

**HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY  
SCIENTIFIC AND CLINICAL ADVANCES GROUP**

<b>Committee:</b>	Scientific and Clinical Advances Group
<b>Meeting Date:</b>	14 <sup>th</sup> February 2006
<b>Agenda Item:</b>	5
<b>Paper Number:</b>	SCAG (02/06)01
<b>Paper Title:</b>	<b>The Use of Bar Coding and RFID in the IVF Laboratory</b>
<b>Author:</b>	Charles Lister
<b>Recommendation to the Committee:</b>	<p>Members are asked to:</p> <ul style="list-style-type: none"> <li>• Consider the available evidence on the risks to embryos from exposure to laser light from bar code readers and to advise SANT and the Authority on the advice to be given to centres;</li> <li>• To give a preliminary view on the extent to which rules on double witnessing could be relaxed, conditions which should apply and what evidence should be gathered;</li> <li>• Give views on issues that the Executive should consider in addressing this issue.</li> </ul>

**THE USE OF RFID AND BAR CODING IN THE IVF LABORATORY**

**Background & Purpose**

1. The HFEA's advisory group on Safety and New Technologies (SANT) is drafting advice for clinics on the safety and efficacy of bar coding and radio frequency ID technologies. These technologies are currently being marketed for use in IVF laboratories to track gametes and embryos and to aid witnessing and record keeping procedures.
2. A brief summary of the technologies is at Annex A. The draft advice on safety and efficacy is at Annex B.
3. The draft advice was considered by the Authority at its January meeting, where some specific concerns were raised:
  - Whether, on safety grounds, there should be a strong recommendation to clinics not to use bar coding systems using laser light;

- That in issuing advice on safety and efficacy, the Authority should also give guidance on the extent to which these technologies can reduce the need for laboratory staff to carry out double witnessing checks.
4. SCAG is invited to give a view on both these issues, specifically:
- To consider the available evidence on the risks to embryos from exposure to laser light from bar code readers and to advise SANT and the Authority on the advice to be given to centres;
  - To give a preliminary view on the extent to which the Authority's strict rules on double witnessing could be relaxed for centres operating bar code or RFID witnessing systems, and what evidence should be gathered prior to a final decision. Current witnessing guidance is at Annex C.

This discussion will be preceded by a brief presentation on the issues.

5. SANT is meeting immediately following SCAG for a more detailed discussion on these issues. Final decisions will be taken by the Regulation Committee and the Authority in June.

### **Bar Code Readers Using Laser Light**

6. Manufacturers are offering two types of bar code reader to clinics: one type using white light, one using laser light. These are used to scan bar codes attached, for example, to the bottom of Petri dishes containing embryos.
7. There is reasonable confidence that use of white light readers should impose no additional risks to gametes and embryos given that the exposure is considerably less than they are already exposed to in the laboratory. However, given the limited specific evidence on safety, it is not possible to say that they are completely free from risk.
8. Laser light exposure is of greater concern. There are no scientific studies which examine the effect of laser light on human gametes or embryos but there is a good deal to suggest that such exposure may be harmful:
- Some manufacturers use scanners which emit 630-650nm laser light. This is roughly three times more powerful than the laser light used in zona pellucida drilling of embryos (which damages the outer coating of the embryo).

- Whereas there are strict guidelines on the use of lasers in assisted hatching, scanning of a bar code on a Petri dish would potentially expose the embryo in a way that is undirected
- A number of published studies suggest laser light may be harmful to mammalian cells or embryos. For example,
  - 630nm laser light causes cell destruction of in vitro cell lines (Berki et al, 1991);
  - 633nm laser light compromises the developmental potential of bovine embryos (Dinkins et al, 2002);
  - 632.8nm laser light induces the acrosome reaction of bull sperm (Simonian & Voskanian, 1988);
  - viability of blood cells is gradually decreased after laser irradiation (Luza & Hubacek, 1996);
  - exposure of actively replicating human skin fibroblasts to 193nm or 248nm laser radiation can cause chromosomal aberrations and therefore cause genotoxicity (Rimoldi et al, 1991).

