


4. Information to be provided prior to consent

This guidance note contains:

 Refer to principle 5

Mandatory requirements

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

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

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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



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
- For further information on multiple births, please go to the One at a Time website at – www.oneatatime.org.uk