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

Consent

Ref: 0007
Version: 14

These Directions are:	General Directions
Sections of the Act providing for these Directions:	Sections 12(1)(d), 12(1)(g), 13(2)(f), 14(1)(d) and 15(2)
These Directions come into force on:	1 October 2010
These Directions remain in force:	Until revoked
This version was issued on:	14 August 2024

1. Licensed centres must record any consent of a person whose consent is required under:

   (a) Schedule 3 and Section 33B of the Human Fertilisation and Embryology Act 1990 (as amended); and
   (b) Sections 37(1) and 44(1) of Part 2 of the Human Fertilisation and Embryology Act 2008

   in the appropriate form listed in the Schedule to these Directions.

2. Electronic methods for providing information about consent and renewal of consent (including information that gametes or embryos will be removed from storage if patients do not renew their consent within the prescribed timeframe), and for recording consent and renewing consent, including electronic signature capture, are acceptable either as a supplement to the traditional paper-based approach or as a routine replacement for it. Licensed centres must retain capabilities and competence for paper-based consenting, to use if a patient requests it and to serve as a back-up to electronic methods if they fail.

3. Consent captured through paper-based or electronic means is considered written consent as required in Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended).

4. Licensed centres must give prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions about their treatment and any consent

they provide, as set out in guidance note 4 of the Code of Practice. Electronic formats, including informational videos, can be used as a supplementary part of the process of providing patients with information but are not an acceptable substitute for the consent discussion between clinic staff and patients about treatment options and their implications, during which patient concerns can be responded to.

5. Where clinics use electronic means to record consent referred to in paragraph 1, the electronic version of the consent form must precisely replicate the current version of the relevant HFEA form, as published on the Clinic Portal. This means that regardless of what electronic platform is used, consent form wording including accompanying guidance, branding i.e. HFEA colours and logo, and the format and layout, must mirror the current version of the consent form on the Clinic Portal.

6. Clinics are responsible for ensuring the correct consent form has been completed by a patient and for guiding patients to ensure that the appropriate sections or questions within a consent form are completed. Where electronic methods for taking consent employ conditional logic or algorithms, clinics must have documented procedures in place to regularly test the conditional logic or algorithms, and keep a record of the test results, to avoid the risk of errors when patients complete the consent forms.
7. Licensed centres must have safeguards in place to ensure that the person completing and signing the consent form is in fact the person who is meant to be completing it, as outlined in guidance note 6 of the Code of Practice.
8. Centres must obtain and retain consent in a way that ensures patient confidentiality and compliant record keeping, as outlined in guidance notes 5 and 31 of the Code of Practice, whether consent is recorded in paper-based or electronic format. This includes access to stored completed consents.
9. If implementing an electronic system for recording consent, centres must maintain an evidence base in support of the system's validation and compliance with the relevant requirements detailed in these General Directions.
10. Where the storage period of a person's gametes or embryos has been extended, in accordance with the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009, the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020 or the Health and Care Act 2022 (Storage of Gametes and Embryos) (Transitional Provision) Regulations 2024, the Person Responsible of the licensed centre at which those gametes or embryos are stored must maintain a record of evidence that the conditions for extended storage of those gametes or embryos have been fulfilled.

11. Where the storage period of a person's gametes or embryos has been renewed, in accordance with the Human Fertilisation and Embryology Act 1990 (as amended), the Person Responsible of the licensed centre at which those gametes or embryos are stored must maintain a record of evidence that the centre has complied with statutory requirements to issue notices to patients regarding renewing their consent to storage, and has used the relevant Statutory Notices, as listed in the Schedule to this General Direction, at the relevant time.

12. Licensed centres must maintain a record of any withdrawal of consent by a person who has previously given a consent required under Schedule 3 to the Human Fertilisation and Embryology Act 1990, as amended, or under sections 37(1) or 44(1) of Part 2 of the Human Fertilisation and Embryology Act 2008. This withdrawal of consent should be recorded using the appropriate Withdrawal of Consent form, as listed in the Schedule to these Directions.