It should be noted however that the duration, and in some cases power, of laser light used in these studies may vary greatly from that to which embryos would be exposed from bar code readers. Also, the Authority has previously licensed the use of lasers for Assisted Hatching.

9. The current draft advice to clinics on the basis of this evidence is that:

“There is evidence of damage to human cells from laser light, although it is recognised that gametes and embryos would be exposed to laser light for a very short time from bar coding. For that reason we consider that centres should be aware of this when deciding whether to purchase bar coding solutions involving laser light”.

Authority members considered this advice too cautious, and wanted either unambiguous advice that bar code readers using laser light should not be used or possibly an outright prohibition by classifying it as an unsuitable practice.

10. SCAG's views are sought on the advice to be given to clinics bearing in mind:

- the limited information available on safety;
- the availability of alternative products to perform the same function;
- the Authority licenses Assisted Hatching with lasers.

The evidence supporting any conclusion reached should be cited.

## Witnessing

11. An attraction for clinics considering purchasing this equipment is its potential to reduce witnessing errors without the need for the number of human checks currently required by the Authority. The Executive will be reviewing this issue with SANT members with a view to reaching a decision with Regulation Committee in May and the Authority in June.

12. Issues under consideration will include:

- Current error rates associated with manual double witnessing;
- The critical points in a RFID/bar coding process at which manual double checking would still be required;
- Risk reduction measures to minimise the risk of human error at these critical points;
- The development of detailed protocols for witnessing using RFID and bar coding systems, possibly informed by a trial.

13. At this early stage in thinking about these issues, it would be helpful to have a general view from SCAG on:

- the conditions that should apply before centres could be allowed to relax the current manual double witnessing requirements in favour of electronic solutions;
- issues that the Executive should consider in addressing this issue.

## **ANNEX A**

### **Information about Bar Coding systems**

1. The HFEA has been aware for some time that manufacturers of bar coding and radio frequency identification (RFID) technologies have been approaching centres. Some centres have started exploring the use of these technologies in the ART laboratory to track gametes and embryos and aid witnessing and record keeping procedures.
2. Bar coding systems, such as IMT International's Matcher System, work by storing patient information in bar codes which are attached to all the components used in the treatment/laboratory process (petri dishes, semen cups, vials, files etc) which are linked to a particular patient, and patients are required to wear bar code bracelets. Each patient is assigned a unique bar code.
3. At every procedure where double witnessing normally takes place the embryologist must use either a digital camera on the work bench or a bar code scanner attached to a pocket PC to read and analyse these bar codes, thereby confirming identity match. Clinics can generate their own unique bar code numbers and the system also has a security alarm to prevent unauthorised use. This type of system still requires active witnessing i.e. embryologists will need to remember to read the bar codes at every stage.

### **Information about RFID systems**

1. RFID systems, such as Research Instrument's IVF Witness, are live systems that constantly check the work area, therefore providing passive witnessing.
2. Patient information is stored in radio frequency tags (small microchips embedded into labels, each with a unique number) which are attached to all components used in the treatment/laboratory process and patient bracelets. RFID readers placed in the laboratory emit a low level radiation which automatically detects the RFID tags in the work area. If two non-matching samples are detected in the working area an alarm will sound and 'stop' will appear on the computer screen.
3. These systems could also potentially be used to aid auditing the contents of dewers.

## **ANNEX B: Draft advice to clinics regarding the safety and efficacy of bar coding and RFID**

Dear...

### **Bar Coding and Radio Frequency Identification in Assisted Conception Laboratories**

Our Advisory Group on Safety and New Technologies (SANT) has recently been looking into the use of bar coding and RFID in the assisted conception laboratory. A number of centres have started exploring the use of these technologies to help meet Code of Practice requirements, and there is an increased focus on coding and traceability in the wake of the European Tissues and Cells Directive.

