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Relevant regulations / legislation / guidelines	*HFEA Code of Practice 8th Edition* *NICE Guidelines April 2013 Updated September 2017*

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Version Control			
Date	*Version Number*	*Change Details*	*Approved by*
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1. INTRODUCTION / PURPOSE

Any Fertility Centre offering licensed fertility treatment i.e. IVF/ICSI or any treatment involving donated gametes in the UK needs to be registered with the Human Fertilisation and Embryology Authority (HFEA) and therefore be a licensed Centre. Consent as in all aspects of licensed treatment has strict guidance which therefore must be met.

Consent can be verbal, implied or a written agreement for a process or processes to take place. The patient must be given a complete description of the process/ procedure being carried out, its implications and attempts to ensure that the patient understands what is being asked / consented to. As much information as possible should be given and the patients able to make a decision without duress.

It is the policy of MCHFT that no one will be discriminated against on grounds of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex or sexual orientation. The Trust will provide interpretation services or documentation in other mediums as requested and necessary to ensure natural justice and equality of access.

2. SCOPE

This standard operating procedure describes the duties of medical and nursing staff that are required to take consent for any licensable or non-licensable process or treatment that requires consent as defined in the HFEA Code of Practice 8th Edition.

If a medical student or a student nurse wishes to be present when a patient is being examined or interviewed, the clinician seeing the patient should explain beforehand to the patient and state who the observer is. They should give the patient as much information as possible about the proposed observation and gain the patient's consent.

Any observer in a clinic should sign a confidential disclaimer after full explanation by the clinic staff regarding the implications of the requirements set by the HFEA.

This standard operating procedure also defines the appropriate action taken when a patient withdraws consent to gamete or embryo storage or usage. The intended outcome is that valid consent for storage and use for gametes and embryos is in place at all times.

3. PROCEDURE

3.1 Consent to use and storage of gametes and embryos

The law requires licensed fertility centres to obtain written informed consent from a person before it performs the following procedures.

a) Storage of gametes.

b) Using gametes for the treatment of others or for non-medical fertility services.

c) Creating embryos in vitro with their gametes.

d) Storing embryos created with their gametes.

e) Using embryos created with their gametes for their own treatment, treatment of a partner or treatment of others.

f) Using embryos created with their gametes for training people in embryo biopsy, embryo storage or other embryological techniques.

g) Using embryos created with their gametes for any research project.

h) Using their cells to create embryos for research.

i) Creating human admixed embryos with the gametes or cells.

The fertility centre must ensure it obtains written informed consent from a person before procuring their gametes. If gametes are collected without proper consent, it may be considered assault. Gametes may not be taken from a person if written; informed consent to storage has not been obtained.

- The law allows gametes to be stored without consent if the conditions met in paragraph 9 or 10, and 11 of Schedule 3 of the HFE Act 1990 (as amended) are met.

- The law requires that gametes stored without consent cannot be used, unless the gamete provider becomes competent and consents to such use.

- If gametes or embryos are to be transferred to a fertility centre outside the UK, the UK fertility centre must obtain the consent of the gamete provider(s) to their export to the country in which the receiving centre is situated. Such consent must then be provided to the fertility centre receiving the gametes or embryos.

- If gametes or embryos are to be transferred into the UK from a fertility centre outside the UK, the person responsible for the UK fertility centre must be satisfied that the provider has given written consent to the transfer of the gametes or embryos to the UK, and has not withdrawn that consent.

- Further requirements and the exemptions regarding obtaining consent to the use of gametes, cells and embryos for research (including for the creation of admixed embryos), and the exemptions, are outlined in guidance note 22 – Research and training. HFEA Code of Practice 8th edition 2010.

- Requirements regarding consent to parenthood are outlined in guidance note 6 – Legal parenthood. HFEA Code of Practice 8th edition 2010.

3.2 Written consent

Written consent should be taken from a person before carrying out the following procedures:

a) Using their own gametes for their own treatment or their partner's treatment.

b) Using their gametes for research and training.