13. Licensed centres holding any of the consents, renewal consent, Statutory Notices and records referred to in these Directions must be able to produce a copy of those (either electronically or as a hard copy) upon request from an HFEA member or employee. It is a requirement that even if a consent form has been completed electronically, it must be possible to provide a printout if requested.

14. From 1 May 2010, anyone receiving treatment at a licensed centre must complete a 'Consent to the disclosure of identifying information form' (CD form) if they have not already done so, regardless of when they first registered for treatment.

Julia Chain **14 August 2024**

Chair, Human Fertilisation and Embryology Authority

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Schedule

Consent forms

All forms below now use gender neutral language except for the SPP, LC, SWP and WP forms. The SPP, LC, SWP and WP forms are also available in gender neutral versions (see below).

Storage

GS	Your consent to the storage of your eggs or sperm

Renewal of consent to storage

RG	Renewal of consent to storage of your eggs or sperm for treatment
RE	Renewal of consent to storage of your embryos for treatment

Donation

MD	Your consent to donating your sperm
WD	Your consent to donating your eggs
ED	Your consent to donating embryos

Treatment

WT	Your consent to your eggs and embryos created using your eggs being used in treatment (IVF and ICSI) or stored
MT	Your consent to your sperm and embryos created outside the body using your sperm being used in treatment (IVF and ICSI) or stored
MGI	Your consent to the use of your sperm in artificial insemination
WGI	Your consent to the use of your eggs in GIFT
WPT	Your consent to providing eggs or embryos created with your eggs for your partner's treatment
ET(PH)	Your consent to the creation of embryos (IVF and ICSI) with your deceased partner's eggs or sperm or to storage of those embryos for up to 55 years (under the 2024 Regulations)

Surrogacy

MSG	Your consent to the use and storage of sperm or embryos for surrogacy
WSG	Your consent to the use and storage of eggs or embryos for surrogacy
SPP	Your consent to being the legal parent in surrogacy
SWP	Your consent (as a surrogate) nominating an intended parent to be the legal parent

Mitochondrial donation

WMT	Mitochondrial donation: consent to use your eggs in treatment and storage
MMT	Mitochondrial donation: consent to use your sperm in treatment and storage
WDM	Mitochondrial donation: consent to donating your eggs

MD (including PNT)	Consent to donating your sperm (including for use in pronuclear transfer)

Disclosure of information

CD	Your consent to disclosing identifying information

Parenthood

WP	Your consent to your partner being the legal parent
PP	Your consent to being the legal parent
PBR	Your consent to being the legal parent after your death

Withdrawal or stating lack of consent

WCS	Withdrawing your consent to the storage of your own eggs, sperm and embryos
WCU	Withdrawing your consent to use of your eggs, sperm or embryos in someone else's treatment
WCP	Withdrawing your consent to legal parenthood
LC	Stating your spouse or civil partner's lack of consent

Training in the event of mental incapacity

MIT	Your consent to your eggs, sperm and embryos being stored and used for training purposes in the event of mental incapacity

Transgender patients

NOTE: Where a gender neutral form is not listed below, the standard form should be used. This is because the standard form does not have any male or female references and can therefore be used in all cases.

Gender neutral: SPP	Your consent to being the legal parent in surrogacy
Gender neutral: SWP	Your consent (as a surrogate) nominating an intended parent to be the legal parent
Gender neutral: WP	Your consent to your partner being the legal parent
Gender neutral: LC	Stating your spouse or civil partner's lack of consent

Statutory notices

RNG – Request to renew consent to storage of eggs or sperm within the renewal period

RNE – Request to renew consent to storage of embryos within the renewal period

NDG – Notification that eggs or sperm will be removed from storage and disposed of if the patient does not renew consent to storage before the end of the renewal period

NDE – Notification that embryo(s) may be removed from storage and disposed of if patients do not renew their consent to storage before the end of the renewal period

NWC – Notification to each person whose eggs or sperm were used to create embryo(s) that consent to storage has been withdrawn

DFS - Statutory notice establishing the date of first storage of gametes or embryos