SANT has focussed on the potential benefits of these products in helping clinics with HFEA requirements around traceability, audit and witnessing, and the future EU Tissues and Cells Directive requirements. SANT has also explored issues of safety and efficacy associated with using these technologies, which are new to assisted conception.

We have been in correspondence with the companies that offer bar coding and RFID products to request information on the safety and efficacy of these technologies in respect of human gametes (eggs and sperm) and embryos.

It has not been the intention that this work will lead to the recommendation of any particular product. Rather it will help clinics to implement solutions that will adequately meet legal requirements, and effectively improve the safety of laboratory processes. These systems could potentially be used to apply electronic witnessing at all stages e.g. at the point of insemination, fertilisation check and transfer of embryos from dish to dish.

### **Summary of work undertaken by SANT**

- Collation of information on bar coding and RFID products available so that the HFEA can understand more about the technologies behind the products and how they can apply to assisted conception;
- Research into the use of bar coding and RFID in relation to gametes and embryos worldwide in order to assess the safety and efficacy of the technologies in this context;
- Account has been taken of trials of bar coding and RFID products at licensed HFEA clinics;
- A specification has been drawn up to help centres when considering implementing bar coding and RFID technologies.

### **Bar coding**

#### **Summary of Evidence**

The following evidence was used to form the advice we are issuing regarding the use of bar coding systems. The main sources of information considered were test reports and technical information from manufacturers, scientific literature, reports from other organisations and reports of bar coding systems in other settings:

### **Reports on use of bar coding and efficacy**

- In other settings bar codes have been used for decades and become the standard for identifying and tracking products. The Health Industry Bar Code Standard (HIBC) was developed nearly 20 years ago and is approved by the European Committee for Standardisation.
- The NHS National Patient Safety Agency (NPSA), in a recent report, concluded that bar coding is currently the best technology for labelling patients and specimens because the technology is readily available, relatively cheap and has a good track record in health care.
- The National Blood Service has implemented bar coding. Reviews on the use of bar code identification for blood transfusion safety found that the systems improved safety and efficiency (Murphy & Kay, 2004; Miyata et al, 2004).
- In 2004 the US Food and Drug Administration (FDA) introduced mandatory bar code labelling for human drug and biological products. They estimate that this will result in more than 500, 000 fewer adverse events over the next 20 years (a 50% reduction in medication errors).
- In 2003 a large health care institute in Italy piloted a 2D bar code system for identifying patients which resulted in a 71% reduction in medication errors and 100% reduction in patient ID errors. The system had a high patient acceptability with 91.3% accepting the wristband system.
- In a trial of a particular bar coding system in a fertility clinic Troup et al found that there were no 'miss read' events (false positives). 'No match' events occurred on 229 occasions out of 3800 procedures. System error accounted for 87.3% of these 'no match' events. A new version of this system has been developed following this trial.

### **Safety issues regarding bar coding systems which use white light**

- When considering the safety of systems which use white light, comparisons were made with levels of light which gametes and embryos are already routinely exposed to in the ART laboratory. Gametes and embryos in the laboratory are routinely examined using microscopes. The white light used in a microscope is significantly more powerful (35000 milliwatts) than that used in bar coding systems that use white light in their scanning equipment (60 milliwatts). Also, gametes and embryos are exposed to microscope light for a significantly longer period than the brief period it would take for a bar code to be scanned (one second per procedure for one system). However, there are no specific scientific studies which examine the effect of white light on human gametes and embryos.

