

Directions given under the Human Fertilisation and Embryology Act 1990 as amended

Collecting and recording information for the Human Fertilisation Embryology Authority

Ref: 0005
Version: 2

These Directions are:	GENERAL DIRECTIONS
Sections of the Act providing for these Directions:	Section 12 (1) (d) and (g)
These Directions come into force on:	1 October 2009
These Directions remain in force:	Until revoked
This version issued on:	1 May 2010

1. All licensed centres undertaking licensed treatments, with the exception of IUI and GIFT using partner sperm, must use the Authority's Electronic Data Interchange (EDI) to submit records relating to such activities to the Authority.
2. All licensed centres must use the following EDI forms to submit their records to the Authority:

Type of form	Purpose of form
Patient registration	To provide details of the patient receiving fertility treatment.
Partner registration	To provide details of the partner of the patient receiving fertility treatment.
Donor information	To provide identifiable details of a donor and the reasons why they are donating Licensed centres must use Donor Information form D v. 2009 to record information relating to donors and ensure that sections 1 to 20 are completed for each donor. Patients providing gametes for a surrogacy arrangement must be registered as donors, therefore Donor Information forms must be completed for them.
Donor re-registration (also known as a B form)	This form enables a previously anonymous donor to register as identifiable on the HFEA register
Intention to treat	To inform the HFEA when a cycle in which eggs are to be collected has started
IVF treatment & embryo creation and use	To inform the HFEA about the circumstances surrounding egg collection, embryo creation and /or transfer
Donor insemination treatment	To inform the HFEA when a patient has

	been inseminated with donor sperm
Early pregnancy outcome	To inform the HFEA of the early outcome of a treatment
Pregnancy outcome	To inform the HFEA of the outcome of any early outcome recording 'fetal pulsation seen'
Donor sperm procurement	To inform the HFEA about the quantity of sperm donated by each donor
Embryo and gamete movement - in	To inform the HFEA about the number of embryos, eggs and ampoules, straws or vials of donor sperm transferred from another UK centre or imported from outside the UK
Embryo and gamete movement - out	To inform the HFEA of the number of embryos, eggs and ampoules, straws or vials of donor sperm removed from storage at a centre and the reason for the removal
Consent Variation	To inform the HFEA of a patient's or partner's variation of their preferences set out in the 'Consent to the disclosure of identifying information form' (CD form); to inform the HFEA of the initial completion of the CD form by a patient or partner registered for treatment prior to 1 October 2009; to inform the HFEA of preferences regarding the disclosure of information about children born as a consequence of treatment

3. All licensed centres must submit the relevant EDI forms to the Authority within the following timescales:

Category of information	Timescale for records to be submitted to the Authority
Patient registration details	5 working days after the patient has confirmed intention to undergo treatment
Partner registration details	5 working days after the patient has confirmed intention to undergo treatment
Intention to treat	3 calendar days after last menstrual period or stimulatory drugs being administered to/taken by a patient with the intention to perform IVF treatment
Donor information	5 working days after confirmation of sperm being released for use by the clinic, the harvesting of oocytes or in the case of imports, receipt of the imported eggs, sperm or embryos
IVF treatment & embryo creation and use	5 working days after the treatment cycle completion date
Donor insemination treatment	5 working days after the last

	insemination of the cycle
Early pregnancy outcome	8 weeks after the treatment cycle completion date
Pregnancy outcome	8 weeks after the predicted outcome date
Embryo and gamete movement - in	Within 5 working days of gametes or embryos coming into storage
Embryo and gamete movement - out	Within 5 working days of gametes or embryos being removed from storage
Consent variation	5 working days after the patient has completed the CD form

4. All licensed centres must ensure that EDI forms submitted to the Authority are completed according to the guidance issued by the Authority (the most recent versions of which are available, alongside the forms, on the HFEA website). Where an error is identified, centres must correct the error within 2 calendar months.
5. Any licensed centre wishing to amend records that it has previously submitted to the Authority must do so via EDI on a “correcting form”. This must be the same as the original form supplied to the Authority, but must be clearly marked as a correcting form, and must reference the number of the original form that is to be corrected.
6. Licensed centres must notify the HFEA within 5 working days of any change to the patient or partner consent decision in relation to disclosure of HFEA Register information for research purposes. To do so, for patients registered after 1 October 2009 the centre must amend previously submitted Patient registration or Partner registration forms via EDI on a “correcting form”. This must be the same as the original form supplied to the Authority, but must be clearly marked as a correcting form, and must reference the number of the original form that is to be corrected. For patients registered before 1 October 2009 the centre must submit a Consent Variation form.
7. Where a licensed centre has submitted duplicate forms, that clinic must submit a deletion request to the Authority via the EDI system, clearly referencing the form to be deleted and stating the reasons for the request.
8. When a Person Responsible is satisfied with the accuracy of the data for their licensed centre, they must sign off this data. To do this, the Person Responsible must sign and date a hard copy of the draft ‘Choose a Clinic’ entry and return it to the Authority no later than 5pm on the date notified to the centres by the Authority (the sign-off deadline). The draft entry can be returned by post, fax or by email with a scanned image of the signed document.
9. Persons Responsible must ensure that, before they sign off their data, they are satisfied that:

a) the number of treatment cycles (both generic IVF and DI) completed within the reporting period is 100% accurate;

(b) all early outcome forms relating to cycles in a) above and all outcome forms relating to clinical pregnancies in a) above have been submitted to the Authority and have been filled in accurately; and

(c) all registration forms relating to patients undergoing treatment received in a) above have been submitted to the Authority and have been filled in accurately.

Other Submissions

10. All licensed centres undertaking Intra Uterine Insemination (IUI) or Gamete Intra-Fallopian Transfer (GIFT) with partner sperm must submit an annual return to the Authority no later than 28 February in each calendar year. The annual return must be in the format set out. Guidance is available on the HFEA website at <http://www.hfea.gov.uk/2508.html>
11. Sections 21 to 27 of the Donor Information form must be submitted to the HFEA in paper format with the donor code and the centre's code referenced.

Signature



Gemma Hobcraft
Deputy Chair of Compliance Committee

Date 28/4/10

Deputy Chair of the Compliance Committee in accordance with delegated powers granted by the Human Fertilisation and Embryology Authority on 17 December 2008.

Version control	
Directions name:	Collecting and recording information for the Human Fertilisation Embryology Authority
Reference number:	0005
Date version 1 issued:	1 October 2009
Date version 2 issued:	1 May 2010
Chair's letter reference:	CH(10)05