

Unit 20: Procedures for Witnessing in the HFEA-licensed Fertility Clinic

Level:	3
Unit type:	Optional (Reproductive Science)
Credit value:	2
Guided learning hours:	15

Unit summary

In this unit, you will gain the knowledge and understanding of the principles and practice of procedures used when acting as a witness within the HFEA-licensed fertility clinic.

There is a statutory requirement to have robust and effective processes to ensure that no mismatches of gametes, embryos or identification occur within the HFEA-licensed fertility clinic. Identification of samples must be double-witnessed, and the witness step recorded at all critical points of the clinical and laboratory process. This includes, but is not limited to, witnessing for: procurement of gametes; mixing of sperm and oocytes; transfer of gametes or embryos between tubes, dishes or cryopreservation carriers; transfer of gametes or embryos to an individual in a clinical procedure; disposal of gametes or embryos; the placing into or retrieving from long-term storage vessels of cryopreserved gametes or embryos.

The witnessing of laboratory and clinical procedures is undertaken using local policies and procedures to verify and document compliance with regulatory requirements.

Unit assessment requirements

There are no specific assessment requirements for this unit. Please refer to the assessment strategy in *Annexe B*.

Additional information

All procedures must be undertaken in accordance with the Standard Operating Procedures and in accordance with the Human Fertilisation and Embryology Act 2008 and HFEA licence.

Training must be performed under the supervision of a designated assessor and with the approval of the person responsible within the HFEA-licensed Fertility Clinic. All activities during the training period require direct supervision of learners by a suitably qualified member of the multidisciplinary team.

Any external assessor or trainer must be authorised to access the HFEA-licensed Fertility Clinic.

The evidence presented to demonstrate the achievement of the assessment criteria must be anonymised to remove patient-identifiable data. Section 30 of the Human Fertilisation and Embryology Act 1990 imposes a legal duty of confidentiality, and a breach of this provision is a criminal offence.

AC1.1 includes:

- policies, protocols, Standard Operating Procedures, and professional guidelines
- the Human Fertilisation and Embryology Authority Code of Practice for witnessing procedures.

AC1.2 includes:

- carrying out all relevant aspects of witnessing procedures
- noting, reporting, and following up any discrepancies or omissions in witnessing.

AC1.10 includes:

- the effect of omission or irregularity.

AC2.1 includes:

- where to find the local Standard Operating Procedures and standard laboratory documentation relating to witnessing
- how to check that the consent for the procedure to be witnessed is in place. Where consent is required from more than one individual for a single procedure, describe how to check that consents for each individual are in agreement and in accordance with the proposed procedure.
- the checks performed to ensure that the specific procedure to be witnessed is the correct procedure, for the correct individual(s), with the correct partner, with all items, on the right day and at the right time
- the use of personal protective equipment (PPE) if required, to be used when acting as a laboratory witness
- the current local documentation used to record the witnessing of laboratory procedures
- the reference points used to verify individual/vessel identity during witnessing steps.

AC2.2 includes:

- following the local Standard Operating Procedures for witnessing
- verbally confirming the identifying information, which is being examined in different process steps, with the practitioner
- checking that the unique identifier corresponds to the individual's details
- checking that the unique identifiers for each individual are in accordance with the proposed procedure, where gametes or embryos from more than one individual are involved in the process step

- taking action in the event of a requirement for non-confirmation with the practitioner, for example a mismatch of information or deviation from local policy/procedure
- act if a documentation error or omission is noted.

AC2.5 includes:

- updating records in accordance with local policies and procedures
- communicating effectively on all aspects of witnessing in accordance with local policies and procedures
- acting on any event that requires immediate action in accordance with local policies and procedures
- compiling reports on witnessing for audit or quality-assurance purposes.

Learning outcomes and assessment criteria

To pass this unit, learners need to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements that the learner is expected to meet **in own area of work, in accordance with Standard Operating Procedures (SOPs)** and in accordance with the **Human Fertilisation and Embryology Act 2008, HFEA licence and the clinic's HFEA licence** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand current national guidelines, local protocols, Standard Operating Procedures (SOPs) and professional guidelines relating to witnessing procedures in the HFEA-licensed Fertility Clinic	1.1	Summarise the requirements of current national and local guidelines relating to witnessing procedures in the HFEA-licensed Fertility Clinic			
		1.2	Evaluate the SOP relating to witnessing procedures			
		1.3	List the circumstances where laboratory witnessing is mandatory			
		1.4	Describe how witnessing tasks are scheduled and why they are completed contemporaneously			
		1.5	Describe the steps to ensure that the requirements for consent are in place for the procedure, which is to be witnessed, in line with local and HFEA requirements			
		1.6	Discuss the concept of involuntary automaticity in relation to witnessing procedures			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
		1.7	Describe manual and electronic witnessing systems and how these may be used in the HFEA-licensed Fertility Clinic			
		1.8	Describe local witnessing procedures, including but not limited to: • an oocyte collection procedure • preparation of a sperm sample • IVF insemination • embryo transfer • cryopreservation of embryos			
		1.9	Summarise the local health and safety information and risk assessment(s) relating to witnessing procedures			
		1.10	Describe the factors that might influence the quality and validity of witnessing procedures			
		1.11	Describe the witnessing events that might give rise to risks for the safety and quality of gametes or embryos			
		1.12	Summarise the elements of the local quality management system that relate to witnessing procedures in the HFEA-licensed Fertility Clinic			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to perform laboratory witnessing following standard operating procedures	2.1	Prepare to act as a laboratory witness			
		2.2	Perform laboratory witnessing			
		2.3	Keep contemporaneous records of the witnessing event in accordance with local policies and procedures			
		2.4	Maintain and update records in accordance with local policies and procedures			
		2.5	Report and conclude the witnessing procedure			
		2.6	Describe the actions taken for any items requiring disposal after the witnessing procedure, including any necessity for further witnessing			
3	Understand the context, troubleshooting and when to take advice in relation to witnessing procedures	3.1	Explain when and why a discrepancy in witnessing should be reported			
		3.2	Describe the remedial action to take when adverse situations, problems or events occur			
		3.3	Describe the contingency arrangements in the event of an unforeseen problem arising			
		3.4	Describe limits of own authority and who to report to			
		3.5	Describe the context where events occurring, or observations made while acting as a witness may become an incident to be reported to the Human Fertilisation and Embryology Authority			

Learner name: _____

Date: _____

Learner signature: _____

Date: _____

Assessor signature: _____

Date: _____

Internal verifier signature: _____

Date: _____

(if sampled)