### **Safety issues regarding bar coding systems which use laser light**

- When considering the use of bar coding systems that use laser light it was noted that some manufacturers use scanners which emit 630-650nm laser light. This is roughly three times more powerful than the laser light used in zona pellucida drilling of embryos (which damages the outer coating of the embryo).
- A number of scientific studies were found that suggested laser light may be harmful to mammalian cells or embryos. In particular these studies found that 630nm laser light causes cell destruction of in vitro cell lines (Berki et al, 1991); 633nm laser light compromises the developmental potential of bovine embryos (Dinkins et al, 2002); 632.8nm laser light induces the acrosome reaction of bull sperm (Simonian & Voskianian, 1988); viability of blood cells is gradually decreased after laser irradiation (Luza & Hubacek, 1996) and exposure of actively replicating human skin fibroblasts to 193nm or 248nm laser radiation can cause chromosomal aberrations and therefore cause genotoxicity (Rimoldi et al, 1991). However, it has to be noted that there are no specific scientific studies which examine the effect of laser light on human gametes or embryos. The duration and in some cases the power of laser light used in the studies mentioned above may vary greatly from that which gametes and embryos would be exposed to from laser light bar code scanners.

## Advice

There is a substantial evidence base concerning the use of bar coding with human tissue, however there is little published data specific to human gametes or embryos in the assisted conception context.

In view of the limited specific evidence available we consider that it would not be appropriate for the HFEA to categorically conclude that bar code readers that use white light are completely free of risk. However, we are satisfied that there is no evidence that bar coding using white light imposes any notable additional risk to gametes and embryos when existing laboratory equipment (e.g. white light from microscopes) is taken into account.

There is evidence of damage to human cells from laser light, although it is recognised that gametes and embryos would only be exposed to laser light for a very short time from bar coding. For that reason we consider that centres should be aware of this when deciding whether to purchase bar coding solutions involving laser light.

Taking into account evidence from trials of bar coding systems and use of the technology in other settings we are satisfied about the efficacy of these systems for use in the ART laboratory.

## RFID

### Summary of evidence

The following evidence was used to form the advice we are issuing regarding the use of RFID systems. The main sources of information considered were test reports and technical information from manufacturers, scientific literature, reports from other organisations and reports of RFID systems in other settings:

#### Reports on use of RFID and efficacy

- RFID systems have been shown to be effective in the retail setting and a number of UK companies have recently introduced RFID systems into their stores. It is a relatively new technology in the medical setting but a number of hospitals across the world have successfully introduced RFID systems. For example: to track patients in an A&E department, to store patient information in a military hospital, improve blood transfusion safety and track pathology samples.
- The US Food and Drug Administration (FDA) believe that RFID is safe enough to approve 'Verichip', the world's first implantable RFID microchip for humans (134.2kHz), for medical uses in the US.
- The NHS National Patient Safety Agency (NPSA), in a recent report, concluded that RFID is a more sophisticated and potentially more powerful technology (than bar coding) but is currently relatively expensive, lacks specific standards and may face negative patient perceptions related to fears of covert tracking.

#### Safety issues

- A number of scientific studies and reviews suggest that radio frequency radiation of the wavelength used in RFID systems is not damaging to DNA, therefore suggesting that it is not damaging to human eggs and embryos: RF Radiation of 2459MHz was not found to cause chromosomal damage of lymphocytes significantly different to control cells (Vijaylaxmi et al, 1997); RF radiation of 2450MHz, 836MHz and 848MHz was not found to cause DNA damage to rat brain cells (Malyapa et al, 1997); RF waves are not sufficiently energetic to have genotoxic effects (Krewski et al, 2001; Meltz et al, 2003; Moulder et al, 1999).
- One RFID system manufacturer carried out a mouse embryo assay test which found no effect from radiation and no toxicity effect from labels. They also carried out an electromagnetic energy absorption test which found energy absorption to be negligible. However, the reliability and extent of these tests may be questionable.

