suddenly, later in life, about donor origins can be emotionally damaging to children and to family relations.
- 20.8** 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 give patients information about how counselling may allow them to explore the implications of treatment, in particular how information may be shared with any resultant children.

### Implications of donor conception and the provision of counselling

- 20.9** If it is possible that the question of treatment with donated gametes or embryos may arise, the centre should raise this with the person or couple seeking treatment before their treatment starts. The centre should allow people enough time to consider the implications of using donated gametes or embryos, and to receive counselling before giving consent.

See also guidance note:

- [3 – Counselling](#)

### Access to information for donors, donor-conceived people and parents



#### Interpretation of mandatory requirements

20B

A donor may request information from a centre as to the number, sex, and birth year of any children born by means of their gametes or embryos. If the centre holds that information, it must provide it, unless the person responsible considers that special circumstances increase the likelihood of the donor being able to identify any of those children.

- 20.10** The centre should inform people seeking treatment with donated gametes or embryos that the donor will be able to request the following information about any children born as a result of their donated gametes or embryos:
- the number of children born
  - their sex, and
  - their year of birth.
- 20.11** The centre should inform people seeking treatment with donated gametes or embryos that any resulting children will have access to the following non-identifying information about the donor (if the donor has provided it) from the age of 16:
- physical description (height, weight, and eye, hair and skin colours)
  - year and country of birth
  - ethnic group
  - whether the donor had any genetic children when they registered, and the number and sex of those children
  - other details the donor may have chosen to supply (eg, occupation, religion and interests)
  - the ethnic group(s) of the donor's parents
  - whether the donor was adopted or donor conceived (if they are aware of this)
  - marital status (at the time of donation)
  - details of any screening tests and medical history



## HFEA guidance (cont)

### 20.11 (cont)

- (j) skills
- (k) reason for donating
- (l) a goodwill message, and
- (m) a description of themselves as a person (pen portrait)

**20.12** The centre should inform people seeking treatment with gametes or embryos donated after 31 March 2005, or with those donated before this date by a donor who subsequently re-registered as identifiable, that any children born as a result of the donation will have access to the following identifying information about the donor, from the age of 18:

- (a) full names (and any previous names)
- (b) date of birth, and town or district where born, and
- (c) last known postal address (or address at time of registration).

**20.13** The centre should inform people seeking treatment with donated gametes or embryos that, once they give birth to a child as a result of that donation, they will be entitled to access:

- (a) all non-identifying information about the donor.
- (b) information about the number, sex and year of birth of their children's genetically related donor-conceived siblings.

It is recommended that this information is shared with the child born as a result of donation. If the centre is unable to provide this information, it should direct parents to the HFEA.

**20.14** Centres should inform parents seeking information about their child's donor or genetically related donor-conceived siblings that they may find counselling, or similar support services, on the implications of receiving such information helpful.



## Other legislation, professional guidelines and information

- Donor Conception Network website - contains information for parents on how to tell their children of their donor-conceived origins – [www.dcnetwork.org](http://www.dcnetwork.org)
- British Infertility Counselling Association - Guidelines for Good Practice in Infertility Counselling (2008) – [www.bica.net/books/guidelines-good-practice-infertility-counselling](http://www.bica.net/books/guidelines-good-practice-infertility-counselling)

# 21. Intra-cytoplasmic sperm injection (ICSI)

## This guidance note contains:

### HFEA guidance

- Information for people seeking treatment with ICSI
- The use of ICSI

 Refer to principles 5, 7 and 9

### Other legislation, professional guidelines and information



## HFEA guidance

### Information for people seeking treatment with ICSI

- 21.1** Before treatment is offered, the centre should give the woman seeking treatment and her partner, if applicable, specific information about the risks of ICSI which might lead to:
- (a) a reduced number of eggs being available for treatment (compared to IVF), due to eggs being immature or damaged by the process of ICSI
  - (b) children conceived having inherited genetic, epigenetic or chromosomal abnormalities (including cystic fibrosis gene mutations, imprinting disorders, sex chromosome defects and heritable sub-fertility).
- 21.2** Where appropriate, centres should also provide patients with information about the possibility of genetic testing of the male partner.

See also guidance note:

- **4 – Information to be provided prior to consent**

### The use of ICSI

- 21.3** The centre's clinical protocols should set out when ICSI can be used. The reasons for using ICSI in any particular case should be explained in the patient's medical records.
- 21.4** With respect to any ICSI programme, the centre should ensure that:
- (a) ICSI and other embryos are transferred during the same treatment cycle only in exceptional circumstances, with an upper limit of 2% of all ICSI embryo transfers,
  - (b) the circumstances justifying such a transfer are specified in the patient's notes, and
  - (c) eggs that have failed to fertilise by normal IVF or ICSI are not re-inseminated by any means.




## Other legislation, professional guidelines and information

- Association of Clinical Embryologists – Accreditation Standards and Guidelines for IVF Laboratories – [www.embryologists.org.uk/download\\_resources/accreditation\\_standards](http://www.embryologists.org.uk/download_resources/accreditation_standards)

# 22. Research and training

This guidance note contains:

 Refer to principles 3, 5, 6 and 12

## Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Extracts from licence conditions
- Reference to relevant Regulations
- Reference to relevant HFEA Directions

## HFEA guidance

- General ■
- Disclosure of interests
- Information provided to donors ■
- Consent ■
- Additional requirements for stem cell research ●
- Use of human cells ●■
- Human admixed embryos: general requirements ●■
- Human admixed embryos: information provided to donors ■
- Human admixed embryos: consent and storage ■

● Section includes mandatory requirements

■ Section includes interpretation of mandatory requirements



## Mandatory requirements

### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

3 Prohibitions in connection with embryos

(2) No person shall place in a woman–

- (a) an embryo other than a permitted embryo (as defined by section 3ZA), or
- (b) any gametes other than permitted eggs or permitted sperm (as so defined).

(3) A licence cannot authorise–

- (a) keeping or using an embryo after the appearance of the primitive streak,
- (b) placing an embryo in any animal, or
- (c) keeping or using an embryo in any circumstances in which regulations prohibit its keeping or use.

(4) For the purposes of subsection (3)(a) above, the primitive streak is to be taken to have appeared in an embryo not later than the end of the period of 14 days beginning with the day on which the process of creating the embryo began, not counting any time during which the embryo is stored.

4A Prohibitions in connection with genetic material not of human origin

(1) No person shall place in a woman –

- (a) a human admixed embryo,
- (b) any other embryo that is not a human embryo, or
- (c) any gametes other than human gametes.



## Mandatory requirements (cont)

### 14 Conditions of licences for treatment

- (12) No embryo appropriated for the purpose mentioned in paragraph 1(1)ca of Schedule 2 (training in embryological techniques) shall be kept or used for the provision of treatment services.

### 15 Conditions of research licences

- (1) The following shall be conditions of every licence under paragraph 3 of Schedule 2 to this Act.
- (2) The records maintained in pursuance of the licence shall include such information as the Authority may specify in directions about such matters as the Authority may so specify.
- (3) No information shall be removed from any records maintained in pursuance of the licence before the expiry of such period as may be specified in directions for records of the class in question.
- (4) No embryo appropriated for the purposes of any project of research shall be kept or used otherwise than for the purposes of such a project.

### 12 General conditions

- (1) The following shall be conditions of every licence granted under this Act–
- (a) except to the extent that the activities authorised by the licence fall within paragraph (aa), that those activities shall be carried on only on the premises to which the licence relates and under the supervision of the person responsible,

### 41 Offences

- (1) A person who–

- (a) contravenes section 3(2), 3A or 4A(1) of this Act, or
- (b) does anything which, by virtue of section 3(3) of this Act, cannot be authorised by a licence,

is guilty of an offence and liable on conviction on indictment to imprisonment for a term not exceeding ten years or a fine or both.

- (2) A person who–

- (a) contravenes section 3(1) or (1A) of this Act, otherwise than by doing something, which by virtue of section 3(3) of this Act, cannot be authorised by a licence ...

is guilty of an offence.

### Schedule 2

#### Licences for treatment

- 1 (1) A licence under this paragraph may authorise any of the following in the course of providing treatment services –
- (ca) using embryos for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques,

#### Licences for research

- 3 (1) A licence under this paragraph may authorise any of the following–

- (a) bringing about the creation of embryos in vitro, and
- (b) keeping or using embryos,

for the purposes of a project of research specified in the licence.

- (2) A licence under this paragraph may authorise mixing sperm with the egg of a hamster, or other animal specified in Directions, for the purpose of developing more effective techniques for determining the fertility or normality of sperm, but only where anything which forms is destroyed when the research is complete and, in any event, no later than the two cell stage.



## Mandatory requirements (cont)

- (3) A licence under this paragraph may authorise any of the following–
- (a) bringing about the creation of human admixed embryos in vitro, and
  - (b) keeping or using human admixed embryos,
- for the purposes of a project of research specified in the licence.
- (4) A licence under sub-paragraph (3) may not authorise the activity which may be authorised by a licence under sub-paragraph (2).
- (5) No licence under this paragraph is to be granted unless the Authority is satisfied that any proposed use of embryos or human admixed embryos is necessary for the purposes of the research.
- (6) Subject to the provisions of this Act, a licence under this paragraph may be granted subject to such conditions as may be specified in the licence.
- (7) A licence under this paragraph may authorise the performance of any of the activities referred to in sub-paragraph (1), (2) or (3) in such manner as may be so specified.
- (8) A licence under this paragraph may be granted for such period not exceeding three years as may be specified in the licence.
- (9) This paragraph has effect subject to paragraph 3A.

### Purposes for which activities may be licensed under paragraph 3

- 3A (1) A licence under paragraph 3 cannot authorise any activity unless the activity appears to the Authority–
- (a) to be necessary or desirable for any of the purposes specified in sub-paragraph (2) (“the principal purposes”),
  - (b) to be necessary or desirable for the purpose of providing knowledge that, in the view of the Authority, may be capable of being applied for the purposes specified in sub-paragraph (2)(a) or (b), or
  - (c) to be necessary or desirable for such other purposes as may be specified in regulations.
- (2) The principal purposes are–
- (a) increasing knowledge about serious disease or other serious medical conditions,
  - (b) developing treatments for serious disease or other serious medical conditions,
  - (c) increasing knowledge about the causes of any congenital disease or congenital medical condition that does not fall within paragraph (a),
  - (d) promoting advances in the treatment of infertility,
  - (e) increasing knowledge about the causes of miscarriage,
  - (f) developing more effective techniques of contraception,
  - (g) developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation, or
  - (h) increasing knowledge about the development of embryos.

### General

- 4 (1) A licence under this Schedule can only authorise activities to be carried on–
- (a) on premises specified in the licence or, in the case of activities to which section 3(1A)(b) or (1B) or 4(1A) applies, on relevant third party premises, and
  - (b) under the supervision of an individual designated in the licence.



## Mandatory requirements (cont)

(1A) A licence which authorises activities falling within paragraph 1 or 1A above may not also authorise activities falling within paragraph 3 above.

(2) A licence cannot–

- (a) authorise activities falling within both paragraph 1 [Licenses for treatment] and paragraph 3 above,
- (b) apply to more than one project of research,
- (c) authorise activities to be carried on under the supervision of more than one individual, or
- (d) apply to premises of the person who holds the licence in different places.

### Schedule 3

#### Consent

2 (1) A consent to the use of any embryo must specify one or more of the following purposes–

... (ba) use for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques, or

(c) use for the purposes of any project of research,

and may specify conditions subject to which the embryo may be so used.

#### In vitro fertilisation and subsequent use of embryos

6 (1) A person's gametes or human cells must not be used to bring about the creation of any embryo in vitro unless there is an effective consent by that person to any embryo, the creation of which may be brought about with the use of those gametes or human cells, being used for one or more of the purposes mentioned in paragraph 2(1)... (c) above.

(2) An embryo the creation of which was brought about in vitro must not be received by any person unless there is an effective consent by each relevant person in relation to the embryo to the use for one or more of the purposes mentioned in paragraph 2(1)... (ba) and (c) above of the embryo.

(3) An embryo the creation of which was brought about in vitro must not be used for any purpose unless there is an effective consent by each relevant person in relation to the embryo to the use for that purpose of the embryo and the embryo is used in accordance with those consents.

#### Embryos obtained by lavage etc.

7 (1) An embryo taken from a woman must not be used for any purpose unless there is an effective consent by her to the use of the embryo for that purpose and it is used in accordance with the consent.

(2) An embryo taken from a woman must not be received by any person for use for any purpose unless there is an effective consent by her to the use of the embryo for that purpose.

(4) An embryo taken from a woman must not be used to bring about the creation of any embryo in vitro or any human admixed embryo in vitro.

#### Variation and withdrawal of consent

4 (1) The terms of any consent under this Schedule may from time to time be varied, and the consent may be withdrawn, by notice given by the person who gave the consent to the person keeping the gametes, human cells, embryo or human admixed embryo to which the consent is relevant.

(2) Subject to sub-paragraph (3), the terms of any consent to the use of any embryo cannot be varied, and such consent cannot be withdrawn, once the embryo has been used–

... (aa) in training persons in embryo biopsy, embryo storage or other embryological techniques, or

(b) for the purposes of any project of research.



## Mandatory requirements (cont)

(3) Where the terms of any consent to the use of an embryo (“embryo A”) include consent to the use of an embryo or human admixed embryo whose creation may be brought about in vitro using embryo A, that consent to the use of that subsequent embryo or human admixed embryo cannot be varied or withdrawn once embryo A has been used for one or more of the purposes mentioned in sub-paragraph (2)(a) or (b).

### Licence conditions

- R18 The provisions of Schedule 3 to the Human Fertilisation and Embryology Act 1990 (as amended) must be complied with (relating to consent to the use of embryos and human admixed embryos and for the storage of gametes, embryos and human admixed embryos for use in research).
- R19 Prior to giving consent, persons providing gametes or human cells must be provided with the necessary information including:
- the nature of the research project
  - that the decision whether to donate will not affect their treatment in any way
  - that they can vary or withdraw the terms of their consent until the point the embryos or human admixed embryos are used in the project of research
  - whether the embryos or human admixed embryos will be reversibly or irreversibly anonymised, and the implications of this
  - whether any information will be fed back to the them, and
  - how the research is funded, including any benefit which will accrue to the researchers and/or their departments.
- R20 Prior to giving consent persons providing gametes or human cells for use in research that involves the derivation of embryonic stem cells/lines, must be provided with the following additional information:
- that once an embryo or human admixed embryo has been used in the project of research they will have no control over any future use of the embryonic cells or any stem cells derived
  - that any stem cells/lines created may continue indefinitely and be used in many different research projects and/or clinical therapy
  - that stem cells derived in this research project will be deposited in the UK Stem Cell Bank and the implications of this including that they may be available to other research groups nationally or internationally
  - that the stem cells/lines may be used for commercial purposes, but that they will not benefit financially from this, and
  - that any stem cells/lines derived or discoveries made using them, could be patented, but that they will not benefit financially from this.
- R21 The information referred to in licence conditions R19 and R20 must be given by trained personnel in a manner and using terms that are easily understood by the persons providing gametes or human cells.
- R22 The centre must ensure that a designated individual, who is not directly involved in the patient’s treatment is available to discuss with the patient the project of research and the possibility of donating material to the project.
- R23 No embryo/human admixed embryo obtained for the purposes of any research project may be kept or used for any purpose other than the purposes of that research project.
- R24 No money or other benefit must be given or received in respect to any supply of gametes, embryos or human admixed embryos unless authorised by directions.
- R26 Each embryo or human admixed embryo must be uniquely labelled in accordance with any directions and/or guidance issued by the Authority.



## Mandatory requirements (cont)

- R27 The centre must establish, implement and comply with documented procedures to ensure that clinical and research roles are separated.
- R28 The centre must establish, implement and comply with documented procedures to ensure that embryos or human admixed embryos do not develop after 14 days or the primitive streak has appeared (if earlier).
- R29 If embryos or human admixed embryos have been created using human cells that have been stored before 1 October 2009 then the centre must take steps to ensure that the embryos or human admixed embryos cannot subsequently be attributed to the person whose cells were so used.
- R31 Gametes of a person must only be placed in storage (for use in licensed research) only if
- received from that person
  - acquired in circumstances in which by virtue of paragraphs 9 and 10 of Schedule 3 to the Human Fertilisation and Embryology Act 1990 (as amended) that person's consent to the storage is not required, or
  - acquired from a person to whom a licence or third party agreement applies.
- R32 Embryos taken from a woman must be placed in storage only if –
- received from that woman, or
  - acquired from a person to whom a licence or third party agreement applies.
- R33 Embryos which have been created in vitro otherwise than in pursuance of this licence must be placed in storage only if acquired from a person to whom a licence or third party agreement applies.
- R34 Human admixed embryos which have been created in vitro otherwise than in pursuance of this licence must be placed in storage only if acquired from a person to whom a licence under paragraph 2 or 3 of Schedule 2 to the Human Fertilisation and Embryology Act 1990 (as amended) applies.
- R35 The statutory storage period in respect of gametes is such period not exceeding ten years as the licence may specify.
- R36 The statutory storage period in respect of embryos is such period not exceeding ten years as the licence may specify.
- R37 The statutory storage period in respect of human admixed embryos is such period not exceeding ten years as the licence may specify.
- R38 Regulations may provide that licence conditions R35, R36 and R37 must have effect as if for ten years there were substituted –
- such shorter period, or
  - in such circumstances as may be specified in the relevant Regulations, such longer period, as may be specified in the relevant Regulations.
- R39 No gametes, embryos or human admixed embryos shall be kept in storage for longer than the statutory storage period and, if stored at the end of the period, must be allowed to perish.
- T92 No embryo appropriated for the purpose of training staff in embryological techniques must be kept or used for the provision of treatment services.
- T93 Embryos may only be used, for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques and in those activities that are expressly authorised by the Authority.
- T94 Embryos may only be used, for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques, where both gamete providers have consented to the use of embryos, created using their gametes, for the purpose of training.
- T95 The centre must have procedures in place to ensure that there is no actual or perceived conflict of interest between the use of embryos in training and the use of embryos in the provision of treatment services.



## Mandatory requirements (cont)

T95 (cont)

This would normally consist of:

- having a designated individual, who is not directly involved in the patient's treatment, to discuss with the patient the training activity and the possibility of donating material for it; and
- making sure that the person obtaining consent for the use of the embryos in training is not involved in the training project.

Where limited staffing makes this difficult to achieve, the centre must develop its own robust procedures for ensuring that the conflict of interest requirement is met.

T97 Prior to giving consent, each gamete provider must be provided with the necessary information including:

- a. the nature of the training for which embryos will be used
- b. that the decision whether to donate will not affect their treatment in any way
- c. that they can vary or withdraw the terms of their consent until the point the embryos are used in training, and
- d. whether any information will be fed back to the them.

T98 The information referred to in licence condition T97 must be given by trained personnel in a manner and using terms that are easily understood by the persons providing gametes.

### Directions

**0002** – Recording and providing information to the Human Fertilisation and Embryology Authority under a research licence

**0008** – Information to be submitted to the HFEA as part of the licensing process

For a copy of the relevant Directions visit [www.hfea.gov.uk](http://www.hfea.gov.uk)

### Regulations

The Human Fertilisation and Embryology (Special Exemptions) Regulations 2009



## HFEA guidance

### General



#### Interpretation of mandatory requirements

22A

The law prohibits:

- (a) embryos being placed in any animal
- (b) embryos that are not human being placed in a woman
- (c) gametes that are not human being placed in a woman
- (d) mixing human gametes with animal gametes, except when carrying out the 'hamster test' in line with a licence
- (e) embryos being kept or used after 14 days from when the process of creating the embryo began, or after the primitive streak has appeared (if earlier than 14 days)
- (f) embryos intended for a research project being used for any purposes other than those of that research project



### Interpretation of mandatory requirements (cont)

22A

- (g) an embryo created or obtained for research being placed in a woman
- (h) keeping the results of the 'hamster test' after any research is complete or, in any event, after the two cell stage
- (i) a research licence being used for any project other than the one specified in that licence
- (j) research activities being carried out on premises other than those specified in the licence
- (k) research activities being carried out under the supervision of anyone other than the specific person designated in the licence
- (l) a treatment licence authorising the activities of a research project, and
- (m) a research licence applying to more than one research project.

The HFE (Special Exemptions) Regulations 2009 allow gametes to be stored without a licence for research on gametes, for developing pharmaceutical or contraceptive products, or for teaching, provided that the gametes are not used for treatment purposes or for other prohibited purposes set out in the Regulations.

