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

Collecting and recording information for the Human Fertilisation and Embryology Authority

Ref: 0005
Version: 4

These Directions are:	General Directions
Sections of the Act providing for these Directions:	Sections 12(1)(d) and 12(1)(g)
These Directions come into force on:	1 October 2009
These Directions remain in force:	Until revoked
This version was issued on:	29 October 2015

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 to record information relating to donors and ensure that sections 1-20 are completed for each donor Sections 21 to 27 of the Donor Information form (pages 3-4) must be submitted to the HFEA in paper format with the donor code and the centre's code referenced Intended parents supplying gametes in a surrogacy

	arrangement are to be registered with the IP prefix to their donor code. When registering an intended parent as a donor, pages 3-4 of the donor form are not required by the HFEA
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, and 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	10 working days after the patient has confirmed intention to undergo treatment
Partner registration details	10 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	10 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	10 working days after the treatment cycle completion date
Donor insemination treatment	10 working days after the last insemination of the cycle
Early pregnancy outcome	8 weeks after the treatment cycle completion date
Pregnancy outcome	14 weeks after the predicted outcome date
Embryo and gamete movement – in	Within 10 working days of gametes or embryos coming into storage
Embryo and gamete movement – out	Within 10 working days of gametes or embryos being removed from storage
Consent variation	10 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 10 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 www.hfea.gov.uk/2508.html

11. All licensed centres undertaking maternal spindle transfer (MST) and/or pronuclear transfer (PNT) must use the following paper or EDI forms to submit their records to the Authority within the following timescales:

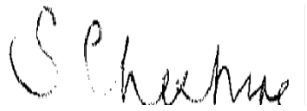
Type of form	Purpose of form	Mechanism and timescales for submission
Patient registration	To provide identifying information about the female patient having treatment	To be submitted via EDI 10 working days after the patient has confirmed intention to undergo treatment
Partner registration	To provide identifying information about the partner (sperm provider) of the patient	To be submitted via EDI 10 working days after the patient has confirmed intention to undergo treatment
Mitochondrial donor registration	To provide identifying information about the mitochondrial donor. This is required even if the mitochondrial donor is also registered as a patient or egg donor	To be submitted in paper* form 10 working days after the patient has confirmed intention to undergo treatment
Pronuclear **only** sperm donor registration	To provide identifiable details of a donor whose sperm will **only** be used in pronuclear transfer mitochondrial donation treatment for fertilisation of the mitochondrial donor's eggs Note: This form is not required if the individual is already registered as a sperm donor or is the partner of the woman being treated	To be submitted in paper* form 10 working days after confirmation of sperm being released for use by the clinic, or in the case of imports, receipt of the imported sperm
Intention to treat	To inform the HFEA when a cycle in which eggs are to be collected has started	To be submitted via EDI 3 **calendar** days after the last menstrual period or stimulatory drugs being administered to/taken by a patient with the intention to perform IVF treatment
IVF egg donation/storage	To inform the HFEA about the egg donation by the mitochondrial donor. The number of eggs donated for use in mitochondrial donation treatments are to be recorded in the comments section of the form	To be submitted on current IVF egg donation/storage form via EDI within 10 working days after the donation date
Mitochondrial donation treatment	To inform the HFEA of a treatment cycle involving mitochondrial donation	To be submitted using a paper* form 10 working days after the treatment cycle completion date

Early pregnancy outcome	To inform the HFEA of the early outcome of a treatment	To be submitted via EDI 8 weeks after the treatment cycle completion date
Pregnancy outcome	To inform the HFEA of the outcome of any early outcome recording 'fetal pulsation seen'	To be submitted via EDI 14 weeks after the predicted outcome date

* All paper forms submitted should be sent by recorded delivery and addressed to the HFEA's Register Information Team.

12. All licensed centres must ensure that paper 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.

13. All licensed centres undertaking maternal spindle transfer and/or pronuclear transfer must complete and submit to the Authority a copy of the 'Mitochondrial donation follow-up information sheet', available on the HFEA website, no later than 29 October each year. Licensed centres holding these records must be able to produce copies of those records upon request from an HFEA member or employee.



Sally Cheshire **16 September 2015**

Chair, Human Fertilisation and Embryology Authority

Version control	
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