

# 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

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.