- 22.1** The person named as the person responsible on a research licence should not also be named as the person responsible on a treatment licence.
- 22.2** The centre should have documented procedures for:
- (a) obtaining embryos to be used for research or training purposes, and
  - (b) obtaining written informed consent from donors for research and training purposes, and ensuring that embryos are used only in line with this consent.
- 22.3** If embryos or human admixed embryos will be used for research or training purposes, the research centre should record, before the project starts:
- (a) the proposed duration of the culture period
  - (b) the procedure that will be used to ensure that embryos do not develop after 14 days or the primitive streak has appeared (if earlier), and
  - (c) the method that will be used to terminate development.
- 22.4** The centre should have documented procedures for ensuring that embryos and human admixed embryos are used within the maximum period of storage permitted by law or within any period of storage specified in the donor's consent (if shorter).

See also guidance note:

- [17 – Storage of gametes and embryos](#)

### Disclosure of interests

- 22.5** Staff involved in research should follow relevant guidelines produced by the respective professional bodies (eg, the General Medical Council, or the Nursing and Midwifery Council). The centre should ensure that:
- (a) all financial interests and sums of money known or estimated to be paid for the research are disclosed to a research ethics committee, and
  - (b) all members of the research team, including nurses and non-medical staff, are informed about how the research is being financed and managed.



### Information provided to donors



#### Interpretation of mandatory requirements

22B

The law requires that before a person consents to donating embryos, or gametes or cells to be used to create embryos, for research or training, they should be given:

- (a) enough information to understand the nature, purpose and implications of their donation, and
- (b) information about the procedure for varying or withdrawing any consent given, including the fact that they can do this only until the embryos are used in the research project.

Embryos will be regarded as having been used for research or training as soon as they are under the control of the researchers or trainers/trainees and are being cultured for use in research or training.

Specific additional information must be given to individuals before they consent to any donation of their embryos to research projects involving, or intending to involve, human embryonic stem cell lines.

- 22.6** The centre should ensure that donors are given information about how the research is funded, including any direct payments or benefits that researchers, their departments or both would receive, and any financial interests the centre has in the research project or in its sponsoring organisations.
- 22.7** For any research project, the centre should ensure that before donors give their consent to their gametes or embryos, or cells used to create embryos, being used in research, they are given oral information (supported by relevant written material) that confirms:
- (a) the specific research project and its aims
  - (b) details of the research project, including likely outcomes and how any individual donation will impact on the overall project
  - (c) whether the embryos will be reversibly or irreversibly anonymised, and the implications of this
  - (d) whether donors will be given any information that is obtained during the research and is relevant to their health and welfare
  - (e) that donors are expected to have an opportunity to ask questions and discuss the research project
  - (f) that donating gametes or embryos to research in the course of treatment services will not affect the patient's treatment in any way
  - (g) that patients are under no obligation to donate gametes and embryos for research and that their decision whether to do so will have no repercussions for any treatment they may receive
  - (h) that only fresh or frozen gametes and embryos not required for treatment can be used for research
  - (i) that research is experimental, and so any gametes and embryos used and created for any research project must not be used in treatment
  - (j) that donors may specify conditions for the use of the gametes or embryos
  - (k) that after the research has been completed, all donated gametes and embryos will be allowed to perish, and
  - (l) that, for any individual who donates cells for creating embryos for research, consent to use these cells includes consent to do so after the individual's death, unless stated otherwise.
- 22.8** If donated gametes or embryos could be used in secondary research, the centre should inform those considering donation of this possibility and explain that:
- (a) secondary research could include the fixing of gametes, embryos or embryo cell samples for future studies



### 22.8 (cont)

- (b) secondary research could also include genetic research (the implications of which the centre should describe)
- (c) to protect confidentiality, gametes and embryos for secondary research may be anonymised but this may be reversible
- (d) if gametes and embryos will be reversibly anonymised and genetic research proposed, those considering donation will be offered counselling about the implications and given the opportunity to reconsider the terms of their consent
- (e) if gametes and embryos will be irreversibly anonymised, those considering donation will be fully informed of the implications, ie, that no information or results from the research, including clinically relevant information, could be fed back to them, and
- (f) if embryos will be used for stem cell research, those considering donation will be given thorough and appropriate information about the nature of this kind of research and its implications, including that any stem cell lines created may continue indefinitely and be used in different research projects.

### 22.9 If genetic research will be done on identifiable samples, the centre should:

- (a) first inform the donor about the project and what, if any, information may be fed back to them, and
- (b) then obtain the explicit consent of those considering donation.

### 22.10 The centre should ensure that before donors consent to their gametes or embryos being used for training purposes, they are given oral information (supported by relevant written material) that confirms:

- (a) the specific training
- (b) details of the training, including likely outcomes and how any individual donation will impact on the overall training
- (c) whether the gametes or embryos will be reversibly or irreversibly anonymised, and the implications of this
- (d) whether any information, obtained during the training, that is relevant to the donor's health and welfare will be fed back to the donor
- (e) that donors are expected to have an opportunity to ask questions and discuss the training
- (f) that donating gametes or embryos to training in the course of treatment services will not affect the patient's treatment in any way
- (g) that patients are under no obligation to donate gametes or embryos for training and that their decision whether to do so will have no repercussions for any treatment they may receive
- (h) that only fresh or frozen gametes or embryos not required for treatment can be used for training
- (i) that any embryos used in training must not be used in treatment
- (j) that donors may specify conditions for the use of the embryos, and
- (k) that after the training has been completed, all donated embryos will be allowed to perish.

### 22.11 If genetic research will be done on identifiable samples, the centre should:

- (a) first inform the donor about the training and what, if any, information may be fed back to them, and
- (b) then obtain the explicit consent of those considering donation.



### Consent



#### Interpretation of mandatory requirements

22C

The law requires written, signed consent (subject to specific exemption for illness, injury or disability) from any individual before they donate embryos, or gametes or human cells used to create embryos in vitro, for the use in any research project. This consent can be varied or withdrawn at any time until the resulting embryo has been used for the purposes of the research project.

The law requires written, signed consent (subject to specific exemption for illness, injury or disability) from any individual before they donate embryos for training. This consent can be varied or withdrawn at any time until the embryo has been used for training people in embryo biopsy, embryo storage or other embryo techniques.

The HFE (Special Exemptions) Regulations 2009 allow gametes to be stored without a licence for research on gametes, for developing pharmaceutical or contraceptive products, or for teaching, provided that the gametes are not used for treatment purposes.

The law also requires the centre to obtain written informed consent from a person before procuring their gametes.

- 22.12** The centre should obtain written informed consent from a person before using their gametes for research or training.
- 22.13** If donated material is used for research or training, the centre should ensure that clinical and research roles are separated. Individuals involved in advising patients when making clinical decisions about their licensed treatment should not be involved in research or training that patients are considering donating to.
- 22.14** If embryos or gametes, or cells used to create embryos, are used for licensed research, the centre should ensure that:
- (a) a designated individual who is not directly involved in the donor's treatment (but could be part of the clinical team) is available to discuss with the donor the research project and the possibility of donating material
  - (b) the individual obtaining consent is suitably trained and qualified, has sufficient knowledge of the proposed research, understands the risks involved, complies with professional guidelines, and is not directly involved with the research, and
  - (c) the donor is given sufficient time to consider the implications of their donation before the donated material is used in any research project.
- 22.15** Consent should not be obtained under duress, especially if the donor is in a dependent relationship with someone involved in the research project.
- 22.16** The centre should not take gametes or cells from people under the age of 18 for research unless it can satisfy itself that the donor is capable of giving and actually gives effective consent to such research. The exception is in cases where cells may be taken from a person under the age of 18 for research if certain parental consent conditions have been met (as outlined below).
- 22.17** The centre should ensure that all the appropriate consents from all the gamete or embryo donors are in place before embryos are transferred between centres.



See also guidance note:

- [3 – Counselling](#)
- [5 – Consent to treatment, storage, donation, and disclosure of information](#)
- [12 – Egg sharing arrangements](#)

See also:

- [HFEA consent forms available at www.hfea.gov.uk](http://www.hfea.gov.uk)

### Additional requirements for stem cell research



#### Mandatory requirements

The Human Fertilisation and Embryology Act 1990 (as amended):

Licence conditions

12 General conditions

(2) Subsection (3) applies to–

... (c) every licence under paragraph 3 of that Schedule, so far as authorising activities in connection with the derivation from embryos of stem cells that are intended for human application.

(3) It shall be a condition of every licence to which this subsection applies that–

(a) such information as is necessary to facilitate the traceability of gametes and embryos, and

(b) any information relating to the quality or safety of gametes or embryos,

Shall be recorded and provided to the Authority upon request.

14A Conditions of licences: human application

(1) This section applies to–

(c) every licence under paragraph 3 of that Schedule [Schedule 2], so far as authorising activities in connection with the derivation from embryos of stem cells that are intended for human application.

(2) A licence to which this section applies may not authorise the storage, procurement, testing, processing or distribution of gametes or embryos unless it contains the conditions required by Schedule 3A.

(3) In relation to any gametes or embryos imported into the United Kingdom from an EEA state other than the United Kingdom or from Gibraltar, compliance with the requirements of the laws or other measures adopted in the relevant state or territory for the purpose of implementing the first, second and third Directives shall be taken to be compliance with the conditions required by Schedule 3A.

(4) Subsection (3) shall not apply to any licence conditions imposed by the Authority which amount to more stringent protective measures for the purposes of Article 4(2) of the first Directive.



### Mandatory requirements (cont)

#### Licence conditions

- R20 Prior to giving consent persons providing gametes or human cells for use in research that involves the derivation of embryonic stem cells/lines, must be provided with the following additional information:
- that once an embryo or human admixed embryo has been used in the project of research they will have no control over any future use of the embryonic cells or any stem cells derived
  - that any stem cells/lines created may continue indefinitely and be used in many different research projects and/or clinical therapy
  - that stem cells derived in this research project will be deposited in the UK Stem Cell Bank and the implications of this including that they may be available to other research groups nationally or internationally
  - that the stem cells/lines may be used for commercial purposes, but that they will not benefit financially from this, and
  - that any stem cells/lines derived or discoveries made using them, could be patented, but that they will not benefit financially from this.
- R30 Where this licence authorises the derivation of human embryonic stem cell lines:
- a sample of all stem cell lines derived must be deposited in the UK Stem Cell Bank in accordance with any relevant Bank guidelines, and
  - the remainder of all stem cell lines (in so far as not used or destroyed as part of or in the course of the research project) must be deposited in the UK Stem Cell Bank or distributed in accordance with any relevant guidelines issued by the UK Stem Cell Bank.
- R41 Centres deriving stem cells for intended human application must comply with the additional conditions set out in Annex A to the Research Licence.
- R68 The centre must record such information as is necessary to facilitate the traceability of stem cells derived from embryos that are intended for human application and any information relating to the quality or safety of gametes and embryos. This information must be provided to the Authority upon request.

Centres deriving stem cells for human application should adhere to the mandatory requirements and guidance, outlined in other guidance notes, regarding:

- Traceability and coding system  
(19 – Traceability)
- Serious adverse events and serious adverse reactions  
(27 – Adverse incidents)
- Third party agreements and termination of licensed activities  
(24 – Third party agreements)
- Procurement of gametes and embryos  
(15 – Procuring, processing and transporting gametes and embryos)
- Selection criteria and laboratory tests required for donors of reproductive cells  
(11 – Donor recruitment, assessment and screening)
- Donation and procurement procedures and reception at the tissue establishment  
(15 – Procuring, processing and transporting gametes and embryos)



- 22.18** The centre should have documented procedures for depositing samples of all embryonic stem cell lines developed or used in a research project in a stem cell bank.
- 22.19** Donors must give specific consent to their gametes, or embryos created with their gametes, being used in stem cell research.

See also guidance note:

- [19 – Traceability](#)

See also:

- [Regulatory Route Map for Stem Cell Research and Manufacture, Gene Therapy Advisory Committee: \[www.advisorybodies.doh.gov.uk/genetics/gtac\]\(http://www.advisorybodies.doh.gov.uk/genetics/gtac\)](#)

### Use of human cells



#### Mandatory requirements

##### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

##### 15 Conditions of research licences

- (5) If by virtue of paragraph 15F of Schedule 3 (existing cell lines) qualifying cells, as defined by paragraph 15F(2) of that Schedule, of a person (“P”) are used to bring about the creation in vitro of an embryo or human admixed embryo without P’s consent, steps shall be taken to ensure that the embryo or human admixed embryo cannot subsequently be attributed to P.

##### Schedule 3

##### In vitro fertilisation and subsequent use of embryos

- 6 (3A) If the Authority is satisfied that the parental consent conditions in paragraph 15A are met in relation to the proposed use under a licence of the human cells of a person who has not attained the age of 18 years (“C”), the Authority may in the licence authorise the application of sub-paragraph (3B) in relation to C.
- (3B) Where the licence authorises the application of this sub-paragraph, the effective consent of a person having parental responsibility for C—
- (a) to the use of C’s human cells to bring about the creation of an embryo in vitro for use for the purposes of a project of research, or
- (b) to the use for those purposes of an embryo in relation to which C is a relevant person by reason only of the use of C’s human cells,
- is to be treated for the purposes of sub-paragraphs (1) to (3) as the effective consent of C.
- (3C) If C attains the age of 18 years or the condition in paragraph 15(3) ceases to be met in relation to C, paragraph 4 has effect in relation to C as if any effective consent previously given under sub-paragraphs (1) to (3) by a person having parental responsibility for C had been given by C but, subject to that, sub-paragraph (3B) ceases to apply in relation to C.
- (3ZD) Sub-paragraphs (1) to (3) have effect subject to paragraphs 15B and 15F.



### Mandatory requirements

#### Storage of gametes and embryos

- 8 (2A) Where a licence authorises the application of paragraph 6(3B) in relation to a person who has not attained the age of 18 years (“C”), the effective consent of a person having parental responsibility for C to the storage of an embryo in relation to which C is a relevant person by reason only of the use of C’s human cells is to be treated for the purposes of sub-paragraph (2) as the effective consent of C.
- (2B) If C attains the age of 18 years or the condition in paragraph 15(3) ceases to be met in relation to C, paragraph 4 has effect in relation to C as if any effective consent previously given under sub-paragraph (2) by a person having parental responsibility for C had been given by C but, subject to that, sub-paragraph (2A) ceases to apply in relation to C.
- (2C) For the purposes of sub-paragraphs (2) and (2A), each of the following is a relevant person in relation to an embryo the creation of which was brought about in vitro (“embryo A”)–
- each person whose gametes or human cells were used to bring about the creation of embryo A,
  - each person whose gametes or human cells were used to bring about the creation of any other embryo, the creation of which was brought about in vitro, which was used to bring about the creation of embryo A, and
  - each person whose gametes or human cells were used to bring about the creation of any human admixed embryo, the creation of which was brought about in vitro, which was used to bring about the creation of embryo A.

#### Parental consent conditions

- 15 (1) In relation to a person who has not attained the age of 18 years (“C”), the parental consent conditions referred to in paragraphs 6(3A) and 12(4) are as follows.
- (2) Condition A is that C suffers from, or is likely to develop, a serious disease, a serious physical or mental disability or any other serious medical condition.
- (3) Condition B is that either–
- C is not competent to deal with the issue of consent to the use of C’s human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of a project of research, or
  - C has attained the age of 16 years but lacks capacity to consent to such use of C’s human cells.
- (4) Condition C is that any embryo or human admixed embryo to be created in vitro is to be used for the purposes of a project of research which is intended to increase knowledge about–
- the disease, disability or medical condition mentioned in sub-paragraph (2) or any similar disease, disability or medical condition, or
  - the treatment of, or care of persons affected by, that disease, disability or medical condition or any similar disease, disability or medical condition.
- (5) Condition D is that there are reasonable grounds for believing that research of comparable effectiveness cannot be carried out if the only human cells that can be used to bring about the creation in vitro of embryos or human admixed embryos for use for the purposes of the project are the human cells of persons who–
- have attained the age of 18 years and have capacity to consent to the use of their human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of the project, or



### Mandatory requirements (cont)

(5) (cont)

- (b) have not attained that age but are competent to deal with the issue of consent to such use of their human cells.

(6) In relation to Scotland, sub-paragraphs (1) to (5) are to be read with the following modifications–

(a) for sub-paragraph (3) substitute–

“(3) Condition B is that C does not have capacity (within the meaning of section 2(4ZB) of the Age of Legal Capacity (Scotland) Act 1991) to consent to the use of C’s human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of a project of research.”,

(b) in sub-paragraph (5)(a), for “have capacity to consent” substitute “are not incapable (within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000) of giving consent”, and

(c) in sub-paragraph (5)(b), for “are competent to deal with the issue of” substitute “have capacity (within the meaning of section 2(4ZB) of the Age of Legal Capacity (Scotland) Act 1991) to”.

Adults lacking capacity: exemption relating to use of human cells etc.

16 (1) If, in relation to the proposed use under a licence of the human cells of a person who has attained the age of 18 years (“P”), the Authority is satisfied–

- (a) that the conditions in paragraph 17 are met,
- (b) that paragraphs (1) to (4) of paragraph 18 have been complied with, and
- (c) that the condition in paragraph 18(5) is met,

the Authority may in the licence authorise the application of this paragraph in relation to P.

(2) Where a licence authorises the application of this paragraph, this Schedule does not require the consent of P–

- (a) to the use (whether during P’s life or after P’s death) of P’s human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of a project of research,
- (b) to the storage or the use for those purposes (whether during P’s life or after P’s death) of an embryo or human admixed embryo in relation to which P is a relevant person by reason only of the use of P’s human cells.

(3) This paragraph has effect subject to paragraph 19.

Consent to use of human cells etc. not required: adult lacking capacity

17 (1) The conditions referred to in paragraph 16(1)(a) are as follows.

- (2) Condition A is that P suffers from, or is likely to develop, a serious disease, a serious physical or mental disability or any other serious medical condition.
- (3) Condition B is that P lacks capacity to consent to the use of P’s human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of a project of research.
- (4) Condition C is that the person responsible under the licence has no reason to believe that P had refused such consent at a time when P had that capacity.
- (5) Condition D is that it appears unlikely that P will at some time have that capacity.



### Mandatory requirements (cont)

- (6) Condition E is that any embryo or human admixed embryo to be created in vitro is to be used for the purposes of a project of research which is intended to increase knowledge about–
- (a) the disease, disability or medical condition mentioned in sub-paragraph (2) or any similar disease, disability or medical condition, or
  - (b) the treatment of, or care of persons affected by, that disease, disability or medical condition or any similar disease, disability or medical condition.
- (7) Condition F is that there are reasonable grounds for believing that research of comparable effectiveness cannot be carried out if the only human cells that can be used to bring about the creation in vitro of embryos or human admixed embryos for use for the purposes of the project are the human cells of persons who–
- (a) have attained the age of 18 years and have capacity to consent to the use of their human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of the project, or
  - (b) have not attained that age but are competent to deal with the issue of consent to such use of their human cells.
- (8) In this paragraph and paragraph 18 references to the person responsible under the licence are to be read, in a case where an application for a licence is being made, as references to the person who is to be the person responsible.
- (9) In relation to Scotland–
- (a) references in sub-paragraphs (3) to (5) to P lacking, or having, capacity to consent are to be read respectively as references to P being, or not being, incapable (within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000) of giving such consent, and
  - (b) sub-paragraph (7) is to be read with the following modifications–
    - (i) in paragraph (a), for “have capacity to consent” substitute “are not incapable (within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000) of giving consent”, and
    - (ii) in paragraph (b), for “are competent to deal with the issue of” substitute “have capacity (within the meaning of section 2(4ZB) of the Age of Legal Capacity (Scotland) Act 1991) to”.

#### Consulting carers etc. in case of adult lacking capacity

- 18 (1) This paragraph applies in relation to a person who has attained the age of 18 years (“P”) where the person responsible under the licence (“R”) wishes to use P’s human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of a project of research, in a case where P lacks capacity to consent to their use.
- (2) R must take reasonable steps to identify a person who–
- (a) otherwise than in a professional capacity or for remuneration, is engaged in caring for P or is interested in P’s welfare, and
  - (b) is prepared to be consulted by R under this paragraph of this Schedule.
- (3) If R is unable to identify such a person R must nominate a person who–
- (a) is prepared to be consulted by R under this paragraph of this Schedule, but
  - (b) has no connection with the project.



### Mandatory requirements (cont)

- (4) R must provide the person identified under sub-paragraph (2) or nominated under sub-paragraph (3) (“F”) with information about the proposed use of human cells to bring about the creation in vitro of embryos or human admixed embryos for use for the purposes of the project and ask F what, in F’s opinion, P’s wishes and feelings about the use of P’s human cells for that purpose would be likely to be if P had capacity in relation to the matter.
- (5) The condition referred to in paragraph 16(1)(c) is that, on being consulted, F has not advised R that in F’s opinion P’s wishes and feelings would be likely to lead P to decline to consent to the use of P’s human cells for that purpose.
- (6) In relation to Scotland, the references in sub-paragraphs (1) and (4) to P lacking, or having, capacity to consent are to be read respectively as references to P being, or not being, incapable (within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000) of giving such consent.

