

## DIRECTIONS GIVEN UNDER THE HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

### Directions on records

Ref. **D 2006/6**

These Directions are:	General Directions
Section of the Act providing for these Directions:	Section 12 (d) (g), 13 (2), 14(1) (d), 15(2) and 24(2)
These Directions take effect on:	1 January 2007
These Directions remain in force:	Until revoked

1. These Directions relate to any activities referred to which occur on or after **1<sup>st</sup> January 2007**. Directions D1999/1 as modified by Directions 2004/3 remain in force only in relation to any activities carried out using paper forms before 1<sup>st</sup> January 2007 and are otherwise revoked.
2. It is the duty of all Persons Responsible at licensed centres to ensure that the duties under Section 17(1) of the Human Fertilisation & Embryology Act 1990 (“the 1990 Act”) are complied with in relation to all patient records, whether manually or electronically held. Persons Responsible will ensure that the duty of confidentiality under Section 33(5) of the 1990 Act is maintained in relation to those records. In particular, Persons Responsible will ensure that no information falling within Section 31(2) of the 1990 Act will be disclosed other than in accordance with one or more of the exemptions set out in Section 33(6) of the 1990 Act, as amended.
3. The records referred to in paragraph 4 below (“records”) are to be created, kept and submitted by licensed centres to the Human Fertilisation & Embryology Authority (“the Authority”) in accordance with the following instructions:-
  - (i) Licensed centres must use the Authority’s Electronic Data Interchange (EDI) system to create, store and submit records to the Authority **unless** the licensed centre concerned has been issued by the HFEA with prior written authority allowing a different method of record submission. Where

a Centre intends to use an alternative electronic system which integrates with the HFEA EDI interface:-

- a) The electronic system facilitating the creation, submission and amendment of records must present data in an identical format to that created by the Authority's EDI system; and
- b) The Authority must have agreed with the licensed centre a system specification, tested the delivered system and agreed for it to go live; and
- c) The licensed centre undertakes to maintain compliance with that specification, any subsequent edition of it and any minimum performance standards contained therein; and
- d) The licensed centre undertakes to provide expert resource to support and develop the linked systems in response to developments of the Authority's EDI system.

(ii) Licensed centres will follow any current instructions for electronic submission of records issued from time to time by the Authority, including but not limited to:-

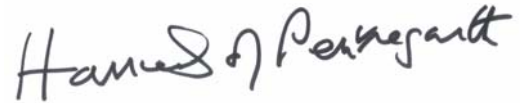
- the creation of records;
- their submission to the Authority;
- their amendment and correction;
- their security and backup.

4. Licensed centres will submit to the Authority within the timescales listed below the following information:-

- (i) **Patient & Partner Registration Details** - records to be submitted within 5 days of being known by the licensed centre.
- (ii) **Donor Information (Registration)** - records to be submitted within 5 days of being known by the licensed centre.
- (iii) **IVF Treatment & Embryo Creation and Use** - records to be submitted within 2 months of the embryo transfer date (to allow for early outcome reporting).
- (iv) **Donor Insemination Treatment** - records to be submitted within 2 months of the treatment cycle last date (allowing for early outcome reporting)

- (v) **Pregnancy Outcome** - records to be submitted within 2 months of the expected outcome date (and within 11 months of the treatment date)

Treatment records for new patients and partners must be preceded by the relevant registration records.

A handwritten signature in black ink, reading "Harries of Pentregarth". The signature is written in a cursive style with a large initial 'H'.

Date:  
29 September 2006

Lord Harries of Pentregarth  
**Interim Chair**