When a woman is to undergo an embryo transfer, consent should be obtained to the proposed number of embryos to be transferred. A copy of the consent form should be filed in the patient notes.

3.3 Procedure for obtaining consent

The law requires that before a person consents to the procedures outlined above, they should be given

a) Enough information to enable them to understand the nature, purpose and implications of their treatment or donation.

b) A suitable opportunity to receive proper counselling about the implications of the steps which they are considering taking.

c) Information about the procedure for varying or withdrawing any consent given and about the implications of doing so.

Before giving consent, a person should have received sufficient verbal and written information that they can understand. They should be given the opportunity to ask clarifying questions. They should also be able to specify extra conditions for storing or using their gametes (or embryos created using them).

Patients seeking treatment or considering donation or storage should have enough time to reflect on their decisions before obtaining their consent. Consent should be given voluntarily and by a person who has capacity to do so as defined by the mental capacity act 2005, England and Wales and by a person authorised by the person responsible to do so. Patients giving consent should declare that:

a) They were given enough information to enable them to understand the nature, purpose and implications of the treatment or donation.

b) They were given a suitable opportunity to receive proper counselling about the implications of the proposed procedures.

c) They were given information about the procedures for varying or withdrawing consent.

Before consent is taken, the identity of each person seeking treatment should be actively identified including the use of photographic evidence. The patient brings a passport sized photograph of themselves and their passport /driving licence to the appointment. The Fertility Nurse needs to check these and sign to confirm that they have provided photographic evidence

3.4 Recording Consent and related information

- Copies of signed consent forms should be filed in the health care records and patients should be offered a copy of the consent forms if they so wish.

- It should be documented in the health care records that relevant information has been provided to patients who are giving their consent.

Additional consent requirements for storing gametes and embryos.

- When patients are asked to give consent to the use of gametes and embryos they should also be asked to consent for storage at the same time.

3.5 Additional consent requirements for using gametes and embryos

If consent to the use of gametes or embryos for the treatment of others is given, this should state the number of families that may have children using the donated gametes or embryos.

When an individual gives consent to the use of gametes for the treatment of others, it is not required to gain consent from the donor's partner or spouse. However, it is best practice to seek their partner's support for the donation of their gametes and document this in the medical records.

a) For men wishing to donate embryos originally created for the treatment of their partner and themselves, and those people considering treatment with such embryos, they should be informed of the uncertain legal status of men donating embryos originally created for the treatment of their partner and themselves when the embryos are used in the treatment of a single woman.

b) The clinic should refer them to information on the HFEA website on this issue and should advise them to seek independent legal advice before consenting to donate their embryos or being treated with the embryos.

3.6 Withdrawal of Consent

3.6.1 Initial contact from the patient

It is important that the identity of anyone withdrawing or varying consent is confirmed against identifying information held in the health care records.

3.6.2 Withdrawal of Consent by Mutual Agreement

<u>Verbal receipt of instruction to withdraw consent</u>

A note should be made in the patient's health care records.

The patient should be asked to complete the HFEA WC form to record their withdrawal of consent in writing. The patient/couple should be offered an appointment to see a member of the counselling team.

<u>Written receipt of instruction to withdraw consent</u>

The patient /couple should be asked to complete HFEA WC form.
The patient/couple should be offered an appointment to see a member of the counselling team.

3.6.3 Withdrawal of Consent in the Event of a Dispute

Where there is no mutual agreement for the withdrawal of consent, reference to the HFEA Code of Practice must take place.

If one of the gamete provider's withdraws consent to the continued storage of embryos intended for treatment (created from their gametes) the law requires the fertility centre to take all reasonable steps to notify the intended recipient(s).

The law allows embryos to be stored for 12 months from the date that the fertility centre receives written withdrawal of consent, or less if the fertility centre receives written signed consent from all intended recipients for the embryos to be destroyed.

This 12 month 'cooling off' period must not extend beyond the end of the statutory period.