#### Effect of acquiring capacity

- 19 (1) Paragraph 16 does not apply to the use of P’s human cells to bring about the creation in vitro of an embryo or human admixed embryo if, at a time before the human cells are used for that purpose, P–
  - (a) has capacity to consent to their use, and
  - (b) gives written notice to the person keeping the human cells that P does not wish them to be used for that purpose.
- (2) Paragraph 16 does not apply to the storage or use of an embryo or human admixed embryo whose creation in vitro was brought about with the use of P’s human cells if, at a time before the embryo or human admixed embryo is used for the purposes of the project of research, P–
  - (a) has capacity to consent to the storage or use, and
  - (b) gives written notice to the person keeping the human cells that P does not wish them to be used for that purpose.
- (3) In relation to Scotland, the references in sub-paragraphs (1)(a) and (2)(a) to P having capacity to consent are to be read as references to P not being incapable (within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000) of giving such consent.

#### Use of cells or cell lines

- 20 (1) Where a licence authorises the application of this paragraph in relation to qualifying cells, this Schedule does not require the consent of a person (“P”)–
  - (a) to the use of qualifying cells of P to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of a project of research, or
  - (b) to the storage or the use for those purposes of an embryo or human admixed embryo in relation to which P is a relevant person by reason only of the use of qualifying cells of P.
- (2) “Qualifying cells” are human cells which–
  - (a) were lawfully stored for research purposes immediately before the commencement date, or
  - (b) are derived from human cells which were lawfully stored for those purposes at that time.
- (3) The “commencement date” is the date on which paragraph 9(2)(a) of Schedule 3 to the Human Fertilisation and Embryology Act 2008 (requirement for consent to use of human cells to create an embryo) comes into force.



### Mandatory requirements (cont)

Conditions for grant of exemption in paragraph 20

- 21 (1) A licence may not authorise the application of paragraph 20 unless the Authority is satisfied–
- (a) that there are reasonable grounds for believing that scientific research will be adversely affected to a significant extent if the only human cells that can be used to bring about the creation in vitro of embryos or human admixed embryos for use for the purposes of the project of research are–
    - (i) human cells in respect of which there is an effective consent to their use to bring about the creation in vitro of embryos or human admixed embryos for use for those purposes, or
    - (ii) human cells which by virtue of paragraph 16 can be used without such consent, and
  - (b) that any of the following conditions is met in relation to each of the persons whose human cells are qualifying cells which are to be used for the purposes of the project of research.
- (2) Condition A is that–
- (a) it is not reasonably possible for the person responsible under the licence (“R”) to identify the person falling within sub-paragraph (1)(b) (“P”), and
  - (b) where any information that relates to P (without identifying P or enabling P to be identified) is available to R, that information does not suggest that P would have objected to the use of P’s human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of the project.
- (3) Condition B is that–
- (a) the person responsible under the licence (“R”) has taken all reasonable steps to contact the person falling within subparagraph (1)(b) (“P”) but has been unable to do so,
  - (b) R does not have any reason to believe P to have died, and
  - (c) the information relating to P that is available to R does not suggest that P would have objected to the use of P’s human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of the project.
- (4) Condition C is that–
- (a) the person falling within sub-paragraph (1)(b) (“P”) has died since P’s human cells were first stored,
  - (b) the information relating to P that is available to the person responsible under the licence (“R”) does not suggest that P would have objected to the use of P’s human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of the project, and
  - (c) a person who stood in a qualifying relationship to P immediately before P died has given consent in writing to the use of P’s human cells to bring about the creation in vitro of an embryo or human admixed embryo for use for the purposes of the project.
- (5) The HTA consent provisions apply in relation to consent for the purposes of sub-paragraph (4)(c) as they apply in relation to consent for the purposes of section 3(6)(c) of the Human Tissue Act 2004; and for the purposes of this sub-paragraph the HTA consent provisions are to be treated as if they extended to Scotland.



### Mandatory requirements (cont)

- (6) In sub-paragraph (5) “the HTA consent provisions” means subsections (4), (5), (6), (7) and (8)(a) and (b) of section 27 of the Human Tissue Act 2004.
- (7) In this paragraph references to the person responsible under the licence are to be read, in a case where an application for a licence is being made, as references to the person who is to be the person responsible.
- (8) Paragraphs 1 to 4 of this Schedule do not apply in relation to a consent given for the purposes of sub-paragraph (4)(c).

#### Interpretation

- 22
- (1) In this Schedule references to human cells are to human cells which are not–
    - (a) cells of the female or male germ line, or
    - (b) cells of an embryo.
  - (4) Reference in this Schedule (however expressed) to the use of human cells to bring about the creation of an embryo or a human admixed embryo include the use of human cells to alter the embryo or, as the case may be, the human admixed embryo.
  - (5) References in this Schedule to parental responsibility are–
    - (a) in relation to England and Wales, to be read in accordance with the Children Act 1989,
    - (b) in relation to Northern Ireland, to be read in accordance with the Children (Northern Ireland) Order 1995, and
    - (c) in relation to Scotland, to be read as references to parental responsibilities and parental rights within the meaning of the Children (Scotland) Act 1995.
  - (6) References in this Schedule to capacity are, in relation to England and Wales, to be read in accordance with the Mental Capacity Act 2005.
  - (7) References in this Schedule to the age of 18 years are, in relation to Scotland, to be read as references to the age of 16 years.



### Interpretation of mandatory requirements

22D

Human cells may be used to create embryos or human admixed embryos in vitro for use in research, or embryos may be used in research, without the consent of the person providing the cells in the following circumstances:

- (a) If the person is under the age of 18
  - (i) The Authority must be satisfied that specified parental consent conditions have been met.
  - (ii) A parent of the person must have given effective consent on their behalf.
  - (iii) The parental conditions must remain satisfied.
  - (iv) The child must not have reached the age of 18, and must not have withdrawn or varied the consent, before the embryo is used for the research project.



### Interpretation of mandatory requirements (cont)

22D

- (b) If the person is an adult
- (i) The Authority must be satisfied that specified conditions relating to adults and consent have been met.
  - (ii) An appropriate person must have been consulted by the person responsible, and given suitable information and an opportunity to state what the adult's wishes and feelings would have been about the proposed use of their cells for that purpose.
  - (iii) The person consulted must not have stated that the adult would have been likely to refuse to consent.
  - (iv) Consent must not have been validly withdrawn by the person providing the cells before the use of the cells or any resulting embryo or human admixed embryo.

For both a) and b), the cells or embryos (or cells derived from these) must have been lawfully stored for research purposes before 1 October 2009, and certain conditions must have been met.

## Human admixed embryos: general requirements



### Mandatory requirements

#### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

#### 4A Prohibitions in connection with genetic material not of human origin

- (1) No person shall place in a woman—
  - (a) a human admixed embryo,
  - (b) any other embryo that is not a human embryo, or
  - (c) any gametes other than human gametes.
- (2) No person shall—
  - (a) mix human gametes with animal gametes,
  - (b) bring about the creation of a human admixed embryo, or
  - (c) keep or use a human admixed embryo,except in pursuance of a licence.
- (3) A licence cannot authorise the keeping or using of a human admixed embryo after the earliest of the following—
  - (a) the appearance of the primitive streak, or
  - (b) the end of the period of 14 days beginning with the day on which the process of creating the human admixed embryo began, but not counting any time during which the human admixed embryo is stored.
- (4) A licence cannot authorise placing a human admixed embryo in an animal.
- (5) A licence cannot authorise keeping or using a human admixed embryo in any circumstances in which regulations prohibit its keeping or use.



### Mandatory requirements (cont)

- (6) For the purposes of this Act a human admixed embryo is–
- (a) an embryo created by replacing the nucleus of an animal egg or of an animal cell, or two animal pronuclei, with–
    - (i) two human pronuclei,
    - (ii) one nucleus of a human gamete or of any other human cell, or
    - (iii) one human gamete or other human cell,
  - (b) any other embryo created by using–
    - (i) human gametes and animal gametes, or
    - (ii) one human pronucleus and one animal pronucleus,
  - (c) a human embryo that has been altered by the introduction of any sequence of nuclear or mitochondrial DNA of an animal into one or more cells of the embryo,
  - (d) a human embryo that has been altered by the introduction of one or more animal cells, or
  - (e) any embryo not falling within paragraphs (a) to (d) which contains both nuclear or mitochondrial DNA of a human and nuclear or mitochondrial DNA of an animal (“animal DNA”) but in which the animal DNA is not predominant.
- (7) In subsection (6)–
- (a) references to animal cells are to cells of an animal or of an animal embryo, and
  - (b) references to human cells are to cells of a human or of a human embryo.
- (8) For the purposes of this section an “animal” is an animal other than man.
- (9) In this section “embryo” means a live embryo, including an egg that is in the process of fertilisation or is undergoing any other process capable of resulting in an embryo.
- 11 Licences for treatment, storage and research
- (1) The Authority may grant the following and no other licences–
- (b) licences under that Schedule authorising the storage of gametes, embryos or human admixed embryos
- 14 Conditions of storage licences
- (1) The following shall be conditions of every licence authorising the storage of gametes, embryos or human admixed embryos–
- (ac) that a human admixed embryo the creation of which has been brought about in vitro otherwise than in pursuance of that licence shall be placed in storage only if acquired from a person to whom a licence under paragraph 2 or 3 of Schedule 2 applies...
  - (ba) that human admixed embryos shall not be supplied to a person unless that person is a person to whom a licence applies,.
  - (c) that no gametes, embryos or human admixed embryo shall be kept in storage for longer than the statutory storage period and, if stored at the end of the period, shall be allowed to perish,
- (4A) The statutory storage period in respect of human admixed embryos is such period not exceeding ten years as the licence may specify.



### Mandatory requirements (cont)

#### Schedule 2

#### Licences for storage

- 2 (1A) A licence under this paragraph or paragraph 3 may authorise the storage of human admixed embryos (whether or not the licence also authorises the storage of gametes or embryos or both).

#### Licences for research

- 3 (3) A licence under this paragraph may authorise any of the following–
- (a) bringing about the creation in vitro of things that are human admixed embryos by virtue of paragraph (a), (b), (c) or (d) of section 4A(5), and
  - (b) keeping or using things that are human admixed embryos by virtue of any of those paragraphs,  
for the purposes of a project of research specified in the licence.
- (4) A licence under sub-paragraph (3) may not authorise the activity which may be authorised by a licence under sub-paragraph (2).
- (5) No licence under this paragraph is to be granted unless the Authority is satisfied that any proposed use of embryos or human admixed embryos is necessary for the purposes of the research.

#### Purposes for which activities may be licensed under paragraph 3

- 3A (1) A licence under paragraph 3 cannot authorise any activity unless the activity appears to the Authority–
- (a) to be necessary or desirable for any of the purposes specified in sub-paragraph (2) (“the principal purposes”),
  - (b) to be necessary or desirable for the purpose of providing knowledge that, in the view of the Authority, may be capable of being applied for the purposes specified in sub-paragraph (2)(a) or (b), or
  - (c) to be necessary or desirable for such other purposes as may be specified in regulations.
- (2) The principal purposes are–
- (a) increasing knowledge about serious disease or other serious medical conditions,
  - (b) developing treatments for serious disease or other serious medical conditions,
  - (c) increasing knowledge about the causes of any congenital disease or congenital medical condition that does not fall within paragraph (a),
  - (d) promoting advances in the treatment of infertility,
  - (e) increasing knowledge about the causes of miscarriage,
  - (f) developing more effective techniques of contraception,
  - (g) developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation, or
  - (h) increasing knowledge about the development of embryos.



### Mandatory requirements (cont)

#### Schedule 3

#### Terms of consent

- 2 (1A) A consent to the use of any human admixed embryo must specify use for the purposes of a project of research and may specify conditions subject to which the human admixed embryo may be so used.
- (2) A consent to the storage of any gametes, any embryo or any human admixed embryo must—
- (a) specify the maximum period of storage (if less than the statutory storage period),
  - (b) except in a case falling within paragraph (c), state what is to be done with the gametes, embryo or human admixed embryo if the person who gave the consent dies or is unable, because the person lacks capacity to do so, to vary the terms of the consent or to withdraw it, and
  - (c) where the consent is given by virtue of paragraph 8(2A) or 13(2), state what is to be done with the embryo or human admixed embryo if the person to whom the consent relates dies,
- and may (in any case) specify conditions subject to which the gametes, embryo or human admixed embryo may remain in storage.
- (2A) A consent to the use of a person's human cells to bring about the creation in vitro of an embryo or human admixed embryo is to be taken unless otherwise stated to include consent to the use of the cells after the person's death.
- (4) A consent under this Schedule may apply—
- (a) to the use or storage of a particular embryo or human admixed embryo, or
  - (b) in the case of a person providing gametes or human cells, to the use or storage of—
    - (i) any embryo or human admixed embryo whose creation may be brought about using those gametes or those cells, and
    - (ii) any embryo or human admixed embryo whose creation may be brought about using such an embryo or human admixed embryo.
- (5) In the case of a consent falling within sub-paragraph (4)(b), the terms of the consent may be varied, or the consent may be withdrawn, in accordance with this Schedule either generally or in relation to—
- (a) a particular embryo or particular embryos, or
  - (b) a particular human admixed embryo or particular human admixed embryos.

#### Variation and withdrawal of consent

- 4 (1) The terms of any consent under this Schedule may from time to time be varied, and the consent may be withdrawn, by notice given by the person who gave the consent to the person keeping the gametes, human cells, embryo or human admixed embryo to which the consent is relevant.
- (4) Subject to sub-paragraph (5), the terms of any consent to the use of any human admixed embryo cannot be varied, and such consent cannot be withdrawn, once the human admixed embryo has been used for the purposes of any project of research.
- (5) Where the terms of any consent to the use of a human admixed embryo (“human admixed embryo A”) include consent to the use of a human admixed embryo or embryo whose creation may be brought about in vitro using human admixed embryo A, that consent to the use of that subsequent human admixed embryo or embryo cannot be varied or withdrawn once human admixed embryo A has been used for the purposes of any project of research.



### Mandatory requirements (cont)

#### Creation, use and storage of human admixed embryos

- 12
- (1) A person's gametes or human cells must not be used to bring about the creation of any human admixed embryo in vitro unless there is an effective consent by that person to any human admixed embryo, the creation of which may be brought about with the use of those gametes or human cells, being used for the purposes of any project of research.
  - (2) A human admixed embryo the creation of which was brought about in vitro must not be received by any person unless there is an effective consent by each relevant person in relation to the human admixed embryo to the use of the human admixed embryo for the purposes of any project of research.
  - (3) A human admixed embryo the creation of which was brought about in vitro must not be used for the purposes of a project of research unless—
    - (a) there is an effective consent by each relevant person in relation to the human admixed embryo to the use of the human admixed embryo for that purpose, and
    - (b) the human admixed embryo is used in accordance with those consents.
  - (4) If the Authority is satisfied that the parental consent conditions in paragraph 15 are met in relation to the proposed use under a licence of the human cells of a person who has not attained the age of 18 years ("C"), the Authority may in the licence authorise the application of sub-paragraph (5) in relation to C.
  - (5) Where the licence authorises the application of this subparagraph, the effective consent of a person having parental responsibility for C—
    - (a) to the use of C's human cells to bring about the creation of a human admixed embryo in vitro for use for the purposes of a project of research, or
    - (b) to the use for those purposes of a human admixed embryo in relation to which C is a relevant person by reason only of the use of C's human cells,is to be treated for the purposes of sub-paragraphs (1) to (3) as the effective consent of C.
  - (6) If C attains the age of 18 years or the condition in paragraph 15(3) ceases to be met in relation to C, paragraph 4 has effect in relation to C as if any effective consent previously given under subparagraphs (1) to (3) by a person having parental responsibility for C had been given by C but, subject to that, sub-paragraph (5) ceases to apply in relation to C.
- 13
- (1) A human admixed embryo the creation of which was brought about in vitro must not be kept in storage unless—
    - (a) there is an effective consent by each relevant person in relation to the human admixed embryo to the storage of the human admixed embryo, and
    - (b) the human admixed embryo is stored in accordance with those consents.
  - (2) Where a licence authorises the application of paragraph 12(5) in relation to a person who has not attained the age of 18 years ("C"), the effective consent of a person having parental responsibility for C to the storage of a human admixed embryo in relation to which C is a relevant person by reason only of the use of C's human cells is to be treated for the purposes of sub-paragraph (1) as the effective consent of C.
  - (3) If C attains the age of 18 years or the condition in paragraph 15(3) ceases to be met in relation to C, paragraph 4 has effect in relation to C as if any effective consent previously given under subparagraph (1) by a person having parental responsibility for C had been given by C but, subject to that, sub-paragraph (2) ceases to apply in relation to C.



### Mandatory requirements (cont)

- 14 For the purposes of paragraphs 12 and 13, each of the following is a relevant person in relation to a human admixed embryo the creation of which was brought about in vitro (“human admixed embryo A”)–
- each person whose gametes or human cells were used to bring about the creation of human admixed embryo A,
  - each person whose gametes or human cells were used to bring about the creation of any embryo, the creation of which was brought about in vitro, which was used to bring about the creation of human admixed embryo A, and
  - each person whose gametes or human cells were used to bring about the creation of any other human admixed embryo, the creation of which was brought about in vitro, which was used to bring about the creation of human admixed embryo A.



### Interpretation of mandatory requirements

22E

The law prohibits:

- human admixed embryos being placed in a woman, or
- human admixed embryos being kept or used after 14 days from when the process of creating the embryo began or after the primitive streak has appeared (if earlier than 14 days).

## Human admixed embryos: information provided to donors



### Interpretation of mandatory requirements

22F

The law requires that before a person consents to donating embryos, gametes or cells to create human admixed embryos for research purposes, they should be given:

- enough information to understand the nature, purpose and implications of their donation
- information about the procedure for varying or withdrawing any consent given, including the fact that they can do this only until the human admixed embryos are used in the research project.

NOTE: Human admixed embryos will be regarded as having been used for research as soon as they are under the control of the researchers and are being cultured for use in research.

- 22.20** The centre should inform any individual who donates cells for creating human admixed embryos for research that, unless they state otherwise, consent to use these cells includes consent to do so after the individual's death.



### Human admixed embryos: consent and storage



#### Interpretation of mandatory requirements

22G

The law requires written, signed consent (subject to specific exemption for illness, injury or disability) from any individual before they donate gametes or human cells used to create human admixed embryos in vitro for use in any research project.

The consent must specify the maximum storage period (which must be less than the 10-year statutory storage period for human admixed embryos).

This consent can be varied or withdrawn at any time until the embryo has been used for the purposes of the research project.


In certain situations, the law permits human cells to be used to create human admixed embryos without the consent of the person providing them.

See also guidance note:

- [5 – Consent to treatment, storage, donation and disclosure of information](#)
- [17 – Storage of gametes and embryos](#)

# 23. The quality management system

This guidance note contains:

 Refer to principles 7, 8, 10 and 11

## Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Extracts from licence conditions

## HFEA guidance

- Definition of the quality management system
- Establishing, maintaining and documenting the quality management system
- Quality policy and quality objectives
- Quality manual
- The quality management review ■
- Quality indicators
- Assessing user satisfaction
- Staff suggestions
- Internal audit
- Participating in external reviews, and inter-centre and inter-laboratory comparisons
- Monitoring, evaluation and improvement ■

■ Section includes interpretation of mandatory requirements

## Other legislation, professional guidelines and information



## Mandatory requirements

### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Schedule 3A – Supplementary licence conditions: human application

Requirements for holding a licence under paragraph 1, 1A or 2 of Schedule 2

- 10 Licence conditions shall require compliance with the requirements laid down in the provisions of the third Directive...

Relevant provisions of the third Directive	
Quality review (quality management system, investigations, corrective action, and reviews)	Annex I, Part F

### Licence conditions

- T32 The centre must put in place a quality management system and implement this system to continually improve the quality and effectiveness of the service provided in accordance with the conditions of this licence and the guidance on good practice as set out in the HFEA's Code of Practice.
- T33 The following documentation must form part of the quality management system:
- a. a quality manual
  - b. standard operating procedures (SOPs) for all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence
  - c. guidelines



## Mandatory requirements (cont)

- T33 (cont)
- d. training and reference manuals, and
  - e. reporting forms.
- T35 Required standards of quality and safety, in the form of quality indicators for all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence, must be established.
- T36 Centres must audit the activities and processes authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence against compliance with the regulatory requirements and their own approved protocols and quality indicators. These audits must be performed at least every two years, by trained and competent staff and in an independent way. Findings and corrective actions must be documented and implemented.



