

# 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.