

**Direction D2007/1**

2<sup>nd</sup> February 2006

Dear Colleague

**General Directions on reporting Intention To perform IVF Treatment (ITT)**

The Authority has approved the issue of new general directions on reporting Intention To perform IVF Treatment which come into force on April 1, 2007. From this date, a small transaction (as detailed in the Direction) should be submitted through EDI within 3 calendar days of a stimulatory drug being administered to a patient with the intention of performing IVF treatment. In circumstances where EDI is temporarily not working at a clinic, the details should be sent to the HFEA via facsimile.

The information will be analysed to identify cancelled cycles and conversions to alternative treatment types.

Should you have any queries in relation to these directions or should you wish to discuss a variation or exception for your licensed centre, please contact your QA Officer at the HFEA.



Shirley Harrison  
Chair of the HFEA

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

**DIRECTIONS ON RECORDS**

**Ref. D 2007/1**

These Directions are	General Directions
Section of the Act providing for these Directions	Section 12 (d) and (g), 13 (2), 14(1) (d), 15(2) and 24(2)
These Directions take effect on:	1 April 2007 or 30 June 2007 *
These Directions remain in force:	Until revoked

1. These Directions relate to any activities referred to herein which occur on or after **1<sup>st</sup> April 2007**. These Directions supplement Directions Ref. D2006/6, which remain in force as modified and added to by these Direction.
2. It is the duty of all Persons Responsible at licensed centres to secure that the duties under Section 17(1) of the Human Fertilisation and Embryology Act 1990 (“ the 1990 Act”) are complied with in relation to all patient records, whether manually or electronically held. Persons Responsible will secure 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. Intention To Treat (perform IVF Treatment)

This process will be used to identify cancelled cycles and conversions to alternative types of licensed treatment.

The following minimal information will be collected through EDI from all UK Centres within 3 calendar days of stimulatory drugs being administered to/taken by a patient with the intention to perform IVF treatment. For natural (unstimulated) IVF treatment cycles, the date of the patient’s last menstrual period should be supplied:-

- Centre number        }
- Form number         } These fields are completed automatically by the software
- Transaction date     }

- Patient ID
- Patient surname
- Date of drug administration

Those centres using HFEA EDI application which is integrated with an Electronic Patient Record (EPR) system (as opposed to standalone EDI) may have an additional period of time to introduce the new process whilst the software is being developed/upgraded. Special exemption shall be provided to those centres up to 30 June 2007 \* after which time all centres must comply with these Directions.

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

- (i) **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 (unstimulated) IVF treatment cycles, the date of the patient's last menstrual cycle should be supplied.
- (ii) **Patient & Partner Registration Details** - Records to be submitted within 5 days of being known by the licensed centre.
- (iii) **Donor Information (Registration)** - Records to be submitted within 5 days of being known by the licensed centre.
- (iv) **IVF Treatment & Embryo Creation and Use** - Records to be submitted within 2 months of the embryo transfer date (to allow for early outcome reporting) or within 3 days of the index date (egg collection/embryo creation).
- (v) **Donor Insemination Treatment** - Records to be submitted within 2 months of the treatment cycle last date (allowing for early outcome reporting)
- (vi) **Pregnancy Outcome** - Records to be submitted within 2 months of likely outcome date (and within 11 months of the treatment date)

Records (iv) to (vi) above must be preceded or accompanied by the relevant registration forms (Records (i), (ii) and (iii) above).

*Shirley Harrison*

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**Shirley Harrison**  
**Chair**  
**Date:02.02.2007**