## HFEA guidance

### Definition of the quality management system

#### 23.1 The quality management system is defined as:

'the organisational structure, defined responsibilities, procedures, processes and resources for implementing quality management (ie, the co-ordinated activities to direct and control an organisation with regard to quality), including all activities which contribute to quality, directly or indirectly'.<sup>1</sup>

NOTE: This definition indicates that every process and activity taking place in the centre is a part of the quality management system.

#### 23.2 The centre should:

- (a) identify the processes needed for quality management, for providing and managing resources and for assisted conception procedures, and
- (b) ensure these processes, including the interaction between them, are effective and continually improved.

### Establishing, maintaining and documenting the quality management system

#### 23.3 Centre management should ensure the quality management system is established and maintained by:

- (a) appointing a quality manager
- (b) establishing a quality policy
- (c) establishing quality objectives and plans
- (d) ensuring resources are available to implement and maintain the system
- (e) making centre staff aware of the importance of the system and the need to keep to its requirements
- (f) defining responsibilities, authorities and reporting relationships in the centre
- (g) conducting management reviews of the system, and
- (h) establishing and reviewing contracts with third parties.

<sup>1</sup> International Organization for Standardization



See also guidance note:

- [24 - Third party agreements](#)

**23.4** Centre management should appoint a quality manager who, regardless of their other responsibilities, must be responsible for:

- ensuring that the quality management system is implemented and maintained
- reporting to centre management on how the quality management system works and how effective it is, and
- co-ordinating awareness of centre users' needs and requirements.

**23.5** The centre's documents to support its quality management system should include:

- the quality policy, with quality objectives and plans
- a quality manual
- documents needed to ensure the centre's processes are planned and operate effectively, and
- records and procedures required by this Code of Practice.

The centre should ensure that all documents are available for inspection by the HFEA.

### Quality policy and quality objectives

**23.6** The quality policy is defined as:

'the overall intentions and direction of an organisation related to quality as formally expressed by centre management. A quality policy statement defines or describes an organisation's intentions and commitment to quality and provides a framework for setting quality objectives and planning'.<sup>2</sup>

**23.7** Centre management should ensure the quality policy includes a commitment to:

- providing a service that meets its users' needs and requirements
- meeting the provisions of this Code of Practice
- continually improving the effectiveness of the quality management system
- upholding good professional practice, and
- ensuring the health, safety and welfare of all staff and visitors to the centre.

**23.8** The quality policy should be:

- signed and issued by the person responsible
- communicated, understood and available throughout the centre, and
- reviewed for continuing suitability.

**23.9** Centre management should establish documented quality objectives. These should:

- include objectives needed to meet users' needs and requirements
- be measurable and consistent with the quality policy, and
- be reviewed regularly.

<sup>2</sup> International Organization for Standardization



**23.10** Centre management should establish a plan to achieve and maintain the quality objectives. The plans should be reviewed regularly.

### Quality manual

**23.11** The centre should establish and maintain a quality manual. The quality manual should include:

- (a) a brief description of the centre, including its legal identity, and the scope of its services
- (b) the quality policy, or reference to it
- (c) an organisation chart defining accountability and reporting relationships in the centre
- (d) text to accompany the organisational chart and a definition of the centre's place in any parent organisation, and
- (e) an outline of the processes and documentation established for the quality management system.

See also guidance note:

- [31 - Record keeping and document control](#)

### The quality management review



#### Interpretation of mandatory requirements

23A

The centre management must regularly review the centre's quality management system and all its services, identifying the need for changes and opportunities for improvement.

**23.12** The review of the quality management system should include consideration of changes in:

- (a) the volume and scope of work
- (b) staff
- (c) premises
- (d) the performance of third parties that could affect the quality management system or the centre's services, and
- (e) the results of the following activities:
  - (i) quality indicators for monitoring the centre's performance in patient care
  - (ii) assessment of user satisfaction, and the monitoring and resolution of complaints
  - (iii) staff suggestions
  - (iv) an internal audit of all elements of the quality management system, including assisted conception processes
  - (v) participation in external reviews, and inter-centre and inter-laboratory comparisons
  - (vi) identification, investigation, control, recording and notification of serious adverse events and reactions, and
  - (vii) continual improvement, including the status of corrective and preventive actions.

**23.13** The centre should normally review its quality management system at least every 12 months but more often when a quality management system is being established.

**23.14** The management review should include the results of monitoring, evaluation and improvement activities.



**23.15** The results of the review of the quality management system should be recorded and should include the decisions and actions for improving the quality management system. Centre staff should be informed of the results of the quality management review.

See also guidance note:

- [27 – Adverse incidents](#)
- [28 – Complaints](#)

### Quality indicators

**23.16** The centre should establish quality indicators for systematically monitoring and evaluating the centre's contribution to patient care.

### Assessing user satisfaction

**23.17** The centre should assess whether or not the service has met users' needs and requirements. It should keep records of the information it collects and the actions it takes. Methods should include user surveys for all aspects of the service.

### Staff suggestions

**23.18** Centre management should encourage staff to make suggestions for improving any aspect of the centre's service. Suggestions should be evaluated, implemented as appropriate, and feedback provided to the staff. Records of suggestions and management action should be maintained.

### Internal audit

**23.19** The centre should establish an internal audit process to determine whether the quality management system:

- conforms to the planned arrangements for assisted conception processes
- conforms to the requirements of this Code of Practice and to the standards established by the centre, and
- is effectively implemented and maintained.

**23.20** The centre should establish a documented procedure to:

- define the responsibilities for planning and conducting audits
- define the audit criteria, scope, frequency and methods
- ensure audits are carried out by trained staff
- ensure action is taken promptly to start corrective action
- check the effectiveness of the action taken, in a subsequent audit, and
- keep records of audits, to include:
  - the processes, areas or items audited
  - any areas that do not comply with the quality management system
  - recommendations and timescales for action, and
  - action taken and its effectiveness.



- 23.21** The quality manager should plan the audit programme. It must take into account the importance of the processes and areas to be audited, and the results of previous audits. Auditors should not audit their own areas of responsibility.
- 23.22** The audit should focus in particular on quality indicators established for systematically monitoring and evaluating the centre's assisted conception processes.

### Participating in external reviews, and inter-centre and inter-laboratory comparisons

- 23.23** The centre should, where possible, participate in inter-centre comparisons and inter-laboratory comparisons. The centre should evaluate the results of these comparisons and use relevant findings to improve its service.
- 23.24** For inter-laboratory comparisons, the laboratory should establish documented procedures to define the responsibilities and requirements for participation to ensure that:
- a record of participation is maintained, to include reasons for failure to participate
  - supervisory staff and staff doing the examinations evaluate the returned results against agreed performance criteria, and, when nonconformities are identified, participate in implementing and recording corrective action, and
  - the effectiveness of the corrective action is verified. When a formal inter-laboratory comparison programme is not available, the laboratory should develop a way of determining the acceptability of procedures not otherwise evaluated. Whenever possible, this should use external materials, such as exchange of samples with other laboratories.
- 23.25** The centre should assess any external reviews indicating nonconformities or potential nonconformities and take appropriate corrective or preventive action to ensure it continues to comply with the requirements and expectations of this Code of Practice. The centre must keep a record of corrective and preventive action it takes.

### Monitoring, evaluation and improvement



#### Interpretation of mandatory requirements

23B

The centre must plan and implement processes for monitoring, evaluation and improvement.

- 23.26** The centre's processes for monitoring, evaluation and improvement should:
- show that procedures and outcomes are satisfactory when judged against relevant professional standards
  - show that the assisted conception processes are followed in a way that meets users' needs and requirements
  - ensure conformity of the quality management system, and
  - continually improve the effectiveness of the quality management system.
- 23.27** The centre should establish a documented procedure to take corrective action to eliminate the cause of nonconformities. This should include:
- reviewing nonconformities
  - determining the causes of nonconformities
  - evaluating the need for action to ensure nonconformities do not recur
  - promptly determining and implementing action needed
  - recording the results of corrective action taken, and
  - reviewing the corrective action taken.



## HFEA guidance (cont)

**23.28** The centre should establish a documented procedure to take preventive action to eliminate the causes of potential nonconformities and so prevent them happening. It should include:

- (a) determining potential nonconformities and their causes
- (b) evaluating the need for action to prevent nonconformities happening
- (c) promptly determining and implementing action needed
- (d) recording the results of preventive action taken, and
- (e) reviewing preventive action taken.

NOTE: Preventive action is a way of actively identifying opportunities for improvement rather than reacting to problems or complaints when they happen.



## Other legislation, professional guidelines and information

- International Organization for Standardization – [www.iso.org](http://www.iso.org)

# 24. Third party agreements

## This guidance note contains:

### Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Extracts from licence conditions
- Reference to relevant HFEA Directions

### HFEA guidance

- Scope ■
- Transport centres ■
- Third party procurement of gametes and embryos
- Agreements between licensed centres

 Refer to principles 7, 8, 10 and 11

■ Section includes interpretation of mandatory requirements



## Mandatory requirements

### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

#### 2A Third party agreements

- (1) For the purposes of this Act, a “third party agreement” is an agreement in writing between a person who holds a licence and another person which is made in accordance with any licence conditions imposed by the Authority for the purpose of securing compliance with the requirements of Article 24 of the first Directive (relations between tissue establishments and third parties) and under which the other person—
- (a) procures, tests or processes gametes or embryos (or both), on behalf of the holder of the licence, or
  - (b) supplies to the holder of the licence any goods or services (including distribution services) which may affect the quality or safety of gametes or embryos.

#### (2) In this Act—

“relevant third party premises”, in relation to a licence, means any premises (other than premises to which the licence relates)—

- (a) on which a third party procures, tests, processes or distributes gametes or embryos on behalf of any person in connection with activities carried out by that person under a licence, or
- (b) from which a third party provides any goods or services which may affect the quality and safety of gametes or embryos to any person in connection with activities carried out by that person under a licence; “third party” means a person with whom a person who holds a licence has a third party agreement.

#### (3) References in this Act to the persons to whom a third party agreement applies are to—

- (a) the third party,
- (b) any person designated in the third party agreement as a person to whom the agreement applies, and
- (c) any person acting under the direction of a third party or of any person so designated.

#### 16 Grant of licence

- (1) The Authority may on application grant a licence to any person if the requirements of subsection (2) below are met.
- (2) The requirements mentioned in subsection (1) above are—



## Mandatory requirements (cont)

16 (cont)

- (d) that the Authority is satisfied that the premises in respect of which the licence is to be granted and any premises which will be relevant third party premises are suitable for the activities...

### Licence conditions

- T111 The centre must establish a written agreement with those third parties who provide goods or services that influence the quality and safety of gametes and embryos, and in particular where:
- the centre entrusts one of the stages of gamete or embryo processing to a third party
  - a third party provides goods or services that affect gamete or embryo quality and safety assurance, including the process of distribution, and
  - the centre distributes gametes or embryos processed by third parties.
- T112 The centre must evaluate and select third parties on the basis of their ability to meet the requirements of these licence conditions and the guidance set out in the HFEA Code of Practice.
- T113 Agreements with third parties must specify the terms of the relationship and responsibilities as well as the protocols to be followed to meet the required performance specification.
- T114 The centre must ensure that the following core requirements are included in any third party agreement, namely:
- full address and contact details of the third party, and nature of the service to be provided
  - identification of person(s) responsible for managing arrangement between the centre and the third party
  - provision setting out how often the agreement will be reviewed and by whom
  - summary of the responsibilities of the third party and agreed procedures with regard to each party's respective responsibilities,
  - any specific criteria that the service provided by the third party must meet, particularly in relation to quality and safety, and
  - description of how any test/diagnostic results are relayed to the commissioning centre, including sign off and confirmation that the result applies to the correct sample.
- T115 The centre must keep a complete list of agreements referred to in licence condition T111 that they have established with third parties. Copies of these agreements must be made available to the Authority upon request.
- T116 The centre must ensure that it is made a condition of any agreement with a third party, a satellite or a transport centre that the third party, satellite or transport centre will meet the requirements of the relevant licence conditions and the guidance set out in the HFEA Code of Practice.
- T117 Where the third party procures gametes and/or embryos on behalf of a licensed centre, the third party agreement must require the procuring establishment to produce a report to the licensed centre which must include, but not be limited to, a record of the following:
- where the procurement took place
  - patient/donor identification data including how and by whom identified
  - description and identification of the procured gametes/embryos including samples for testing
  - identification of the person responsible for the procurement process
  - date, time and location of procurement and standard operating procedure used
  - details of any incidents, including any serious adverse events and/or reactions, that occurred during the procurement process



## Mandatory requirements (cont)

T117 (cont)

- g. where appropriate, the environmental conditions at the procurement facility, and
- h. where appropriate, the identification/batch numbers for any reagents and transport media used.

### Directions

**0010** – Satellite and transport IVF

For a copy of the relevant Directions visit [www.hfea.gov.uk](http://www.hfea.gov.uk)



## HFEA guidance

### Scope



#### Interpretation of mandatory requirements

24A

The law requires licensed centres to establish written agreements with third parties every time an external activity will be carried out that influences the quality and safety of gametes procured, tested or processed.

**24.1** A licensed centre should establish a third party agreement where a third party is carrying out the following two categories of activity:

- (a) procuring, testing or processing gametes and embryos, or both, for example:
  - (i) laboratories preparing sperm
  - (ii) centres where patients are assessed, given fertility-stimulating drugs and monitored, and eggs are retrieved (transport centres)
  - (iii) centres where sperm is procured
- (b) supplying goods or services (including distribution services) that may affect the quality and safety of gametes and embryos, for example:
  - (i) companies supplying equipment and materials, eg, suppliers of culture media
  - (ii) companies monitoring air quality in laboratories
  - (iii) clinical or laboratory premises leased from a hospital or other institution, eg, using theatres for collecting eggs under general anaesthetic
  - (iv) courier companies.

**24.2** Third party premises may be inspected as part of the licensing process and when investigating adverse incidents. If third party premises are unsuitable, the licence holder's licence may be varied or revoked.

**24.3** If facilities or services that a third party provides are used in a treatment process, the person responsible for that process should be satisfied that the provider's procedures can be integrated with the centre's quality system. In particular, the third party's procedures should:

- (a) allow the entire service to be audited, and samples to be fully traced
- (b) minimise cross-contamination (where relevant)



### 24.3 (cont)

- (c) follow relevant professional guidelines, and
- (d) ensure that adverse incidents are reported and that any affected gametes and embryos can be effectively recalled.

See also guidance note:

- [15 – Procuring, processing and transporting gametes and embryos](#)
- [23 – The quality management system](#)
- [27 – Adverse incidents](#)

## Transport centres



### Interpretation of mandatory requirements

If any part of treatment takes place in a transport centre, the person responsible for providing the licensable treatment must ensure that the treatment complies with the relevant legal requirements.

- 24.4** Transport centres should give attention to requirements covering information, counselling, the welfare of the child and confidentiality. The person responsible should put in place effective procedures to ensure such centres are given relevant information about these requirements and any changes to them, in a clear and timely way. These requirements should form part of a third party agreement.

## Third party procurement of gametes and embryos

- 24.5** If a centre has a third party agreement with another centre for procuring gametes and embryos, that centre should keep extra third party procurement documents that should include, but not be limited to:
- (a) identification, name and address of the centre to receive the gametes
  - (b) patient, patient's partner or donor identification
  - (c) identification of the procured gametes and embryos
  - (d) identification of the staff member responsible for the procurement session
  - (e) date and time of procurement
  - (f) a record of any procedures performed on the gametes
  - (g) a record of any adverse incidents, and
  - (h) where appropriate, identification or batch numbers (or both) of any reagents and transport media used.

## Agreements between licensed centres

- 24.6** Where a licensed centre arranges for any part of treatment to take place at another licensed centre, the person responsible at the original centre retains overall responsibility for that treatment. The person responsible at the original centre should therefore satisfy themselves that treatment arranged at other licensed centres complies with all relevant legal requirements, quality and safety considerations, and Code of Practice guidance. This will include giving attention to requirements covering information, counselling, the welfare of the child and confidentiality.

The person responsible at the original centre should check HFEA inspection reports about the second centre, and establish regular written confirmation from the second centre. Where the original centre sends a large volume of treatment to a particular centre, checks should be carried out regularly, and no less than annually.

# 25. Premises and facilities

This guidance note contains:

 Refer to principles 2, 7 and 8

## Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Extracts from licence conditions

## HFEA guidance

- Definition of premises ■
- Moving to new premises
- Changing existing premises
- Acquiring additional premises
- Centre facilities
- Clinical facilities
- Counselling facilities
- Laboratory facilities
- Staff facilities

■ Section includes interpretation of mandatory requirements

## Other legislation, professional guidelines and information



## Mandatory requirements

### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

#### 12 General conditions

- (1) The following shall be conditions of every licence granted under this Act –
- (a) except to the extent that the activities authorised by the licence fall within paragraph (aa), that those activities shall be carried out on only on the premises to which the licence relates and under the supervision of the person responsible, (aa) that any activities to which section 3(1A)(b) or (1B) or 4(1A) applies shall be carried on only on the premises to which the licence relates or on relevant third party premises,...

#### 16 Grant of licence

- (1) The Authority may on application grant a licence to any person if the requirements of subsection (2) below are met.
- (2) The requirements mentioned in subsection (1) above are–
- ... (d) that the Authority is satisfied that the premises in respect of which the licence is to be granted and any premises which will be relevant third party premises are suitable for the activities...
- (2) The Authority may revoke a licence otherwise than on application under subsection (1) if–
- ... (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...



## Mandatory requirements (cont)

Schedule 2 – Activities for which licences may be granted

- 4 (1) a licence under this Schedule can only authorise activities to be carried out on –
- (a) on premises specified in the licence or, in the case of activities to which section 3(1A)(b) or (1B) or 4(1A) applies, on relevant third party premises...
- (2) A licence cannot –
- ... (d) apply to premises of the person who holds the licence in different places.

### Licence conditions

- T1 The activities authorised by the licence must be carried out only on the premises specified in this licence and under the supervision of the person responsible (PR). However, where authorised by a licence, procurement, testing, processing or distribution of gametes or embryos intended for human application can also be carried out on relevant third party premises, provided that such premises, and the activities undertaken there, are covered by the terms of a written third party agreement.
- T17 A centre must have suitable facilities to carry out licensed activities, or other activities carried out for the purposes of providing treatment services that do not require a licence.
- T20 In premises where the processing of gametes and embryos exposes them to the environment, the processing must take place in an environment of at least Grade C air quality, with a background environment of at least Grade D air quality as defined in the current European Guide to Good Manufacturing Practice (GMP\_ Annex 1 and Directive 2003/94/EC). It must be demonstrated and documented that the chosen environment achieves the quality and safety required.
- NOTE: Centres storing ovarian or testicular tissue for use in transplantation must refer to the Human Tissue Authority's guidelines as the requirements for processing tissue for use in transplantation are different than those listed above.
- T21 If the centre has laboratories or contracts third party laboratories or practitioners to undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, these laboratories must obtain accreditation by CPA(UK) Ltd or another body accrediting to an equivalent standard. The pathology disciplines involved in diagnosis and investigation include andrology, clinical genetics, (cytogenetics and molecular genetics) haematology, bacteriology, virology and clinical biochemistry. Definition of premises



## HFEA guidance

### Definition of premises



#### Interpretation of mandatory requirements

25A

A licence can apply only to one premises; if a centre wishes to conduct licensed activities in a building different from the licensed premises, and not subject to a third party agreement, a separate licence will be required.

The HFEA must approve all new premises or changes to existing premises before use.

- 25.1** The HFEA defines premises as the specific area where a centre conducts its business, as identified on a floor plan submitted by the centre to the HFEA.
- 25.2** The centre should provide the HFEA with a floor plan that defines the premises to be licensed, including the purpose of each room.



### Moving to new premises

- 25.3** Before moving to new premises, the centre should contact its inspector for advice. The centre should notify the HFEA in writing of the intended move by submitting an application to vary the licence with information about the new premises. The HFEA will consider the application and information, and may need to inspect the premises.

### Changing existing premises

- 25.4** Before planning any changes to the existing premises, the centre should contact its inspector for advice. The centre should notify the HFEA in writing of any planned changes to the premises by submitting, in advance, an application for a variation of the licence with information on the planned changes.
- 25.5** The HFEA will consider the application and information, and may need to inspect the premises.

### Acquiring additional premises

- 25.6** If a centre wishes to conduct licensed activities not subject to a third party agreement in premises other than those specified on the current licence (eg, in a different building), it should contact its inspector for advice and notify the HFEA in writing. The centre should also submit an application for a new licence with information about the additional premises.