Immediately upon receipt of written instruction to withdraw consent, the Lead Consultant Gynecologist and the person responsible (named person who has overall responsibility of the Hewitt Centre's HFEA License) at Liverpool Women's Hospital should be informed.

The patients should be offered an appointment to see a member of the counselling team in order to gain support in resolving the dispute.

4. DEFINITIONS

In Vitro Fertilisation (IVF): One of several techniques available to help couples with fertility problems to have a baby. During IVF, an egg is surgically removed from the woman's ovaries and fertilised with sperm in a laboratory.

Intra Cytoplasmic Sperm Injection (ICSI): An in vitro fertilization procedure in which a single sperm is injected directly into an egg.

Hewitt Centre: A specialist assisted conception unit, The Hewitt Fertility Centre, part of the Liverpool Women's.

5. RESPONSIBILITIES / DUTIES

All staff working within the Trust has an individual responsibility to be aware of the contents of this guideline which may be relevant to their clinical practice.

6. ASSOCIATED DOCUMENTS

The following documents can be found on the Trust Intranet: Services > Women's Health > Document Library > Fertility Frequently Used Forms

- Confidential Declaration
- Consent Form

- HFEA WC Form

7. CONSULTATION AND COMMUNICATION WITH STAKEHOLDERS

This guideline has been developed in consultation with:

This guideline has been developed in consultation with:

- Consultant Gynaecologist/Obstetrician Clinical Lead for Obstetrics and Gynaecology
- Consultant Gynaecologist/Obstetrician Lead for Gynaecology Risk Management
- Consultant Gynaecologist/Obstetrician Lead for Quality Improvement
- Quality Governance Manager for Women and Children's Division
- Lead Nurse for Gynaecology
- Matron for Gynaecology
- Female Surgery Ward Manager
- Colposcopy Nurse Specialist
- Clinical Audit Lead
- Divisional Pharmacist
- Divisional Workforce Development Lead
- Head of Midwifery / Lead Nurse for Paediatrics and Gynaecology
- Divisional General Manager
- Divisional Quality Lead
- Gynaecology Governance Group
- **Governance.policies@mcht.nhs.uk**

8. MONITORING AND REVIEW

Process for Monitoring Compliance with all of the above requirements, review of results and subsequent monitoring of action plans

Adverse incidents relating to this Standard Operating Procedure should be reported via the Trust Incident Reporting System, such incidents will be investigated and managed in accordance Trust Policy *'Incident Investigation, Learning, Reporting and Improving'*.

Monitoring compliance requirements for this Standard Operating Procedure, as a minimum will include:

Standard / process / issue required to be monitored	Monitoring and Audit			
	Process for monitoring e.g. audit	Responsible individual /group	Frequency of monitoring	Responsible Group
Review of the process of this document based on any previous hot spots of clinical incidents.	If there are any deviances from this document found, these are escalated to the Consultant Gynaecologist, – Clinical Lead for further review	Consultant Gynaecologist, – Clinical Lead	Ongoing	Gynaecology Governance Group
Regular review of the process of this document.	Guideline to be reviewed in line with MCHFT standards	Divisional Quality Lead	2 yearly	Gynaecology Governance Group

9. INTERNAL AND EXTERNAL REFERENCES

- The Human Fertilisation and Embryology Authority (HFEA) (2009) 'Code of Practice' 8th Edition. Updated April 2012. London http://www.hfea.gov.uk/docs/8th_Code_of_Practice_Upto102013.pdf
- The Human Fertilisation and Embryology Authority (HFEA) Standards (2006) 'Assisted Conception Standards' v1.0 April 2006. London http://www.hfea.gov.uk/docs/Assisted_Conception_Standards_v1.0_April_2006(1).pdf
- National Institute for Health and Clinical Excellence (NICE) (2013).*' Fertility-Assessment and treatment for people with fertility problems'*. 2013 National Collaborating Centre for Women's and Children's Health, London.
- Department of Health. (2005). *Mental Capacity Act*. London: HMSO

10. APPROVAL

Approving Group: Gynaecology Governance Group

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