# 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: 5

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| **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:** | 1 April 2022 |

1. Centres undertaking any licensed treatments, except for Intrauterine Insemination (IUI) using partner sperm (see 9.), must submit information relating to such activities to the HFEA according to the submission standard outlined in point 2 below.
2. Centres must submit information via an HFEA approved data submission system. Detailed information concerning each information type is available within the HFEA's UK ART Data Set Dictionary published on the Clinic Portal: Click here for latest version of the HFEA data dictionary

| Information type | Purpose | Submission deadline |
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| Patient registration | To provide identifying information about the female patient having Treatment. | Before treatment commences (which we define as before drugs are taken as part of fertility treatment or, if no drugs are given, before insemination, egg collection or embryo transfer if no egg collection has taken place). |
| Partner registration | To provide identifying information about the partner of the patient. | Before treatment commences. (See definition above). |

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| Donor registration | To provide identifying, contact, and personal information about the donor and why they are donating. | Before the first use of donor gametes or embryos or before stimulation to collect eggs from a donor.<br><br>For imported gametes or embryos prior to, or on of receipt of, those imports.<br><br>Pages 3 and 4 of the HFEA Donor Information form must be scanned and attached to the registration record on the HFEA register within 4 weeks of donor registration.<br><br>If pages 3 and 4 are not completed in English, an English translation of the pages must be scanned and attached to the registration record at the same time as pages 3 and 4. |
| Donor re-registration | To re-register an anonymous donor as identifiable<br><br>A donor re-registration form (also known as a B form) must be submitted. B forms are available on the Clinic Portal and HFEA website, and see link below:<br>Click here for B form | Within 5 working days of the donor re-registering at a centre |
| Intended parent registration | To provide identifying information about an intended mother or intended father in surrogacy. | Before the first use intended parents' gametes |
| Surrogate registration | To provide identifying information about a surrogate. | Before the surrogate's treatment commences. |
| 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. | Before stimulation to collect eggs from the mitochondrial donor. |
| Sperm donor registration where sperm is intended for use in **pronuclear mitochondrial donation** only | 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.<br><br>Note: This is not required if the individual is already registered as a sperm donor or is the partner of the woman being treated. | Before the first use of donor gametes or embryos or before stimulation to collect eggs from a donor.<br><br>For imported sperm, prior to, or on receipt of, the import. |

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| Stimulation | To inform the HFEA when a cycle in which it is intended to collect eggs has started. | Three calendar days after the last menstrual period or stimulatory drugs being first administered to, or taken by, a patient with the intention to collect eggs. |
| Donor insemination treatment | To inform the HFEA when a patient has been inseminated with donor sperm. | Two weeks after insemination. |
| IVF treatment and embryo creation and use | To inform the HFEA about the circumstances surrounding egg collection, embryo creation and use (i.e., transfer, storage, donation, discard). | Two weeks after the treatment cycle date.<br><br>Treatment cycle date is defined as the latest date of: egg collection, egg collection abandonment, egg and sperm mixing, embryo transfer or embryo storage. |
| Frozen embryos | To inform the HFEA of the thawing and use of embryos (i.e., whether they have been used in treatment, stored, donated or discarded). | Two weeks after the date of thawing embryos. |
| Early pregnancy outcome | To inform the HFEA of the early outcome of a treatment. | Eight weeks after the treatment cycle date. |
| Pregnancy outcome | To inform the HFEA of the outcome of any early outcome recording 'fetal pulsation seen'. | 52 weeks after insemination or embryo transfer date. |
| Mitochondrial donation treatment [MDT] | To inform the HFEA of a treatment cycle involving mitochondrial donation. | [Before PRISM is enabled for MDT]: To be submitted using an encrypted file two weeks after the treatment cycle completion date – which is the latest on the cycle of transfer, freezing or cancellation.<br><br>[After PRISM is enabled for MDT]: Two weeks after the treatment cycle completion date. |
| 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. | On the day of receipt for embryos, eggs and of 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 removal. | On the day that embryos, eggs and ampoules, straws or vials of donor sperm are removed from storage and transferred to another UK centre or exported outside the UK.<br><br>[Clinics should note that in PRISM, a receiving clinic cannot process a gamete movement in until the sending clinic has processed the |

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| | gamete movement out. Therefore, prompt gamete out processing is essential for smooth PRISM operations across the sector] |

3. Where an error is identified (through being reported on the PRISM homepage), centres must correct the error within four weeks of the initial data submission date. It is expected that the centre will have a standard operating procedure detailing the process for regularly checking errors to ensure this standard is met.
4. **Data Amendments:** All amendments to data previously submitted by centre staff to the Authority must be done via an HFEA approved data submission system.
5. **Recording variation of consent - adults:** The registration record must be updated to record any variation to patient, partner, or donor consent to disclose register information for research purposes within two weeks of the patient varying their consent.
6. **Recording variation of consent – conceived children (under 16):** By consenting to their identifying information being disclosed for research purposes, a patient is also consenting to identifying information about any child(ren) born as a result of their treatment being disclosed. Legally, they are responsible for deciding whether identifying information about their child(ren) is disclosed until their child(ren) reach(es) the age of 16 or an age when they are deemed legally competent to give consent themselves. If the patient wants identifying information about any children born as a result of treatment to be handled differently, they should contact the centre to notify this after their child(ren) is/are born. The centre should notify the HFEA within two weeks of the patient varying their consent.
7. **Recording variation of consent – conceived children (16 and over, or an age when they are deemed legally competent):** Where a child who was conceived through treatment at a licenced fertility centre gives or withholds consent to disclosure of information related to them, and where their consent is different to the consent to such disclosure previously provided by their mother and where relevant, her partner, the child's consent must be notified to the HFEA within two weeks of the child's consent.
8. **Deleting Data:** Where a licensed centre marks data as deleted, clear reasons must be given for the deletion.

## Other submissions

9. All licensed centres undertaking IUI 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 submitted via the Clinic Portal.

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

11. Before centre data is published on Choose a Fertility Clinic (CaFC), the Person Responsible (PR) must satisfy themselves that the data to be published is accurate. A PR sign-off sheet for each CaFC publication is available within the Clinic Portal and must be submitted by the published confirmation deadline.

12. Persons Responsible must ensure that, before they sign off their data via the Clinic Portal, they are

satisfied that:

a) the number of treatment cycles completed (both IVF and DI) and all aspects of cycle details within the reporting period is 100% accurate.

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

c) all registration data relating to persons involved in treatment in (a) above has been submitted to the Authority and is accurate.

**Julia Chain** **1 April 2022**

Chair, Human Fertilisation and Embryology Authority

| **Version control** | |
|---|---|
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