### Centre facilities

- 25.7** The centre should provide for the privacy, dignity and respect of all prospective and current patients and donors, as well as providing a safe working environment for all staff. Consultation and the exchange of personal information should be carried out in private (ie, cannot be overlooked or overheard by others).
- 25.8** The centre should have facilities for reception, clinical and counselling activity, laboratory work, storage of confidential records, storing gametes and embryos, and staff.
- 25.9** The centre should display a copy of its Certificate of Licence where it can easily be read by current and potential patients and donors.
- 25.10** The centre should have appropriate procedures to ensure premises comply with relevant requirements for safety and air quality, and these procedures should be validated.
- 25.11** The person responsible should assess how many treatment cycles can safely be accommodated by the centre. The assessment should consider the centre's premises, equipment, staffing levels and the skill mix of staff members. Activity should be adjusted according to the findings of the assessment.

### Clinical facilities

- 25.12** The centre should ensure that its clinical facilities:
- (a) provide privacy and comfort for those:
    - (i) considering donation and seeking treatment
    - (ii) undergoing examination and treatment, and
    - (iii) producing semen specimens.
  - (b) are equipped with backup and emergency clinical facilities that:
    - (i) are equivalent to those provided as standard practice in other medical facilities
    - (ii) are appropriate to the degree of risk involved in any planned procedure, and
    - (iii) can cope with emergencies known to occur in this clinical field.



### Counselling facilities

**25.13** The centre should ensure that counselling facilities provide quiet and comfortable surroundings for private, confidential and uninterrupted sessions.

See also guidance note:

- **3 – Counselling**

### Laboratory facilities

**25.14** The centre's laboratories should comply with current professional guidelines, legislation and regulations.

**25.15** Procedures must be evaluated for hazards to laboratory staff, and precautions put in place to minimise potential hazards.

See also guidance note:

- **15 – Procuring, processing and transporting gametes and embryos**
- **24 – Third party agreements**

### Staff facilities

**25.16** The centre should have staff amenities that are easily accessible and include:

- (a) toilet facilities
- (b) a rest area with basic catering facilities and a supply of drinking water
- (c) a changing area and secure storage for personal belongings, and
- (d) storage for protective clothing.




## Other legislation, professional guidelines and information

- Clinical Pathology Accreditation (CPA) UK Ltd – [www.cpa-uk.co.uk](http://www.cpa-uk.co.uk)

# 26. Equipment and materials

## This guidance note contains:

 Refer to principles 7 and 8

### Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Extracts from licence conditions

### HFEA guidance

- Scope
- Protection and hygiene of staff
- Managing equipment and material
- Safety of equipment used to store cryopreserved gametes and embryos

### Other legislation, professional guidelines and information



## Mandatory requirements

### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

17 The person responsible

(1) It shall be the duty of the individual under whose supervision the activities authorised by a licence are carried on (referred to in this Act as the “person responsible”) to secure–

...

(b) that proper equipment is used,

...

### Licence conditions

T22 For every critical activity, identifying information about all of the materials and equipment must be documented.

T23 Activities must be carried out using equipment and materials designated for the purpose and maintained to suit their intended purpose and must minimise any hazard to patients and/or staff.

T24 All critical equipment and technical devices must be identified and validated, regularly inspected and maintained in accordance with the manufacturer’s instructions. Where equipment or materials affect critical processing or storage parameters (eg, temperature, pressure, particle counts, microbial contamination levels) they must be identified and be the subject of appropriate monitoring, alerts, alarms and corrective action, as required, to detect malfunctions and defects, and to ensure that the critical parameters are maintained within acceptable limits at all times. All equipment with critical measuring function must be calibrated against a traceable standard if available.

T25 New, repaired and recommissioned equipment must be tested and validated before use. Test results must be documented.

T26 Maintenance, servicing, cleaning, disinfection and sanitation of all critical equipment and premises must be performed regularly and recorded accordingly.

T27 Procedures for the operation of each piece of critical equipment must be established and these procedures must document the action to be taken in the event of malfunctions or failure.

T28 Sterile instruments and devices must be used for the procurement of gametes and embryos. Instruments or devices must be of good quality, validated or specifically certified and regularly maintained for the procurement of tissues and cells.



## Mandatory requirements (cont)

- T29 When reusable instruments are used, a validated cleaning and sterilisation procedure for removal of infectious agents has to be in place.
- T30 Wherever possible only CE marked medical devices must be used.
- T31 The procedures for licensable activities must detail the specifications for all critical materials and reagents. In particular, specifications for additives (eg, solutions) and packaging materials must be defined. Critical reagents and materials must meet documented requirements and specifications and, when applicable, the requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and Directive 98/79/EC of the European Parliament under the Council of 27 October 1998 on In vitro Diagnostic Medical Devices.



## HFEA guidance

### Scope

- 26.1** For the purpose of this Code of Practice, 'equipment and materials' includes all equipment, disposables, reagents, and calibration and control materials used in the conduct of assisted conception processes.

### Protection and hygiene of staff

- 26.2** The centre should provide proper clothing and equipment for the personal protection and hygiene of staff carrying out licensed activities, together with written instructions for their use.

### Managing equipment and material

- 26.3** The centre should establish documented procedures for managing equipment and materials, including:
- selecting and procuring equipment and materials
  - ensuring the traceability of any products or materials that come into contact with gametes or embryos and that affect their quality and safety, and
  - maintaining inventory information and records for stock control.

See also guidance note:

- [19 – Traceability](#)
- [31 – Record keeping and document control](#)

### Safety of equipment used to store cryopreserved gametes and embryos

- 26.4** All centres storing gametes and embryos should have effective alarms and monitoring systems to ensure the safety of cryopreserved gametes and embryos. These systems should have:
- local alarms (ie, on individual dewars for either temperature or liquid nitrogen level)
  - an auto-dial facility or similar (eg, link to fire-alarm board) to contact staff outside normal working hours
  - adequate staffing and funding to implement formal emergency procedures, including having on-call arrangements, and
  - adequate spare storage space or vessels to enable transfer of samples if a vessel fails.



## HFEA guidance (cont)

See also guidance note:

- [17 – Storage and gametes of embryos](#)



## Other legislation, professional guidelines and information

- Directive 98/79/EC and Directive 93/42/EC can be found at [www.eur-lex.europa.eu/en/index.htm](http://www.eur-lex.europa.eu/en/index.htm)

# 27. Adverse incidents


## This guidance note contains:

### Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Extracts from licence conditions
- Reference to relevant HFEA Directions

### HFEA guidance

- Definitions
- Reporting and timescales ■

 Refer to principle 11

■ Section includes interpretation of mandatory requirements



## Mandatory requirements

### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

#### 17 The person responsible

(1) It shall be the duty of the individual under whose supervision the activities authorised by a licence are carried on (referred to in this Act as the “person responsible”) to secure–

- (g) that the Authority is notified and provided with a report analysing the cause and the ensuing outcome of any serious adverse event or serious adverse reaction.

#### 24 Directions as to particular matters

(13) The Authority may give directions as to the information to be provided to it and any measures to be taken by the person responsible in the event of–

- (a) any occurrence which may adversely influence the quality or safety of gametes or embryos intended for human application
- (b) any adverse incident which may be linked to the quality or safety of gametes or embryos intended for human application, or
- (c) any misidentification or mix-up of gametes or embryos intended for human application.

#### Schedule 3A

#### Supplementary licence conditions: human application

#### Serious adverse events and serious adverse reactions

#### 3 Licence conditions shall require such–

- (a) systems to report, investigate, register and transmit information about serious adverse events and serious adverse reactions, and
- (b) accurate, rapid and verifiable procedures for recalling from distribution any product which may be related to a serious adverse event or serious adverse reaction,

to be in place as are necessary to secure compliance with the requirements of Article 11 (notification of serious adverse events and reactions) of the first Directive and Article 5 (notification of serious adverse reactions) and Article 6 (notification of serious adverse events) of the third Directive.



## Mandatory requirements (cont)

### Licence conditions

- T118 The centre must establish, implement and comply with documented procedures to report, investigate, register and transmit information about serious adverse events and serious adverse reactions that occur on any premises to which a licence relates and any relevant third party premises.
- T119 The documented procedures referred to in licence condition T118 must enable the centre to communicate to the Authority, without delay:
- all relevant available information about suspected serious adverse events and reactions, and
  - the conclusion of the investigation to analyse the cause and ensuing outcome in relation to serious adverse events and reactions.
- T120 The person responsible must notify the Authority of any suspected serious adverse events and serious adverse reactions by providing the information set out below and such other information as the Authority may specify in Directions:
- identification of the centre
  - identification of the premises concerned
  - report identification
  - date of notification, and
  - date of serious adverse event/serious adverse reaction

In relation to serious adverse events the following information is also required:

- an evaluation of the event by activity, (procurement, testing, transport, processing, storage, distribution or other) and specification of the source of error, (defect in gametes or embryos, equipment or material failure or defect), human error or other (to identify preventable causes), to be followed by a conclusion report including items (a) to (e) above.

In relation to serious adverse reaction(s) the following additional information is also required:

- date and place of procurement of gametes or application of gametes or embryos
- unique donation identification number
- date of suspected serious adverse reaction
- details of gametes or embryos involved in the suspected serious adverse reaction, and
- type of suspected serious adverse reaction(s).

- T121 The centre must thereafter notify the Authority of the conclusion of the investigation into the serious adverse event/serious adverse reaction by providing at least the information set out below and any such other information as the Authority may specify in Directions:
- identification of the centre
  - identification of the premises concerned
  - report identification
  - date when the serious adverse event/serious adverse reaction was confirmed
  - date of the serious adverse event/serious adverse reaction, and
  - corrective measures taken.

In relation to serious adverse reaction(s) the following additional information is also required:

- date when the serious adverse reaction was confirmed
- unique donation identification number



## Mandatory requirements (cont)

T121 (cont)

- i. confirmation of the type of reaction(s) or a change in the type of reaction(s),
- j. clinical outcome, if known:
  - i. complete recovery
  - ii. minor sequelae
  - iii. serious sequelae, or
  - iv. death
- k. root cause analysis
- l. outcome of investigation and final conclusions, and
- m. recommendations for preventive and corrective actions.

T122 The centre must ensure that an accurate, rapid and verifiable procedure is in place, which will enable it to recall from distribution any product that may be related to a serious adverse event or reaction.

### Directions

**0011** – Reporting adverse incidents and near misses

For a copy of the relevant Directions visit [www.hfea.gov.uk](http://www.hfea.gov.uk)



## HFEA guidance

### Definitions

**27.1** An 'adverse incident' is any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to patients, their embryos and/or gametes, or to staff or a licensed centre. This includes serious adverse events, serious adverse reactions, breaches of confidentiality, and ovarian hyperstimulation syndrome (OHSS) which requires a hospital admission and has a severity grading of severe or critical.

**27.2** A serious adverse event is defined in the HFE Act 1990 (as amended) as:

'(a) any untoward occurrence which may be associated with the procurement, testing, processing, storage or distribution of gametes or embryos intended for human application and which, in relation to a donor of gametes or a person who receives treatment services or non-medical fertility services–

- (i) might lead to the transmission of a communicable disease, to death, or life-threatening, disabling or incapacitating conditions, or
- (ii) might result in, or prolong, hospitalisation or illness, or

(b) any type of gametes or embryo misidentification or mix-up'.

**27.3** A serious adverse reaction is defined in the HFE Act 1990 (as amended) as:

'an unintended response, including a communicable disease, in a donor of gametes intended for human application or a person who receives treatment services or non-medical fertility services, which may be associated with the procurement or human application of gametes or embryos and which is fatal, life threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or illness'.



- 27.4** A 'near miss' is an occurrence that, but for luck, skill or judgment, would in all probability have become an adverse incident.

### Reporting and timescales



#### Interpretation of mandatory requirements

27A

HFEA Directions require centres to report all adverse incidents and near misses to the HFEA. This includes adverse incidents occurring at third party premises, where there is a third party agreement in force between the centre and that third party.

Centres must report all adverse incidents or near misses to the HFEA by telephone within 12 working hours of their identification. This verbal notification must include the:

- (a) centre's name
- (b) HFEA centre identification number
- (c) contact details of the person responsible
- (d) date of the initial notification or report
- (e) name of any individual affected
- (f) date and time of the adverse incidents and near misses
- (g) details of gametes or embryos involved in the incident, and
- (h) type of incident, including any transmission of infectious agents.

In addition, the centre must inform the HFEA in writing of all adverse incidents or near misses occurring at that centre (or, if the event relates to treatment that involves a third party, at a centre with which it has a third party agreement) by completing an adverse incident form.

The centre must email the completed form to [incident.reporting@hfea.gov.uk](mailto:incident.reporting@hfea.gov.uk) within 24 working hours of discovering the incident.

- 27.5** The centre's documented procedures should ensure that any adverse incident or near miss that may result in harm to the patient, patient's partner or donor is recorded and reviewed.

- 27.6** If an adverse incident or near miss occurs, centres are expected to:

- (a) review relevant procedures to minimise the risk of the incident happening again, and
- (b) inform the HFEA of the revised procedures.

- 27.7** When investigating serious adverse events and reactions, the centre should evaluate all assisted-conception processes directly related to the adverse event, and all relevant processes involving the:

- (a) management of resources
- (b) training and competence of staff
- (c) equipment
- (d) materials
- (e) information systems, and
- (f) control of environment.

A copy of the investigation report should be submitted to the HFEA.



## HFEA guidance (cont)

**27.8** The HFEA also expects centres to report adverse incidents that arise from the use of equipment and materials. Reports of this nature should be sent to the Medicines and Healthcare products Regulatory Agency (MHRA), as the relevant 'competent authority'. An 'adverse incident' in this context is an incident that produces, or has the potential to produce, unwanted effects involving the safety of patients, users and others. This reporting is distinct from, but complementary to, that required by the HFEA.

See also guidance note:

- [26 – Equipment and materials](#)
- [32 – Obligations and reporting requirements of centres](#)

**27.9** The centre should, in line with professional body guidance, inform patients/donors of any adverse incidents that may have resulted in harm to them, their gametes or their embryos.



## Other legislation, professional guidelines and information

- National Patient Safety Agency – Being open: communicating patient safety incidents with patients, their families and carers – [www.nrls.npsa.nhs.uk/resources/?entryid45=65077](http://www.nrls.npsa.nhs.uk/resources/?entryid45=65077)
- NHS Litigation Authority – Apologies and Explanations – [www.nhs.uk/NR/rdonlyres/00F14BA6-0621-4A23-B885-FA18326FF745/0/ApologiesandExplanationsMay1st2009.pdf](http://www.nhs.uk/NR/rdonlyres/00F14BA6-0621-4A23-B885-FA18326FF745/0/ApologiesandExplanationsMay1st2009.pdf)
- General Medical Council – Good Medical Practice – [www.gmc-uk.org/guidance/good\\_medical\\_practice.asp](http://www.gmc-uk.org/guidance/good_medical_practice.asp)
- Nursing and Midwifery Council – The code: standards of conduct, performance and ethics for nurses and midwives – [www.nmc-uk.org/Nurses-and-midwives/The-code/The-code-in-full/](http://www.nmc-uk.org/Nurses-and-midwives/The-code/The-code-in-full/)

# 28. Complaints

This guidance note contains:

## HFEA guidance

- Relevant legislation ■
- Complaints procedure
- The complaints officer and complaints register
- Investigating complaints

➔ Refer to principles 1, 2, 5 and 11

## Other legislation, professional guidelines and information

■ Section includes interpretation of mandatory requirements



## HFEA guidance

### Relevant legislation



#### Interpretation of mandatory requirements

28A

The law requires NHS and private centres to have, and adhere to, a complaints procedure. References to the relevant legislation can be found in the 'Other legislation, professional guidelines and information' box at the end of this guidance note.

### Complaints procedure

- 28.1** The centre should ensure that staff understand the complaints procedure and the right of people to complain.
- 28.2** It may be appropriate to deal with a complaint as soon as it arises, without using a formal complaints procedure. In such cases, staff should deal promptly and thoroughly with issues as they are raised. Staff should treat all complaints seriously and show the complainant due respect, however minor the complaint may appear. Staff should not deter people from making formal complaints if they wish to do so.
- 28.3** The centre should ensure that staff are given appropriate training in complaints handling and that there are written procedures for:
- (a) acknowledging and investigating complaints, and
  - (b) collecting suggestions and compliments.

### The complaints officer and complaints register

- 28.4** The centre should nominate a member of staff to act as complaints officer. The complaints officer should be:
- (a) the first point of contact when a person makes a formal complaint, and
  - (b) responsible for investigating complaints and ensuring the complaints procedure operates effectively.
- 28.5** The centre should display notices prominently to explain the complaints procedure and give the complaints officer's name and contact details. This information should also be given to patients and donors.
- 28.6** The centre should ensure there is someone else of at least equivalent seniority available to deal with complaints in case a person feels unable to complain to the complaints officer.



## HFEA guidance (cont)

- 28.7** The centre's complaints officer should keep an accurate complaints register. For each complaint, the following should be recorded in the register:
- what has been done to resolve the complaint
  - all communication with the complainant (including verbal), and
  - the outcome, and any action taken as a result.
- 28.8** The centre's complaints register should be made available to HFEA inspectors during inspections.

### Investigating complaints

- 28.9** Complaints should be investigated by staff who were not involved in the circumstances that gave rise to the complaint.
- 28.10** If a complainant is unhappy with the outcome of the investigation of their complaint, they should be informed of further action they could take (eg, going to the Health Commissioner in the NHS, the HFEA, or the Ombudsman).
- 28.11** In NHS centres, the complaints procedure should comply with standards required of NHS services. In private centres, the procedures should comply with this Code of Practice and with the standards required by:
- the Care Quality Commission (England)
  - the Care Commission (Scotland)
  - the Care and Social Services Standards Inspectorate Wales (Wales)
  - the Regulation and Quality Improvement Authority (Northern Ireland), or
  - relevant successor bodies.



## Other legislation, professional guidelines and information

The National Health Service (Complaints) Regulations 2004  
Arrangements for the handling and consideration of complaints

The Private and Voluntary Health Care (England) Regulations 2001  
Complaints

Other information you may find helpful:

- Care Quality Commission (England) – [www.cqc.org.uk](http://www.cqc.org.uk)
- Care Commission (Scotland) – [www.carecommission.com](http://www.carecommission.com)
- Care and Social Services Standards Inspectorate Wales (Wales) – [www.new.wales.gov.uk](http://www.new.wales.gov.uk)
- The Regulation and Quality Improvement Authority (Northern Ireland) – [www.rqia.org.uk](http://www.rqia.org.uk)
- Department of Health – National Minimum Standards and Regulations for Independent Health Care – [www.dh.gov.uk](http://www.dh.gov.uk)
- National Health Service (Complaints) Regulations 2004
- The Private and Voluntary Care (England) Regulations 2001
- Copies of the relevant legislation can be found at [www.opsi.gov.uk](http://www.opsi.gov.uk)

# 29. Treating people fairly

## This guidance note contains:

### HFEA guidance

- Relevant legislation
- Treating people fairly
- Conscientious objection ●
- Addressing communication barriers

➔ Refer to principles 1, 2, and 5

### Other legislation, professional guidelines and information

● Section includes mandatory requirements



## HFEA guidance

### Relevant legislation

**29.1** The law protects people (including centre staff, current and prospective patients and donors) from direct and indirect discrimination, harassment and victimisation on the basis of:

- race
- any disability
- gender
- religion or belief
- sexual orientation, and
- age.

The Human Rights Act 1998 is also relevant when considering broader issues of discrimination.

**29.2** The person responsible should have and be familiar with documented procedures to ensure their centre complies with equalities legislation. A list of the relevant legislation is included in the 'Other legislation, professional guidelines and information' section at the end of this guidance note.

### Treating people fairly

**29.3** The centre should ensure that all licensed activities are conducted in a non-discriminatory way and with proper respect for the privacy, confidentiality, dignity, comfort and well being of all prospective and current patients and donors.

**29.4** Attitudes towards the use of gametes and embryos may vary widely among cultures and religions. All healthcare professionals must be sensitive to this. Each case and decision is individual and personal, and must be treated as such. The person responsible should ensure employees are given training and support to help them identify and meet the widest possible range of patients' and donors' needs and wishes.<sup>1</sup>

**29.5** A centre should provide or arrange investigations and treatments based on its clinical judgment and assessment. The needs and priorities of prospective or current patients should be taken into account during this process.

**29.6** Staff at a centre should not refuse or delay treatment because they believe that a patient's actions have contributed to their condition. All prospective and current patients and donors must be treated with respect, whatever their life choices or beliefs.

<sup>1</sup> This guidance is based on a paragraph taken from the Human Tissue Authority's Code of Practice on Consent (2008)



- 29.7** Staff at the centre must not unlawfully discriminate against patients or donors by allowing their personal views<sup>2</sup> to affect adversely the professional relationship with them, or the treatment they provide or arrange. Staff should challenge colleagues if they believe their behaviour does not comply with this guidance, or with the relevant legislative requirements.<sup>3</sup>

### Conscientious objection



#### Mandatory requirements

##### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

##### 38 Conscientious Objection

- (1) No person who has a conscientious objection to participating in any activity governed by this Act shall be under any duty, however arising, to do so.
- (2) In any legal proceedings the burden of proof of conscientious objection shall rest on the person claiming to rely on it.
- (3) In any proceedings before a court in Scotland, a statement on oath by any person to the effect that he has a conscientious objection to participating in a particular activity governed by this Act shall be sufficient evidence of that fact for the purpose of discharging the burden of proof imposed by subsection (2) above.

