

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

### Directions on Register submissions from centres

Ref. **D 2007/7**


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 October 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> October 2007**. On this date, all previous Directions relating to the submission of information to the HFEA Register are revoked and replaced. **These Directions mandate the use of the revised dataset for submission (form versions starting with 2007), and the subsequent change in submission deadlines resulting from the separation of treatment and early pregnancy outcome reporting.**
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 Registration Details** - Records to be submitted within 5 working days of the patient being accepted for treatment and prior to the reporting of an Intention To Treat or full treatment record.
  - (ii) **Partner Registration Details** - Records to be submitted within 5 working days of the patient being accepted for treatment and prior to the reporting of an Intention To Treat or full treatment record.
  - (iii) **Intention To Treat** - Records to be submitted within 3 **calendar** days of stimulatory drugs being administered to/taken by a patient with the intention to perform IVF treatment. For natural (un-stimulated) IVF treatment cycles, the date of the patient's last menstrual cycle should be supplied.
  - (iv) **Donor Information (Registration)** - Records to be submitted within 5 working days of being known by the licensed centre.
  - (v) **IVF Treatment & Embryo Creation and Use** - Records to be submitted within 5 working days of the treatment cycle completion date.

- (vi) **Donor Insemination Treatment** - Records to be submitted within 5 working days of the treatment cycle completion date.
- (vii) **EARLY Pregnancy Outcome** - Records to be submitted within 2 months of the treatment cycle completion date.
- (viii) **Pregnancy Outcome** - Records to be submitted within 2 months of the likely outcome date (and within 11 months of the treatment date)

Records (iii) to (vii) above must be preceded by the relevant registration forms (Records (i) and (ii) above).



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**Shirley Harrison**  
**Chair**  
**Date: 7<sup>th</sup> May 2007**