

**DIRECTIONS GIVEN UNDER THE  
HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990**

**Directions on records of witnessing  
clinical and laboratory procedures**

**Ref: D 2004/4**

These Directions are

GENERAL DIRECTIONS

Section of the Act providing  
for these Directions

Section 13(2)(e) and (f) and 12(d) of the 1990 Act

These Directions are deemed  
to have taken effect on :

**1<sup>st</sup> July 2004**

These Directions remain in force:

Until revoked

1. These Directions revoke Directions Ref. D2002/1.
2. Each licensed centre must keep records of the witnessing of all clinical and laboratory procedures set out in the schedule to these Directions. A contemporaneous record must be made in each patient's medical records confirming:
  - (a) the procedure undertaken;
  - (b) the date and time of the procedure;
  - (c) the name and status of the person undertaking that procedure and the signature of that person;
  - (d) the name and status of the witness to the procedure and the signature of that person.

Date:

**Schedule to Directions D2004/4**

**Protocol for Witnessing Clinical and Laboratory Procedures**

	<b>Clinical / Laboratory Activity</b>	<b>Core Witnessing Procedure Required</b>	<b>Checked</b>
1	Egg Collection	<p>a) Ask the patient her name and date of birth in the presence of clinician, nurse and embryologist. This information must be cross-checked against the patient's medical records and laboratory data sheet. Patients must be asked to give their name etc (i.e. the response must not be a passive 'yes / no' to a name read out.</p> <p>b) Identifying information marked on all culture dishes/tubes (lids and dishes) must be cross-referenced to the patient and the patient's documentation by the embryologist and another appropriate person (preferably a second embryologist).</p> <p>c) Where patients have similar names a unique patient identifier must be used</p>	
2	Sperm Collection	<p>a) Ask the male partner to identify himself (name and date of birth).</p> <p>b) An appropriate person must witness that the patient's details correspond with the details written on the sample container and all corresponding paperwork.</p> <p>c) Where patients have similar names a unique patient identifier must be used</p>	
3	Sperm Preparation	<p>a) Identifying information marked on all tubes must be cross-referenced to the male partner and all corresponding documentation by the embryologist / andrologist and another appropriate person (preferably a second embryologist / andrologist).</p> <p>b) Where patients have similar names a unique patient identifier must be used</p> <p>c) Centres must avoid having more than one unprocessed sample on the bench at any one time.</p>	
4	Insemination / ICSI	<p>a) The patient's identifying information on the tube containing the sperm preparation and on all dishes containing eggs must be confirmed by an appropriate person.</p>	

	<b>Clinical / Laboratory Activity</b>	<b>Core Witnessing Procedure Required</b>	<b>Checked</b>
		<p>b) Where patients have similar names a unique patient identifier must be used</p> <p>c) The mixing of sperm and eggs must be witnessed by an appropriate person.</p>	
5	Fertilisation Check	<p>a) Identifying information marked on all culture dishes must be cross-referenced to the patient's documentation by the embryologist and another appropriate person (preferably a second embryologist).</p> <p>b) Where patients have similar names a unique patient identifier must be used</p>	
6	Embryo Transfer	<p>a) Ask the patient to identify herself (name and date of birth) in the presence of the Clinician or Nurse and Embryologist. Patients must be asked to give their name etc (i.e. the response must not be a passive 'yes / no' to a name read out.</p> <p>b) This information must be cross-checked against the patient's medical records and laboratory data sheet.</p> <p>c) Where patients have similar names a unique patient identifier must be used.</p> <p>d) Two appropriate persons must verify that the identifying information on the dish containing the embryos corresponds to the patient and the patient's documentation.</p>	
7	Gamete / Embryo Freezing	<p>a) All ampoules / straws must be clearly labelled with the patient's full name and two unique patient identifiers (e.g. hospital/unit number, date of birth, freeze record number, date of freezing).</p> <p>b) Two appropriate persons must verify that all the information on the tubes / dishes containing the gametes / embryos matches the name on the ampoules / straws.</p> <p>c) The storage of all material must be witnessed by two appropriate persons.</p>	
8	Removal of Cryo-Preserved Material	<p>a) Two appropriate persons must verify that the information on the ampoules / straws matches the information in the patient's medical records.</p> <p>b) Two appropriate persons must witness the removal of all material from storage.</p>	

	<b>Clinical / Laboratory Activity</b>	<b>Core Witnessing Procedure Required</b>	<b>Checked</b>
9	Donor Insemination	a) Ask the patient to identify herself (name and date of birth) in the presence of the Clinician / Nurse and Embryologist.  b) A witness must confirm that sperm from the correct donor is used and verify the information on all tubes / ampoules before the sperm is used.  c) Where patients have similar names a unique patient identifier must be used	
10	Perishing of Gametes / Embryos	a) Two appropriate people, one of whom should be an embryologist / andrologist, must witness the disposal of all gametes / embryos.	

**All witnessing procedures must be fully documented in the patient's medical records.**