- 29.8** The centre should give prospective employees a full description of the centre's activities, and at the interview draw their attention to the provision that anyone who has a conscientious objection to participating in a particular activity done in the centre must not be obliged to do so.
- 29.9** A staff member's views about the lifestyle, beliefs, race, gender, age, sexuality, disability or other perceived status of a patient, patient's partner or donor should not affect that individual's treatment or care.
- 29.10** If a staff member has a conscientious objection to providing a particular licensed activity governed by the Act, they should inform the person responsible. The person responsible should ensure that the patient, patient's partner or donor is given information on or referred to alternative sources of the treatment.
- 29.11** The person responsible should satisfy themselves that the staff member has a conscientious objection to providing a particular licensed activity, and is not unlawfully discriminating against a patient on the basis of their race, disability, gender, religion or belief, sexual orientation or age.
- 29.12** If all staff at the centre conscientiously object to providing a particular licensed activity, the person responsible should:
- (a) try to refer the person to another centre for treatment, and
  - (b) provide the patient with a written explanation of why the centre cannot treat them.

The person responsible of an NHS centre should first consider relevant policies of their primary care trust or NHS board (eg, race, disability and gender equality Schemes as required by equalities legislation) before refusing treatment.

- 29.13** The person responsible should record:
- (a) the reason(s) for the conscientious objection of any member of staff
  - (b) their efforts to provide the particular activity at the centre, and
  - (c) if that activity cannot be provided at the centre, efforts they have made to ensure the patient receives treatment elsewhere.

<sup>2</sup> For instance, their views about a patient's age, colour, culture, disability, ethnic or national origin, gender, lifestyle, marital status or parental status, race, religion or beliefs, sexual orientation, or social or economic status.

<sup>3</sup> This guidance is based on a paragraph taken from Good Medical Practice (GMC, 2006).



### Addressing communication barriers

**29.14** The centre should consider the needs of people whose first language is not English and those who face other communication barriers. Where consent is obtained, the centre should record any difficulties in communicating the implications of giving consent and in providing other information to the person (eg, language barriers or hearing impairment) and an explanation of how these difficulties were overcome (eg, the use of an independent interpreter).<sup>4</sup>

See also guidance note:

- **5 – Consent to treatment, storage, donation and disclosure of information**
- **23 – The quality management system**

**29.15** The centre should ensure it establishes and accommodates any disabled patient's or donor's preferred means of communication. If appropriate, it should consider providing information in a variety of formats such as large print, 'easy read' or Braille.

<sup>4</sup> This guidance is based on a paragraph taken from the Human Tissue Authority's Code of Practice on Consent (2008).



## Other legislation, professional guidelines and information

### Relevant requirements in the following legislation:

#### Race

Race Relations Act 1976

Race Relations (Amendment) Act 2000

#### Disability

Disability Discrimination Act 1995

Disability Discrimination Act 2005 (substantially amends the DDA 1995)

#### Gender

Sex Discrimination Act 1975

Equal Pay Act 1975

Gender Recognition Act 2004

Equality Act 2006

#### Religion or belief

Employment Equality (Religion or Belief) Regulations 2003

Equality Act 2006, Part 2

#### Sexual orientation

Employment Equality (Sexual Orientation) Regulations 2003

Equality Act 2006, s81



## Other legislation, professional guidelines and information (cont)

### Age

Employment Equality (Age) Regulations 2003

Equality Act 2006

### Human Rights

Human Rights Act 1998

Equality Act 2006

Copies of all the relevant legislation can be found at [www.opsi.gov.uk](http://www.opsi.gov.uk)

### Other information you may find useful:

- The Equality and Human Rights Commission was established under the Equality Act 2006 to champion equality and human rights for all, and to work to eliminate discrimination. Among other things, its website – [www.equalityhumanrights.com](http://www.equalityhumanrights.com) – provides practical information for businesses to help them meet their obligations, including a summary of relevant law. Case studies illustrate the various forms of discrimination.
- To illustrate discrimination on the grounds of sexual orientation, the Equality and Human Rights Commission uses the example of a couple who are refused fertility treatment because they are lesbians – [www.equalityhumanrights.com/en/yourrights/equalityanddiscrimination/sexualorientation](http://www.equalityhumanrights.com/en/yourrights/equalityanddiscrimination/sexualorientation)
- General Medical Council – Valuing Diversity Guide – [www.gmc-uk.org/publications/valuing\\_diversity/index.asp](http://www.gmc-uk.org/publications/valuing_diversity/index.asp)
- Good Medical Practice guidance – [www.gmc-uk.org/guidance/good\\_medical\\_practice/GMC\\_GMP.pdf](http://www.gmc-uk.org/guidance/good_medical_practice/GMC_GMP.pdf)  
Links to a range of other diversity and equality websites can be found on the site.
- The HFEA's Diversity Strategy outlines the way we intend to promote diversity and a set of action plans in relation to race, disability, gender, sexual orientation, religion or belief, and age. Centres may wish to refer to this when producing or revising their own diversity strategy. It can be found at [www.hfea.gov.uk](http://www.hfea.gov.uk)

# 30. Confidentiality and privacy


## This guidance note contains:

### Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Extracts from licence conditions

### HFEA guidance

- Confidentiality
- Breach of confidentiality
- Access to medical records
- Requests under the Data Protection Act 1998
- Disclosing non-identifying information: general
- Disclosure authorised by statute ■
- Disclosing information to gamete and embryo donors ■
- Disclosing information to recipients of donated gametes and embryos
- Consent to disclose identifying information ■

 Refer to principles 2, 5, 6 and 10

### Other legislation, professional guidelines and information

■ Section includes interpretation of mandatory requirements



## Mandatory requirements

### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

#### 31 Register of information

- (1) The Authority shall keep a register which is to contain any information which falls within subsection (2) and which–
- (a) immediately before the coming into force of section 24 of the Human Fertilisation and Embryology Act 2008, was contained in the register kept under this section by the Authority, or
  - (b) is obtained by the Authority.
- (2) Subject to subsection (3), information falls within this subsection if it relates 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, or
  - (e) the use of an embryo taken from any identifiable woman, or if it shows that any identifiable individual is a relevant individual.



## Mandatory requirements (cont)

- (3) Information does not fall within subsection (2) if it is provided to the Authority for the purposes of any voluntary contact register as defined by section 31ZF(1).
- (4) In this section “relevant individual” means 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.
- 33A Disclosure of information
- (1) No person shall disclose any information falling within section 31(2) which the person obtained (whether before or after the coming into force of section 24 of the Human Fertilisation and Embryology Act 2008) in the person’s capacity as –
- (a) a member or employee of the Authority,
  - (b) any person exercising functions of the Authority by virtue of section 8B or 8C of this Act (including a person exercising such functions by virtue of either of those sections as a member of staff or as an employee),
  - (c) any person engaged by the Authority to provide services to the Authority,
  - (d) any person employed by, or engaged to provide services to, a person mentioned in paragraph (c),
  - (e) a person to whom a licence applies,
  - (f) a person to whom a third party agreement applies, or
  - (g) a person to whom Directions have been given.
- (2) Subsection (1) does not apply where –
- (a) the disclosure is made to a person as a member or employee of the Authority or as a person exercising functions of the Authority as mentioned in subsection (1)(b),
  - (b) the disclosure is made to or by a person falling within subsection (1)(c) for the purpose of the provision of services which that person is engaged to provide to the Authority,
  - (c) the disclosure is made by a person mentioned in subsection (1)(d) for the purpose of enabling a person falling within subsection (1)(c) to provide services which that person is engaged to provide to the Authority,
  - (d) the disclosure is made to a person to whom a licence applies for the purpose of that person’s functions as such,
  - (e) the disclosure is made to a person to whom a third party agreement applies for the purpose of that person’s functions under that agreement,
  - (f) the disclosure is made in pursuance of Directions given by virtue of section 24,
  - (g) the disclosure is made so that no individual can be identified from the information,
  - (h) the disclosure is of information other than identifying donor information and is made with the consent required by section 33B,
  - (i) the disclosure–
    - (i) is made by a person who is satisfied that it is necessary to make the disclosure to avert an imminent danger to the health of an individual (“P”),
    - (ii) is of information falling within section 31(2)(a) which could be disclosed by virtue of paragraph (h) with P’s consent or could be disclosed to P by virtue of subsection (5), and
    - (iii) is made in circumstances where it is not reasonably practicable to obtain P’s consent.



## Mandatory requirements (cont)

- (j) the disclosure is of information which has been lawfully made available to the public before the disclosure is made,
  - (k) the disclosure is made in accordance with sections 31ZA to 31ZE,
  - (l) the disclosure is required or authorised to be made –
    - (i) under regulations made under section 33D, or
    - (ii) in relation to any time before the coming into force of the first regulations under that section, under regulations made under section 251 of the National Health Service Act 2006,
  - (m) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) for the purpose of carrying out the Authority's duties under section 8A,
  - (n) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) in pursuance of an order of a court under section 34 or 35,
  - (o) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) to the Registrar General in pursuance of a request under section 32,
  - (p) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) to any body or person discharging a regulatory function for the purpose of assisting that body or person to carry out that function,
  - (q) the disclosure is made for the purpose of establishing in any proceedings relating to an application for an order under subsection (1) of section 54 of the Human Fertilisation and Embryology Act 2008 whether the condition specified in paragraph (a) or (b) of that subsection is met,
  - (r) the disclosure is made under section 3 of the Access to Health Records Act 1990,
  - (s) the disclosure is made under Article 5 of the Access to Health Records (Northern Ireland) Order 1993, or
  - (t) the disclosure is made necessarily for –
    - (i) the purpose of the investigation of any offence (or suspected offence), or
    - (ii) any purpose preliminary to proceedings, or for the purposes of, or in connection with, any proceedings.
- (3) Subsection (1) does not apply to the disclosure of information in so far as –
- (a) the information identifies a person who, but for sections 27 to 29 of this Act or sections 33 to 47 of the Human Fertilisation and Embryology Act 2008, would or might be a parent of a person who instituted proceedings under section 1A of the Congenital Disabilities (Civil Liability) Act 1976, and
  - (b) the disclosure is made for the purpose of defending such proceedings, or instituting connected proceedings for compensation against that parent.
- (4) Paragraph (t) of subsection (2), so far as relating to disclosure for the purpose of the investigation of an offence or suspected offence, or for any purpose preliminary to, or in connection with proceedings, does not apply–
- (a) to disclosure of identifying donor information, or
  - (b) to disclosure, in circumstances in which subsection (1) of section 34 of this Act applies, of information relevant to the determination of the question mentioned in that subsection, made by any person acting in a capacity mentioned in any of paragraphs (c) to (g) of subsection (1).



## Mandatory requirements (cont)

- (5) Subsection (1) does not apply to the disclosure to any individual of information which–
- (a) falls within subsection (2) of section 31 of this Act by virtue of any of paragraphs (a) to (e) of that subsection, and
  - (b) relates only to that individual or, in the case of an individual who is treated together with, or gives a notice under section 37 or 44 of the Human Fertilisation and Embryology Act 2008 in respect of, another, only to that individual and that other.
- (6) In subsection (2)–
- (i) in paragraph (p) “regulatory function” has the same meaning as in section 32 of the Legislative and Regulatory Reform Act 2006, and
  - (ii) in paragraph (t) references to “proceedings” include any formal procedure for dealing with a complaint.
- (7) In this section “identifying donor information” means information enabling a person to be identified as a person whose gametes were used in accordance with consent given under paragraph 5 of Schedule 3 for the purposes of treatment services or non-medical fertility services in consequence of which an identifiable individual was, or may have been, born.
- 33C Power to provide for additional exceptions from section 33A(1)
- (1) Regulations may provide for additional exceptions from section 33A(1).
- (2) No exception may be made under this section for –
- (a) disclosure of a kind mentioned in paragraph (a) or (b) of subsection (4) of section 33A, or
  - (b) disclosure in circumstances in which section 32 of this Act applies of information having the tendency mentioned in subsection (2) of that section, made by any person acting in a capacity mentioned in any of paragraphs (c) to (g) of subsection (1) of section 33A.
- 34 Disclosure in interests of justice
- (1) Where in any proceedings before a court the question whether a person is or is not the parent of a child by virtue of sections 27 to 29 of this Act or sections 33 to 47 of the Human Fertilisation and Embryology Act 2008 falls to be determined, the court may on the application of any party to the proceedings make an order requiring the Authority–
- (a) to disclose whether or not any information relevant to that question is contained in the register kept in pursuance of section 31 of this Act, and
  - (b) if it is, to disclose so much of it as is specified in the order, but such an order may not require the Authority to disclose any information falling within section 31(2) (c) to (e) of this Act.
- (2) The court must not make an order under subsection (1) above unless it is satisfied that the interests of justice require it to do so, taking into account–
- (a) any representations made by any individual who may be affected by the disclosure, and
  - (b) the welfare of the child, if under 18 years old, and of any other person under that age who may be affected by the disclosure.
- (3) If the proceedings before the court are civil proceedings, it–
- (a) may direct that the whole or any part of the proceedings on the application for an order under subsection (2) above shall be heard in camera, and
  - (b) if it makes such an order, may then or later direct that the whole or any part of any later stage of the proceedings shall be heard in camera.
- (4) An application for a direction under subsection (3) above shall be heard in camera unless the court otherwise directs.



## Mandatory requirements (cont)

- 35 Disclosure in interests of justice: congenital disabilities, etc
- (1) Where for the purpose of instituting proceedings under section 1 of the Congenital Disabilities (Civil Liability) Act 1976 (civil liability to child born disabled) it is necessary to identify a person who would or might be the parent of a child but for the relevant statutory provisions, the court may, on the application of the child, make an order requiring the Authority to disclose any information contained in the register kept in pursuance of section 31 of this Act identifying that person.
- (2) Where, for the purposes of any action for damages in Scotland (including any such action which is likely to be brought) in which the damages claimed consist of or include damages or solatium in respect of personal injury (including any disease and any impairment of physical or mental condition), it is necessary to identify a person who would or might be the parent of a child but for the relevant statutory provisions, the court may, on the application of any party to the action or, if the proceedings have not been commenced, the prospective pursuer, make an order requiring the Authority to disclose any information contained in the register kept in pursuance of section 31 of this Act identifying that person.
- (2A) In subsections (1) and (2) “the relevant statutory provisions” means –
- (a) sections 27 to 29 of this Act, and
  - (b) sections 33 to 47 of the Human Fertilisation and Embryology Act 2008.
- (3) Subsections (2) to (4) of section 34 of this Act apply for the purposes of this section as they apply for the purposes of that.
- (4) After section 4(4) of the Congenital Disabilities (Civil Liability) Act 1976 there is inserted–
- “(4A) In any case where a child carried by a woman as the result of the placing in her of an embryo or of sperm and eggs or her artificial insemination is born disabled, any reference in section 1 of this Act to a parent includes a reference to a person who would be a parent but for sections 27 to 29 of the Human Fertilisation and Embryology Act 1990.”
- 41 Offences
- (5) A person who discloses any information in contravention of section 33A of this Act is guilty of an offence and liable –
- (a) on conviction on indictment, to imprisonment for a term not exceeding two years or a fine or both, and
  - (b) on summary conviction, to imprisonment for a term not exceeding six months or a fine not exceeding the statutory maximum or both.

### Licence conditions

- T43 The centre must ensure that all information is kept confidential and only disclosed in circumstances permitted by law.
- T44 The centre must have processes in place to ensure that access to a centre’s health data and records is secure at all times; conforms with legislative requirements; and is only available to persons named on a centre’s licence or authorised by the Person Responsible. Such processes shall include:
- a. establishing and maintaining data security measures and safeguards against any unauthorised data additions, deletions or modifications to patient/donor files or records, and the transfer of information
  - b. establishing and maintaining procedures to resolve all data discrepancies
  - c. preventing unauthorised disclosure of information whilst guaranteeing the traceability of gamete, embryo or tissue (cell) donations
  - d. considering and responding to applications for access to confidential records and correctly identifying applicants, and
  - e. receiving, checking and arranging authorised access to confidential data and records.



## Mandatory requirements (cont)

T45 Access to registers and data must be restricted to persons authorised by the PR and to the Authority for the purpose of inspection and control measures.



## HFEA guidance

### Confidentiality

- 30.1** The centre should ensure that information provided in confidence, including all information relating to donors, patients and children born as a result of treatment, is kept confidential and disclosed only in the circumstances permitted by law. The centre should ensure that patients, their partners, and donors do not have access to any other person's records without first getting that person's consent.
- 30.2** If the centre is in doubt about whether a proposed disclosure is lawful, it should seek independent legal advice.

### Breach of confidentiality

- 30.3** If confidentiality is breached, the centre should investigate, deal with the breach, and submit a full explanation to the HFEA. If it appears that a criminal offence has been committed, the centre should inform the police.

### Access to medical records

- 30.4** For the purposes of this Code of Practice, a record is defined as information created, received and maintained as evidence by a centre or person, in meeting legal obligations or in transacting business. Records can be in any form or medium provided they are readily accessible, legible and indelible.
- 30.5** The centre must establish a documented procedure for controlling access to medical records. This should ensure that arrangements are in place for:
- (a) properly identifying applicants
  - (b) promptly considering and responding to applications for access to confidential records
  - (c) a designated individual in the centre being responsible for receiving, checking and arranging authorised access to confidential records
  - (d) notifying the Information Commissioner in line with the Data Protection Act 1998
  - (e) giving all individual donors and recipients who provide information about themselves access to their own individual records of that information and an opportunity to correct it
  - (f) ensuring proper procedures are in place to maintain confidentiality when records are stored off site, and
  - (g) ensuring that individuals are aware of their rights under the Data Protection Act 1998 to access their own medical records.

NOTE: When the centre is part of a larger organisation, the appropriate department of the parent organisation may do some of these procedures, where relevant.

- 30.6** The centre should have clear security procedures to prevent unauthorised access to records, and take particular care if records are kept outside the licensed premises (eg, when counselling takes place outside the centre). The security procedures should be appropriate to the record keeping system, whether paper-based, electronic or in any other format.



- 30.7** A person whose medical records are held by the centre is normally entitled to receive a copy of their own medical records, so long as they ask in writing (including by electronic means) and pay any fee required. The source of the information and an explanation of any unusual or technical terms should be given.

See also guidance note:

- [4 – Information to be provided prior to consent](#)
- [31 – Record keeping and document control](#)

### Requests under the Data Protection Act 1998

- 30.8** The centre should comply promptly with ‘subject access requests’ made under the Data Protection Act 1998. Usually, such requests will be for copies of medical records. The centre must check the identity of the person making the request and may also request written consent and proof of identity from the partners of applicants if the medical record contains information relating to them. The centre may also levy a fee of between £10 and £50 for copying medical records.
- 30.9** When proof of identity and payment has been received, the centre has 40 calendar days to respond to the request. The centre should be aware that some requests for information may fall under different information access regimes; they must ensure that they comply within the appropriate timeframes (eg, 20 working days under the Freedom of Information Act 2000 and the Environmental Information Regulations 2004).
- 30.10** The centre should take into account any other exceptions and modifications to the Data Protection Act 1998 before giving access.

### Disclosing non-identifying information: general

- 30.11** The centre may disclose information that does not identify or could not reasonably be expected to lead to the identification of a person owed a duty of confidentiality. If the centre is unsure whether information it proposes to disclose could identify the person, it should seek independent legal advice.

### Disclosure authorised by statute



#### Interpretation of mandatory requirements

30A

A centre may hold information that could lead to the identification of:

- an individual donor or recipient of gametes or embryos
- an individual or couple seeking or receiving treatment services (other than basic partner services), or
- an individual who may have been born as a result of such services or as a result of donated sperm.

The centre may disclose this information only in the specific circumstances set out in the HFE Act 1990 (as amended). The information may, for example, be disclosed:

- to anyone, provided that it is disclosed in such a way that no individual can be identified from it
- to the Authority
- to another licensed centre to enable that centre to carry out its functions under its licence
- to the person to whom the information relates, and to their partner (if they are being treated together, or their partner has served notice of consent to be treated as the legal parent of any resulting child)



### Interpretation of mandatory requirements (cont)

30A

- (e) with the consent of each person who could be identified from the information (although disclosure in this case is limited to information other than that from which a donor of gametes could be identified)
- (f) in connection with specific proceedings, including, for example, in relation to the formal complaints procedure, or
- (g) in an emergency, if disclosure is necessary to avert imminent danger to the health of the person to whom the information relates, and it is not reasonably practicable to obtain their consent to disclosure.

