

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

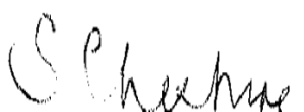
Consent

Ref: 0007
Version: 8

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:	27 September 2019

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 2008in the appropriate form listed in the Schedule to these Directions.
2. Electronic methods for providing information about consent and for recording 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, centre 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 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. 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 WC form, or in the case of surrogacy, the SWC form, as listed in the Schedule to these Directions.
12. Licensed centres holding any of the consents and records referred to in these Directions must be able to produce a copy of those consents and records (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.
13. 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.

**Sally Cheshire****27 September 2019**

Chair, Human Fertilisation and Embryology Authority

Version control	
Name of Directions:	Consent
Reference number:	0007
Date version 1 issued:	1 October 2009
Date version 2 issued:	6 April 2010
Chair's Letter reference:	CH(10)03
Date version 3 issued:	1 May 2010
Chair's Letter reference:	CH(10)05
Date version 4 issued:	1 October 2013
Chair's Letter reference:	CH(13)01
Date version 5 issued:	1 April 2015
Chair's Letter reference:	CH(15)01
Date version 6 issued:	29 October 2015
Chair's Letter reference:	CH(15)02
Date version 7 issued:	3 April 2017
Chair's Letter reference:	CH(17)01
Date version 8 issued:	27 September 2019
Chair's Letter reference:	CH(19)01

Schedule

Consent forms

Storage

GS	Your consent to the storage of your eggs and sperm
LGS	Your consent to extending the storage of your eggs or sperm beyond 10 years
ES	Your consent to extending the storage of your embryos beyond 10 years

Donation

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

Treatment

WT	Women's consent to treatment and storage form (IVF and ICSI)
MT	Men's consent to treatment and storage form (IVF and ICSI)
MGI	Your consent to the use of your sperm in artificial insemination
WGI	Your consent to the use of your eggs in GIFT

Surrogacy

MSG	Men's consent to the use and storage of sperm or embryos for surrogacy
WSG	Women's 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: women's consent to treatment and storage
MMT	Mitochondrial donation: men's consent to treatment and storage
WDM	Mitochondrial donation: consent to donating your eggs
MD (PNT only)	Mitochondrial donation: consent to sperm donation (PNT only)
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

WC	Withdrawing your consent
SWC	Surrogacy – withdrawing your consent
LC	Stating your spouse or civil partner's lack of consent

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: MD	Your consent to donating your sperm
Gender neutral: WD	Your consent to donating your eggs
Gender neutral: WT	Your consent to your eggs and embryos being used in treatment and/or stored form (IVF and ICSI)
Gender neutral: MT	Your consent to your sperm and embryos being used in treatment and/or stored form (IVF and ICSI)
Gender neutral: MGI	Your consent to the use of your sperm in artificial insemination
Gender neutral: WGI	Your consent to the use of your eggs in GIFT
Gender neutral: MSG	Your consent to the use and storage of sperm or embryos for surrogacy
Gender neutral: WSG	Your consent to the use and storage of eggs or embryos for surrogacy
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: WMT	Mitochondrial donation: consent to treatment and storage
Gender neutral: MMM	Mitochondrial donation: consent to use your sperm in treatment and storage
Gender neutral: WDM	Mitochondrial donation: consent to donating your eggs
Gender neutral: MD (PNT only)	Mitochondrial donation: consent to sperm donation (PNT only)
Gender neutral: MD (including PNT)	Consent to donating your sperm (including for use in pronuclear transfer)
Gender neutral: WP	Your consent to your partner being the legal parent
Gender neutral: SWC	Surrogacy - withdrawing your consent
Gender neutral: LC	Stating your spouse or civil partner's lack of consent