If the centre is in doubt about whether a proposed disclosure is lawful, it should seek independent legal advice.

**30.12** If the centre refers a person seeking treatment to another licensed centre, it should provide relevant information in line with good clinical practice. The centre must always supply information relevant to the welfare of the child.

### Disclosing information to gamete and embryo donors



### Interpretation of mandatory requirements

30B

A donor may request information from a centre about the number, sex and birth year of any children born using their gametes or embryos. If the centre holds that information, it must provide it unless the person responsible considers that special circumstances exist that increase the likelihood of the donor being able to identify any of those children.

Once a person conceived using donor gametes reaches the age of 16, they may ask the Authority to give them certain identifying information about the donor and the number, sex and year of birth of any donor-conceived siblings.

**30.13** The HFEA will seek to inform donors of gametes and embryos that it has received an application by a donor-conceived person for identifying information about them. The HFEA will not give the donor any information about the person making the application.

### Disclosing information to recipients of donated gametes and embryos

**30.14** The centre may give non-identifying information about the donor to those who receive donor-assisted conception treatment and those who have received such treatment in the past.

**30.15** The HFEA may also disclose the information that centres may disclose in these circumstances, if that information is contained on its Register.

**30.16** The centre should:

- (a) reassure donors and potential donors that they may ask at any time how many children have resulted from their donation
- (b) reassure identifiable donors that attempts will be made to contact them before their identity is disclosed to a donor-conceived person
- (c) encourage identifiable donors to provide up-to-date contact details to help this, and
- (d) respond as fully as possible to patients' requests for non-identifying information about the donor(s) used in their treatment.



### Consent to disclose identifying information



#### Interpretation of mandatory requirements

30C

Patients have the right to decide what identifying information should be disclosed and to whom. Centres should obtain a patient's written consent before disclosing information relating to their treatment (or providing gametes for a partner's treatment), or storage of their gametes or embryos.

In addition, consent is needed from any person who could be identified through disclosure of information about a person's treatment or storage of gametes or embryos. For example, consent would be needed from a patient's partner if they could be identified through disclosure of information about the patient's treatment.

If a child born as a result of treatment could be identified, consent must be obtained from the parent(s), unless identification is necessary in disclosing information about the patient's treatment. Once a child born as a result of treatment is considered competent to consent, then their consent (if given) will override the consent of the parent(s).

- 30.17** Before obtaining consent to disclose information, the centre should give the person enough information for them to make a properly informed decision, including:
- precisely what information is to be disclosed
  - the terms on which it is to be disclosed
  - the reasons for disclosure (eg, to keep the person's GP informed about the fertility treatment)
  - the implications of disclosure, in particular the fact that, once it is disclosed, the information will be subject no longer to the special provisions of the HFE Act 1990 (as amended) but only to the general law of confidentiality, and
  - the categories of people to whom the information is to be disclosed.
- 30.18** The centre should seek consent to disclosure to the following categories of people:
- the patient's GP or the patient's partner's GP
  - other healthcare professionals outside the centre (provide the patient or the patient's partner with the best possible medical care)
  - auditors or administrative staff outside of the centre (so they can perform functions designated to them in connection with the centre's licensable activities), and
  - medical or other researchers (so they can contact the patient about specific research projects or carry out non-contact research).
- 30.19** The centre should renew consent to disclosure if the nature of the treatment changes after initial consent has been given (eg, if during treatment, it is proposed that donor gametes are used instead of the patient's own, or if the patient moves from unlicensed to licensed fertility treatment).
- 30.20** The centre should ensure that people to whom they disclose identifying information know that the information remains protected by the existing common law on confidentiality. Those receiving information should also be told:
- the precise terms upon which it was disclosed and for which consent has been given, and
  - that if they disclose the information they have received, a child might learn in an inappropriate way that they were born as a result of fertility treatment.



## HFEA guidance (cont)

See also guidance note:

- **5 – Consent to treatment, storage, donation and disclosure of information**
- **31 – Record keeping and document control**

See also

- **HFEA consent forms available at [www.hfea.gov.uk](http://www.hfea.gov.uk)**



## Other legislation, professional guidelines and information

### Legislation

- Human Rights Act 1998
- European Convention for the Protection of Human Rights and Fundamental Freedoms
- Data Protection Act 1998
- The Data Protection (Subject Access Modification) (Health) Order 2000
- Access to Health Records Act 1990
- Access to Health Records (Northern Ireland) Order 1993

### Professional guidelines

- Care Quality Commission – Code of Practice on confidential personal information (2010) – [www.cqc.org.uk/\\_db/\\_documents/20101216\\_Code\\_of\\_Practice\\_on\\_CPI\\_final.pdf](http://www.cqc.org.uk/_db/_documents/20101216_Code_of_Practice_on_CPI_final.pdf)
- Confidentiality: NHS Code of Practice (2003) – [www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4069253](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4069253)
- Records Management: NHS Code of Practice (2006) – [www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4131747](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4131747)
- General Medical Council – Confidentiality guidance: Protecting information (2004) – [www.gmc-uk.org/guidance/ethical\\_guidance/confidentiality\\_12\\_16\\_protecting\\_information.asp](http://www.gmc-uk.org/guidance/ethical_guidance/confidentiality_12_16_protecting_information.asp)
- Guidance from the Information Commissioner – [www.ico.gov.uk](http://www.ico.gov.uk)

# 31. Record keeping and document control


## This guidance note contains:

### Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Extracts from licence conditions
- Reference to relevant HFEA Directions

### HFEA guidance

- Records to keep
- Definitions
- Document control
- Managing information

 Refer to principle 10



## Mandatory requirements

### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

#### 12 General conditions

(1) The following shall be conditions of every licence granted under this Act–

...(b) that any member or employee of the Authority, on production, if so required, of a document identifying the person as such, shall at all reasonable times be permitted to enter those premises and inspect them (which includes inspecting any equipment or records and observing any activity),...

...(d) that proper records shall be maintained in such form as the Authority may specify in Directions,...

...(g) that the Authority shall be provided, in such form and at such intervals as it may specify in Directions, with such copies of or extracts from the records, or such other information, as the Directions may specify.

(2) Subsection (3) applies to–

(a) every licence under paragraph 1 or 1A of Schedule 2,

(b) every licence under paragraph 2 of that Schedule, so far as authorising the storage of gametes or embryos intended for human application, and

(c) every licence under paragraph 3 of that Schedule, so far as authorising activities in connection with the derivation from embryos of stem cells that are intended for human application.

(3) It shall be a condition of every licence to which this subsection applies that–

(a) such information as is necessary to facilitate the traceability of gametes and embryos, and

(b) any information relating to the quality or safety of gametes or embryos, shall be recorded and provided to the Authority upon request.

#### 13 Conditions of licences for treatment

(2) Such information shall be recorded as the Authority may specify in Directions about the following–

(a) the persons for whom services are provided in pursuance of the licence,

(b) the services provided for them,



## Mandatory requirements (cont)

- (2) (cont)
- (c) the persons whose gametes are kept or used for the purposes of services provided in pursuance of the licence or whose gametes have been used in bringing about the creation of embryos so kept or used,
  - (d) any child appearing to the person responsible to have been born as a result of treatment in pursuance of the licence,
  - (e) any mixing of egg and sperm and any taking of an embryo from a woman or other acquisition of an embryo, and
  - (f) such other matters as the Authority may specify in Directions.
- (3) The records maintained in pursuance of the licence shall include any information recorded in pursuance of subsection (2) above and any consent of a person whose consent is required under Schedule 3 to this Act.
- (4) No information shall be removed from any records maintained in pursuance of the licence before the expiry of such period as may be specified in Directions for records of the class in question.

### Schedule 3B

#### Inspection, entry, search and seizure

##### Inspection of statutory records

- (1) A duly authorised person may require a person to produce for inspection any records which the person is required to keep by, or by virtue of, this Act.
- (2) Where records which a person is so required to keep are stored in any electronic form, the power under sub-paragraph (1) includes power to require the records to be made available for inspection—
- (a) in a visible and legible form, or
  - (b) in a form from which they can be readily produced in a visible and legible form.
- (3) A duly authorised person may inspect and take copies of any records produced for inspection in pursuance of a requirement under this paragraph.

### Licence conditions

- T34 A document control procedure must be established that records the history of document reviews and ensures that only current versions of documents are in use.
- T37 Proper records must be maintained in such form as the Authority may specify in Directions.
- T38 Records must be legible and indelible and may be hand written or transferred to another validated system, such as a computer or microfilm.
- T39 Such information must be recorded as the Authority may specify in Directions about the following:
- a. the persons for whom services are provided in pursuance of the licence,
  - b. the services provided for them
  - c. the persons whose gametes are kept or used for the purpose of services provided in pursuance of the licence or whose gametes have been used in bringing about the creation of embryos so kept or used
  - d. any child appearing to the person responsible to have been born as a result of treatment in pursuance of the licence
  - e. any mixing of egg and sperm and any taking of an embryo from a woman or other acquisition of an embryo, and
  - f. such other matters as the Authority may specify in Directions.



## Mandatory requirements (cont)

- T40 Information must not be removed from any records maintained in pursuance of the licence before the expiry of such period as may be specified in Directions for records of the class in question.
- T41 The Authority must be provided, in such form and at such intervals as it may specify in Directions, with such copies of or extracts from the records, or such other information, as the Directions may specify.
- T42 Where gametes or embryos are supplied to a person to whom another licence applies, that person must be provided with such information as the Authority may specify in Directions.
- T46 For each patient/donor the centre must maintain a record containing:
- patient/donor identification: first name, surname, date of birth, age and sex
  - how, and by whom, the patient/donor has been reliably identified
  - the services provided to them
  - medical history
  - welfare of the child assessment
  - consent, including the purpose or purposes for which their gametes or embryos created using their gametes may be used, and any specific instructions for use and/or disposal, and
  - clinical and laboratory data and the results of any test carried out.
- T47 All records must be clear and readable, protected from unauthorised amendment and retained and readily retrieved in this condition throughout their specified retention period in compliance with data protection legislation.
- T48 Patient/donor records required for full traceability must be kept for a minimum of 30 years (or for such longer period as may be specified in Directions) after clinical use, or the expiry date, in an appropriate archive acceptable to the Authority.

### Directions

- 0001 – Gametes and embryos
- 0003 – Multiple births
- 0005 – Collecting and recording information for the HFEA
- 0007 – Consent
- 0012 – Retention of records

For a copy of the relevant Directions visit [www.hfea.gov.uk](http://www.hfea.gov.uk)



## HFEA guidance

### Records to keep

- 31.1** This guidance note does not summarise all the record keeping requirements of a licensed centre. The person responsible should familiarise themselves with these, which are discussed in the following guidance notes:
- 2 – Staff
  - 3 – Counselling
  - 4 – Information to be provided prior to consent
  - 5 – Consent to treatment, storage, donation, and disclosure of information
  - 6 – Legal parenthood
  - 7 – Multiple births



### 31.1 (cont)

- 8 – Welfare of the child
- 9 – Preimplantation genetic screening (PGS)
- 11 – Donor recruitment, assessment and screening
- 12 – Egg sharing arrangements
- 15 – Procuring, processing and transporting gametes and embryos
- 16 – Imports and exports
- 17 – Storage of gametes and embryos
- 18 – Witnessing and assuring patient and donor identification
- 19 – Traceability
- 21 – Intra-cytoplasmic sperm injection (ICSI)
- 22 – Research and training
- 23 – The quality management system
- 24 – Third party agreements
- 26 – Equipment and materials
- 27 – Adverse incidents
- 28 – Complaints
- 29 – Treating people fairly
- 30 – Confidentiality and privacy
- 32 – Obligations and reporting requirements of centres

### Definitions

- 31.2** A record is defined as ‘information created or received, and maintained as evidence by a centre or person, in meeting legal obligations or in transacting business. Records can be in any form or medium providing they are readily accessible, legible and indelible.’
- 31.3** A documented procedure is defined as ‘a set of written instructions describing the steps in a specific process, including the materials and methods to be used, and the expected end product. This term has the same meaning as standard operating procedures.’

### Document control

- 31.4** The centre should have document control procedures in place to:
- (a) ensure that all documents include:
    - (i) a unique identifier (for instance, the edition, or current revision date or revision number)
    - (ii) page numbers and total number of pages (for example ‘page 3 of 10’)
    - (iii) authority for their issue, and
    - (iv) author identification
  - (b) control all records required to:
    - (i) provide evidence of conforming to legal requirements



### 31.4 (cont)

- (ii) operate the quality management system effectively, and
- (iii) conduct assisted conception processes.

The procedures must cover the identification, collection, indexing, access, storage, maintenance, confidentiality and safe disposal of records.

See also guidance note:

- [23 – The quality management system](#)

**31.5** When a centre's document control system allows documents to be amended by hand pending their re-issue, the procedures and authority for such amendments should be defined; amendments should be clearly marked, initialled and dated; and a revised document should be re-issued as soon as practicable.

**31.6** Documents should be reviewed, revised and reapproved at a frequency that ensures they remain fit for purpose. The maximum interval between reviews should be 12 months.

**31.7** Access to registers and data must be restricted to people authorised by the person responsible and the HFEA for inspection purposes.

See also guidance note:

- [30 – Confidentiality and privacy](#)

## Managing information

**31.8** The centre should establish documented procedures for managing data and information. These should include:

- (a) accurate recording of information
- (b) security of data and safeguards against unauthorised modification, addition, deletion, disclosure or transfer of information
- (c) resolution of data discrepancies
- (d) maintenance and disaster recovery
- (e) storage, archiving and retrieval, and
- (f) secure disposal.

**31.9** If using off-site storage facilities for archived records, the centre should establish procedures to ensure patient confidentiality is maintained. These should include:


- (a) removal of all patient identifying information that might be visible to staff outside the licensed centre, and
- (b) ensuring files are properly sealed when they are being transported between the centre and storage facility.

# 32. Obligations and reporting requirements of centres

This guidance note contains:

## Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Extracts from licence conditions
- Reference to relevant HFEA Directions

 Refer to principle 10, 11 and 13

## HFEA guidance

- Legal obligations toward the HFEA ■
- Requests under the Freedom of Information Act 2000

■ Section includes interpretation of mandatory requirements

## Other legislation, professional guidelines and information



## Mandatory requirements

### Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

#### 12 General conditions

(1) The following shall be conditions of every licence granted under this Act–

... (b) that any member or employee of the Authority, on production, if so required, of a document identifying the person as such, shall at all reasonable times be permitted to enter those premises and inspect them (which includes inspecting any equipment or records and observing any activity)...

(g) that the Authority shall be provided, in such form and at such intervals as it may specify in Directions, with such copies of or extracts from the records, or such other information, as the Directions may specify.

(3) It shall be a condition of every licence to which this subsection applies that–

(a) such information as is necessary to facilitate the traceability of gametes and embryos, and

(b) any information relating to the quality or safety of gametes or embryos, shall be recorded and provided to the Authority upon request.

#### 17 The person responsible

(1) It shall be the duty of the individual under whose supervision the activities authorised by a licence are carried on (referred to in this Act as the “person responsible”) to secure–

... (g) that the Authority is notified and provided with a report analysing the cause and the ensuing outcome of any serious adverse event or serious adverse reaction.

### Schedule 3B Inspection, Entry, Search and Seizure

#### Inspection of statutory records

1 (1) A duly authorised person may require a person to produce for inspection any records which the person is required to keep by, or by virtue of, this Act.

(2) Where records which a person is so required to keep are stored in any electronic form, the power under sub-paragraph (1) includes power to require the records to be made available for inspection–

(a) in a visible and legible form, or



## Mandatory requirements (cont)

(2) (cont)

(b) in a form from which they can be readily produced in a visible and legible form.

(3) A duly authorised person may inspect and take copies of any records produced for inspection in pursuance of a requirement under this paragraph.

### Arranging inspections

2 (1) Where a person—

(a) makes an enquiry to the Authority which concerns the making of a relevant application by that person, or

(b) has made a relevant application to the Authority which the Authority has not yet considered,

the Authority may arrange for a duly authorised person to inspect any of the premises mentioned in sub-paragraph (3).

(2) For the purposes of sub-paragraph (1) a “relevant application” means—

(a) an application for authorisation for a person to carry on an activity governed by this Act which the person is not then authorised to carry on, or

(b) an application for authorisation for a person to carry on any such activity on premises where the person is not then authorised to carry it on.

(3) The premises referred to in sub-paragraph (1) are—

(a) the premises where any activity referred to in sub-paragraph (2) is to be carried on;

(b) any premises that will be relevant third party premises for the purposes of any application.

(4) The power in sub-paragraph (1) is exercisable for purposes of the Authority’s functions in relation to licences and third party agreements.

### Entry and inspection of premises

3 (1) A duly authorised person may at any reasonable time enter and inspect any premises to which a licence relates or relevant third party premises.

(2) The power in sub-paragraph (1) is exercisable for purposes of the Authority’s functions in relation to licences and third party agreements.

4 (1) Subject to sub-paragraph (2), the Authority shall arrange for any premises to which a licence relates to be inspected under paragraph 3 by a duly authorised person at intervals not exceeding two years.

(2) The Authority need not comply with sub-paragraph (1) where the premises in question have been inspected in pursuance of paragraph 2 or 3 at any point within the previous two years.

### Entry and search in connection with suspected offence

5 (1) If a justice of the peace is satisfied on sworn information or, in Northern Ireland, on a complaint on oath that there are reasonable grounds for believing—

(a) that an offence under this Act is being, or has been committed on any premises, and

(b) that any of the conditions in sub-paragraph (2) is met in relation to the premises,

the justice of the peace may by signed warrant authorise a duly authorised person, together with any constables, to enter the premises, if need be by force, and search them.

(2) The conditions referred to are—

(a) that entry to the premises has been, or is likely to be, refused and notice of the intention to apply for a warrant under this paragraph has been given to the occupier;

(b) that the premises are unoccupied;



## Mandatory requirements (cont)

(2)(cont)

- (c) that the occupier is temporarily absent;
- (d) that an application for admission to the premises or the giving of notice of the intention to apply for a warrant under this paragraph would defeat the object of entry.

(3) A warrant under this paragraph shall continue in force until the end of the period of 31 days beginning with the day on which it is issued.

(4) In relation to Scotland–

- (a) any reference in sub-paragraph (1) to a justice of the peace includes any reference to a sheriff, and
- (b) the reference in that sub-paragraph to “on sworn information” is to be read as a reference to “by evidence on oath”.

### Execution of warrants

- 6
- (1) Entry and search under a warrant under paragraph 5 is unlawful if any of sub-paragraphs (2) to (4) and (6) is not complied with.
  - (2) Entry and search shall be at a reasonable time unless the person executing the warrant thinks that the purpose of the search may be frustrated on an entry at a reasonable time.
  - (3) If the occupier of the premises to which the warrant relates is present when the person executing the warrant seeks to enter them, the person executing the warrant shall–
    - (a) produce the warrant to the occupier, and
    - (b) give the occupier–
      - (i) a copy of the warrant, and
      - (ii) an appropriate statement.
  - (4) If the occupier of the premises to which the warrant relates is not present when the person executing the warrant seeks to enter them, but some other person is present who appears to the person executing the warrant to be in charge of the premises, the person executing the warrant shall–
    - (a) produce the warrant to that other person,
    - (b) give that other person–
      - (i) a copy of the warrant, and
      - (ii) an appropriate statement, and
    - (c) leave a copy of the warrant in a prominent place on the premises.
  - (5) In sub-paragraphs (3)(b)(ii) and (4)(b)(ii), the references to an appropriate statement are to a statement in writing containing such information relating to the powers of the person executing the warrant and the rights and obligations of the person to whom the statement is given as may be prescribed by regulations made by the Secretary of State.
  - (6) If the premises to which the warrant relates are unoccupied, the person executing the warrant shall leave a copy of it in a prominent place on the premises.
  - (7) Where the premises in relation to which a warrant under paragraph 5 is executed are unoccupied or the occupier is temporarily absent, the person executing the warrant shall when leaving the premises, leave them as effectively secured as the person found them.



## Mandatory requirements (cont)

### Seizure in the course of inspection or search

- 7
- (1) A duly authorised person entering and inspecting premises under paragraph 3 may seize anything on the premises which the duly authorised person has reasonable grounds to believe may be required for –
    - (a) the purposes of the Authority’s functions relating to the grant, revocation, variation or suspension of licences, or
    - (b) the purpose of taking appropriate control measures in the event of a serious adverse event or serious adverse reaction.
  - (2) A duly authorised person entering or searching premises under a warrant under paragraph 5 may seize anything on the premises which the duly authorised person has reasonable grounds to believe may be required for the purpose of being used in evidence in any proceedings for an offence under this Act.
  - (3) Where a person has power under sub-paragraph (1) or (2) to seize anything, that person may take such steps as appear to be necessary for preserving that thing or preventing interference with it.
  - (4) The power under sub-paragraph (1) or (2) includes power to retain anything seized in exercise of the power for so long as it may be required for the purpose for which it was seized.
  - (5) Where by virtue of sub-paragraph (1) or (2) a person (“P”) seizes anything, P shall leave on the premises from which the thing was seized a statement giving particulars of what P has seized and stating that P has seized it.

### Supplementary provision

- 8
- (1) Power under this Schedule to enter and inspect or search any premises includes power to take such other persons and equipment as the person exercising the power reasonably considers necessary.
  - (2) Power under this Schedule to inspect or search any premises includes, in particular–
    - (a) power to inspect any equipment found on the premises,
    - (b) power to inspect and take copies of any records found on the premises, and
    - (c) in the case of premises to which a licence relates or premises which are relevant third party premises in relation to a licence, power to observe the carrying-on of the licensed activity on the premises.
  - (3) Any power under this Schedule to enter, inspect or search premises includes power to require any person to afford such facilities and assistance with respect to matters under that person’s control as are necessary to enable the power of entry, inspection or search to be exercised.
- 9
- (1) A person’s right to exercise a power under this Schedule is subject to production of evidence of the person’s entitlement to exercise it, if required.
  - (2) As soon as reasonably practicable after having inspected premises in pursuance of arrangements made under paragraph 2 or after having exercised a power under this Schedule to inspect or search premises, the duly authorised person shall–
    - (a) prepare a written report of the inspection, or as the case may be, the inspection and search, and
    - (b) if requested to do so by the appropriate person, give the appropriate person a copy of the report.
  - (3) In sub-paragraph (2), the “appropriate person” means–
    - (a) in relation to premises to which a licence relates, the person responsible, or
    - (b) in relation to any other premises, the occupier.



## Mandatory requirements (cont)

### Enforcement

- 10 A person who–
- (a) fails without reasonable excuse to comply with a requirement under paragraph 1(1) or 8(3), or
  - (b) intentionally obstructs the exercise of any right under this Schedule,
- is guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale.

### Interpretation

- 11 In this Schedule–
- (a) “duly authorised person”, in the context of any provision, means a person authorised by the Authority to act for the purposes of that provision, and
  - (b) “licensed activity”, in relation to a licence, means the activity which the licence authorises to be carried on.

### 35B Fees

- (1) The Authority may charge a fee in respect of any of the following–
- (a) an application for a licence,
  - (b) the grant or renewal of a licence,
  - (c) an application for the revocation or variation of a licence,...

## Licence conditions

- T2 Suitable practices must be used in the course of activities authorised by this licence and in other activities carried out in the course of providing treatment services that do not require a licence.
- T3 Any member or employee of the Authority, on production of a document identifying the person as such, if so required, must at all reasonable times be permitted to enter those premises and inspect them (including inspecting any equipment or records and observing any activity).
- T4 In support of an inspection, the Authority must be provided, within 28 days of a request in writing being made, with such information as specified in the written requests or in Directions.
- T6 When carrying out licensable activities, the centre shall only use those processes which have been expressly authorised by the Authority and published on the HFEA website (as amended from time to time).

## Directions

- 0005** – Collecting and recording information for the HFEA
- 0008** – Information to be submitted to the HFEA as part of the licensing process
- 0011** – Reporting adverse incidents and near misses

For a copy of the relevant Directions visit [www.hfea.gov.uk](http://www.hfea.gov.uk)



### Legal obligations toward the HFEA



#### Interpretation of mandatory requirements

32A

Centres have various legal obligations toward the HFEA. The person responsible should familiarise themselves with these, which include:

- (a) allowing HFEA inspectors to enter centre premises or relevant third party premises at reasonable hours
- (b) allowing HFEA inspectors to inspect centre or relevant third party premises, including inspecting equipment and records, taking away copies of records and other required items, and observing any activity, and
- (c) notifying the HFEA of any new activities or treatment services, before those services or activities are carried out.

The law also requires centres to provide certain information to the HFEA, either on request or at intervals or by deadlines specified in Directions. This includes information relating to:

- (a) the quality or safety of gametes and embryos
- (b) the traceability of gametes and embryos
- (c) adverse incidents and near misses, and
- (d) register information, including:
  - (i) registration information for donors, patients and patients' partners
  - (ii) information on the intention to treat
  - (iii) IVF treatment and embryo creation information
  - (iv) donor insemination information
  - (v) treatment outcome information.

Directions also outline how and when information should be submitted. For example, licensed centres must report using the Electronic Data Interchange (EDI) system unless they are given prior written authority to use a different method.

### Requests under the Freedom of Information Act 2000

- 32.1** The Freedom of Information Act 2000 (FOIA) gives the public the right to access information held by central government, local government and other public organisations. The FOIA is intended to improve openness and accountability to the public. Therefore, any recorded information (eg, on paper, computer file, email, disk, tape or microfiche) submitted to the HFEA may be disclosed under the FOIA. This excludes information covered by the confidentiality provisions of the HFE Act 1990 (as amended). The HFEA will consider arguments from information providers for non-disclosure, but may decide that the information must be disclosed.



### Other legislation, professional guidelines and information

- Department of Health – Records Management: NHS Code of Practice, Parts 1 & 2 – [www.dh.gov.uk/en/Managingyourorganisation/Informationpolicy/Recordsmanagement/index.htm](http://www.dh.gov.uk/en/Managingyourorganisation/Informationpolicy/Recordsmanagement/index.htm)
- Freedom of Information Act 2000
- Environmental Information Regulations 2004, paragraph 5(6)

Copies of the relevant legislation can be found at [www.opsi.gov.uk](http://www.opsi.gov.uk)

# Glossary

**A** **Adverse incident:** Any event, circumstance, activity or action which has caused, or has been identified as potentially causing, harm, loss or damage to patients, their embryos, and/or gametes, or to staff or a licensed centre, including serious adverse events, serious adverse reactions, and ovarian hyperstimulation syndrome (OHSS) which requires a hospital admission and has a severity grading of severe or critical.

**B** **Basic partner treatment services:** Defined in the Human Fertilisation and Embryology Act 1990 (as amended) as:

‘treatment services that are provided for a woman and a man together without using—

- (a) the gametes of any other person, or
- (b) embryos created outside the woman’s body...’

Basic partner treatment services include such treatments as intrauterine insemination (IUI) and gamete intrafallopian transfer (GIFT), using partner gametes.

**C** **Centre:** An establishment licensed by the HFEA. Separate licences from the HFEA are required where the centre maintains premises that are in different buildings. A person who has a third party agreement with the establishment licensed by the HFEA is not included within this definition.

**Centre management:** A group of people (including the person responsible) who direct and control a centre at the highest level.

NOTE: The term ‘centre management’ can be considered equivalent to the term ‘top management’. ‘Top management’ is defined in ISO 9000 as a ‘person or group of people who direct and control an organisation at the highest level’.

**Competence (1):** In the context of staff performance, the demonstrated ability to apply knowledge and skills.

NOTE: The term ‘competence’ can be applied both to an individual and to an organisation. An individual can be competent to perform a particular task and an organisation (such as an assisted conception centre) can be competent to fulfil the expectations of this Code of Practice.

For further information, see the International Organization for Standardization.

**Competence (2):** In the context of consent, the integrity of mental function: the capacity to understand, retain and evaluate information in order to weigh risks and benefits associated with treatment and to arrive at a decision that can be communicated.

- Adults (aged 18 and over) are presumed competent unless a clinical judgment, based on evidence of incapacity, is made to the contrary. Irrational decisions are not sufficient evidence of incompetence.
- Minors (under age 16) are presumed incompetent and the right to consent or refuse treatment is delegated to the parents, unless this contradicts the child’s best interests.
- Mature minors (ages 16 and 17) who are able to demonstrate competence under the same level of scrutiny applied to an adult whose competence is in question may consent to treatment.

**Competent authority:** Defined in the Human Fertilisation and Embryology Act 1990 (as amended) as:

‘...in relation to an EEA state other than the United Kingdom, or in relation to Gibraltar...an authority designated in accordance with the law of that state or territory as responsible for implementing the requirements of the first, second and third Directives’.

**Continual improvement:** A set of activities that an organisation periodically carries out to enhance its ability to meet requirements.

NOTE: These activities in an assisted conception centre involve establishing objectives and quality indicators, and using evaluation techniques including audit, user satisfaction surveys and management review, to find opportunities for improvement through corrective or preventive action.

For further information, see the International Organization for Standardization.

# Glossary

**D** **Data subject:** Defined by the Data Protection Act 1998 as:

‘an individual who is the subject of personal data’.

(‘Personal data’ is defined by the Data Protection Act 1998 as:

‘data which relate to a living individual who can be identified—

(a) from those data, or

(b) from those data and other information which is in the possession of, or is likely to come into the possession of, the data controller...

and includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the individual...’.)

**Directions (General and Special):** The HFEA has the power to issue Directions to centres under the Human Fertilisation and Embryology Act 1990 (as amended). Directions are essentially rules.

Directions can be ‘General’, which apply to all centres, or ‘Special’, which apply to particular licensed centres.

If a centre fails to comply with Directions, this would amount to a breach of a statutory licence condition. It might lead to the variation, suspension or revocation of a centre’s licence.

General Directions are normally sent to clinics by the Chair of the Authority, with a letter that explains the reasoning behind issuing the Directions.

**Distribution:** Transport of reproductive tissues intended for human application.

**Documented procedure:** A set of written instructions describing the steps in a specific process, including the materials and methods to be used, and the expected end product. This term has the same meaning as ‘standard operating procedures’.

**Donor:** A person who consents to their gametes or embryos being used in the treatment of others, or for research purposes. Although donors are the genetic parents of children created using their gametes, they are not their legal parents if the treatment is provided in a licensed centre in the UK.

**Donor-conceived person:** A person born as a result of fertility treatment using donor gametes or embryos.

**E** **Egg provider:** A person who provides eggs for the treatment of another.

**Egg sharing arrangement:** When a woman who is having fertility treatment donates some of her eggs in return for discounted treatment services.

**Egg recipient:** A person who receives eggs donated by another woman.

**European Tissue and Cells Directives (‘the Directives’, ‘EUTCD’):** These comprise:

(a) Directive 2004/23/EC (the first Directive) on setting the standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

(b) Directive 2006/17/EC (the second Directive) implementing Directive 2004/23/EC as regards certain technical requirements for the donation, procurement and testing of human tissues and cells

(c) Directive 2006/86/EC (the third Directive) implementing Directive 2004/23/EC as regards traceability requirements, notification of serious adverse reactions and events, and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.

# Glossary

**E** **Evaluation:** Processes that assess to what extent specified requirements or expectations have been fulfilled.

NOTE 1: The 'processes' may include assessment of user satisfaction, monitoring and resolution of complaints, staff suggestions, internal audit of the quality management system and assisted conception processes, participation in inter-centre comparisons and external reviews.

NOTE 2: The 'requirements and expectations' include those set out in this Code of Practice, and those specified by management to ensure that the clinical requirements and interests of the people at the centre are met.

**External review:** Part of the review of the centre's quality management system. It refers to reviews of the centre by external parties.

**Equipment and materials:** All equipment, disposables, reagents, and calibration and control materials used in the conduct of assisted conception processes.

**F** **Female partner (in the context of guidance note 6 – Legal parenthood):** Refers to any woman who:

- intends to be the parent of any child born from treatment, and
- is not in a civil partnership with, or within a prohibited degree of relationship to, the woman being treated (as defined in paragraph 58(2), part 2, Human Fertilisation and Embryology Act 2008).

**FISH (fluorescence in situ hybridisation) :** A technique used to detect the presence or absence of specific DNA sequences on chromosomes.

**G** **Genetic counselling:** The process by which patients or relatives at risk of an inherited disorder are advised of the consequences and nature of the disorder, the probability of developing or transmitting it, and the options open to them.

**Gradient method:** A method of sex selection where sperm is placed in a centrifuge that can separate sperm carrying the X and sperm carrying the Y chromosome. There are concerns about the reliability of this technique.

**I** **Identifying information and non-identifying information:** Identifying information allows an individual to be identified, or could lead to their identification (for example, name, date of birth or address). Non-identifying information could not lead to that individual's identification (for example, hair colour or ethnicity).

**Internal audit:** A process of review and assessment to verify that all processes in a centre conform to the requirements of the quality management system. The audit should consider the effectiveness of the processes, identifying and correcting problems and areas of risk.

**Introductory agencies:** Organisations set up to facilitate contact between gamete donors and recipients.

**L** **Licensed activity:** Any activity that requires a licence from the HFEA, as stated in the Human Fertilisation and Embryology Act 1990 (as amended).

**Licence holder:** It is currently the case in many centres that the individual who is the licence holder is also the person responsible. Either the person responsible or the licence holder may apply for a licence or for its variation or revocation. However, only the licence holder may apply to the HFEA to vary a licence in order to designate another individual as the person responsible.

**M** **Male partner (in the context of guidance note 6 – Legal parenthood):** Refers to any man who:

- intends to be the legal father of any child born from treatment, and
- is not married to, or within a prohibited degree of relationship to, the woman being treated (as defined in paragraph 58(2), part 2, HFE Act 2008).

# Glossary

**N** **Near miss:** Any occurrence that, but for luck, skill or judgment, would in all probability have become an adverse incident.

**Non-conformity:** Failure to fulfil a requirement or expectation of this Code of Practice, or of the centre's own standards.

NOTE: In the context of a centre, any failure to protect the quality and safety of gametes or embryos during donation, procurement, testing, processing, preservation, storage and distribution would be regarded as a major 'non-conformity' requiring immediate investigation and corrective action.

For further information, see the International Organization for Standardization.

**Non-medical fertility services:** The Human Fertilisation and Embryology Act 1990 (as amended) defines non-medical fertility services as:

'any services that are provided, in the course of a business, for the purpose of assisting women to carry children, but are not medical, surgical or obstetric services'.

**P** **Parental order:** An order made under sections 54 and 55 of the Human Fertilisation and Embryology Act 2008.

**Patient:** A person who is receiving treatment services involving the use of gametes or embryos. Also, a person whose gametes or embryos are stored.

**Person responsible (PR):** A person defined in law by the Human Fertilisation and Embryology Act 1990 (as amended). Activities licensed by the HFEA must take place only under the supervision of the person responsible. The person responsible is ultimately responsible for ensuring that all licensed activities are conducted with proper regard for the regulatory framework governing treatment and research involving gametes or embryos within the UK.

**Person Responsible Entry Programme (PREP):** A programme of assessment defined by the HFEA, which a person must complete before being confirmed as person responsible for a centre.

**Premises:** The specific area where a centre conducts its business, as identified on a floor plan submitted by the centre to the HFEA.

**Primary centre (and secondary centre):** These terms are used when referring to satellite and transport in vitro fertilisation (IVF). The primary centre is the licensed centre. The secondary centre is the centre where satellite or transport IVF takes place.

These terms are also used when referring to donor gametes and embryos. In this context, the primary centre is the centre that has recruited the donor. The secondary centre is the centre to which that donor's gametes or embryos have been sent.

**Processing:** All operations involved in preparing, manipulating, preserving and packaging gametes or embryos intended for human application.

**Process:** A set of interrelating or interacting activities that transforms inputs to outputs.

For further information, see the International Organization for Standardization.

**Procurement:** The process by which gametes or embryos are made available.

# Glossary

**Q** **Quality management review:** A review, done at least annually, of all of the services that a centre provides, identifying any need for change and opportunities for improvement.

**Quality management system:** The organisational structure, defined responsibilities, procedures, processes and resources for implementing quality management (ie, the co-ordinated activities to direct and control an organisation with regard to quality), including all activities that contribute to quality, directly or indirectly.

NOTE: This definition indicates that every process and activity that takes place in the centre is an integral part of the quality management system.

For further information, see the International Organization for Standardization.

**Quality policy:** The overall intentions and direction of an organisation with regard to quality, as formally expressed by centre management.

NOTE: A quality policy defines or describes an organisation's intentions and commitment to quality and provides a framework for setting objectives and planning for quality.

For further information, see the International Organization for Standardization.

**Quality objectives:** Documented goals framed in line with the quality policy, and with the clinical requirements and interests of patients, their partners, and donors.

**Quality manager:** The individual in the centre who:

- is responsible for ensuring that the quality management system is implemented and maintained
- reports to centre management on its functioning and effectiveness, and
- co-ordinates awareness of the clinical requirements and interests of patients, their partners and donors.

**R** **Record:** Information created or received, and maintained as evidence by a centre or person in meeting legal obligations or in transacting business. Records can be in any form or medium provided they are readily accessible, legible and indelible.

**Requirement:** Specification, direction or constraint prescribed in relevant legislation, or by the HFEA in line with a power conferred by relevant legislation, eg as a condition of a centre's licence.

NOTE: Failure to comply with a requirement may be grounds for the variation or revocation of a centre's licence or, in certain cases, a criminal offence.

For further information, see the International Organization for Standardization.

**S** **Serious adverse event:** Defined in the Human Fertilisation and Embryology Act 1990 (as amended) as:

- '(a) any untoward occurrence which may be associated with the procurement, testing, processing, storage or distribution of gametes or embryos intended for human application and which, in relation to a donor of gametes or a person who receives treatment services or non-medical fertility services—
  - i) might lead to the transmission of a communicable disease, to death, or life-threatening, disabling or incapacitating conditions, or
  - ii) might result in, or prolong, hospitalisation or illness, or
- (b) any type of gametes or embryo misidentification or mix-up'.

# Glossary

**S** **Serious adverse reaction:** Defined in the Human Fertilisation and Embryology Act 1990 (as amended) as:

‘an unintended response, including a communicable disease, in a donor of gametes intended for human application or a person who receives treatment services or non-medical fertility services, which may be associated with the procurement or human application of gametes or embryos and which is fatal, life threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or illness’.

**Satellite IVF:** When the assessment, drug therapy and monitoring take place at the secondary (satellite) centre, but the egg retrieval, embryology and embryo replacement are all carried out at the primary (licensed) centre.

**T** **Third party:** Defined in the Human Fertilisation and Embryology Act 1990 (as amended) as:

‘a person with whom a person who holds a licence has a third party agreement’.

**Third party agreement:** Defined in the Human Fertilisation and Embryology Act 1990 (as amended) as follows:

‘an agreement in writing between a person who holds a licence and another person which is made in accordance with any licence conditions imposed by the Authority for the purpose of securing compliance with the requirements of Article 24 of the first Directive (relations between tissue establishments and third parties) and under which the other person:

- (a) procures, tests or processes gametes or embryos (or both) on behalf of the holder of the licence, or
- (b) supplies to the holder of the licence goods or services (including distribution services) which may affect the quality and safety of gametes or embryos’.

**Traceability:** Defined in the Human Fertilisation and Embryology Act 1990 (as amended) as the ability:

- ‘(a) to identify and locate gametes and embryos during any step from procurement to use for human application or disposal;
- (b) to identify the donor and recipient of particular gametes or embryos;
- (c) to identify any person who has carried out any activity in relation to particular gametes or embryos; and
- (d) to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety’.

**Transport IVF:** When the assessment, drug therapy, monitoring, and procurement of sperm or eggs (or both) take place at the secondary centre, but the embryology and embryo replacement take place at the primary centre.

**U** **User satisfaction:** A measure of whether the centre has met patients’ and donors’ interests and clinical requirements.

**V** **Validation:** Establishing documented evidence that provides a high degree of assurance that a specific process, procedure, piece of equipment or environment will consistently produce an outcome that meets specified expectations. A process is validated to evaluate the performance of a system in terms of its effectiveness based on intended use.

For further information, see the International Organization for Standardization.

**Verification:** Confirmation, through the provision of objective evidence, that specified requirements or expectations have been fulfilled.

NOTE: For example, the term ‘verification’ is used in the context of the centre receiving reproductive tissue to mean that the reproductive tissue and the accompanying documentation are as specified.

For further information, see the International Organization for Standardization.

## How does the index work?

The index will help you find the relevant guidance, licence conditions and HFEA interpretation of mandatory requirements. The extracts from the HFE Act are not indexed.

Each paragraph of guidance is numbered to indicate the guidance note in which it belongs, and where it appears in that note (eg, paragraph 2.5 is the fifth paragraph in guidance note 2 – Staff).

The interpretation boxes are identified by a number and letter in the top right-hand corner. The number relates to the relevant guidance note, and the letter to the order of the interpretation box within that note (eg, 14B is the second interpretation box in guidance note 14 – Surrogacy).

The licence conditions are identified by a letter and a number denoting the licence condition, followed by, in brackets, the guidance note in which that licence condition appears (eg, T48(31) is licence condition T48, which appears in guidance note 31 – Record keeping and document control).

Abbreviations

PGD - preimplantation genetic diagnosis

RFID - radio frequency identification

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