- The frequency of radiation used in RFID systems is insignificant when taking into account radiation which may already be present in the environment. One RFID system uses a frequency of 13.45MHz. Mobile phones use frequencies of 900-2100MHz and wireless computer networks 2400MHz.
- However, we cannot conclude that the use of RFID systems is risk free because some evidence was found that radio frequency waves may cause damage to animal and human cells: RF Radiation of 2450MHz was found to cause chromosomal aberrations to human lymphocytes (Maes et al, 1993); RF radiation of 60Hz and 2450MHz was found to cause DNA strand breaks in rat brain cells (Lai & Singh, 1995, 1996 & 1998) and RF radiation of 900MHz was found to cause significant DNA damage to mouse sperm (King et al – still to be published). Although these studies used radio frequency radiation at a much higher frequency than that used in RFID systems marketed for the ART lab.

### **Advice**

While there is an evidence base for the use of RFID in a medical setting, there is no published data relating to human gametes and embryos in the assisted conception context. We consider that the frequency of the radio waves used in RFID in the assisted conception laboratory will be relatively low and therefore unlikely to result in any detectable change in temperature. Moreover, while the potential for DNA damage is small, there is not a strong enough evidence base to rule out DNA damage.

We are satisfied that the current evidence for the use of RFID does not indicate any notable additional risk to gametes and embryos when the presence of electromagnetic radiation in the environment is taken into account. However, there is not yet a compelling evidence base to enable the HFEA to categorically consider the technology to be risk free.

Taking into account evidence from the use of RFID technology in other settings we are satisfied about the efficacy of these systems for use in the ART laboratory.

### **Conclusion**

In view of SANT's findings the HFEA is content for clinics to continue exploring the use of bar coding and RFID solutions in the laboratory. We are confident that our review of literature is comprehensive enough to make the recommendations above. However, before implementing these technologies, there is still a need for clinics to satisfy themselves that they are effective and will not cause harm to gametes and embryos. The Authority recommends that clinics should consider the following issues when purchasing products:

- How the manufacturer satisfies itself that the technologies will not cause harm to human gametes and embryos. Whether the manufacturer has commissioned any independent reports as part of their quality assurance arrangements?
- Evidence available for the reliability of the product (e.g. data on miss read rates);
- How the manufacturer is satisfied that the technologies will continue to be effective when used in storage for up to 45 years (e.g. oncology samples in long term storage)

### **Specification**

The work that SANT has carried out underpins the enclosed provisional specification which details the legal requirements around coding, traceability, witnessing and audit. The specification is subject to change as and when the final requirements of the EU Tissues and Cells Directive become clearer.

We also wish to remind clinics that bar coding and RFID do not replace the need for manual double witnessing at the current time. Indeed the European Directive stipulates that a manual

witness is required to sign off the paper trail relating to traceability before material is used. We also consider that the patient's name should still appear on the dish/tube in addition to the identification code or tag.

We are aware that the ability of these technologies to meet witnessing requirements will be an important factor for centres when deciding whether to purchase RFID or bar coding systems. However, we need to explore this issue further before a decision can be made as to whether these systems can replace manual witnessing at certain stages. This is an issue that the HFEA will go on to look at in the future.

### **European Directive for Tissues and Cells**

There remain uncertainties around the requirements of the Directive, which have still not been finalised. The draft technical requirements that have been published for consultation provide a good idea about the final detail and are likely to be subject to only minor changes. However, Article 25 of the Directive states that the Commission shall design a single European coding system. It is highly unlikely that the Commission will do this before the Directive comes into force in April 2006, and it may be a few more years before any single coding system is fully implemented across Member States. In the meantime clinics will be expected to meet the requirements summarised in the specification. Clinics will be made aware of this issue when developing their coding, traceability, audit and witnessing systems.

**ANNEX C: Current Witnessing Guidance**

CH(04)02

To: All Persons Responsible

7 June 2004

Dear Colleague,

**Revised Directions on Witnessing**

The HFEA has been informed of two incidents in the past 9 months where the wrong embryos were selected and thawed. Both of these incidents were caused by avoidable administrative and procedural errors. Although a pregnancy did not result, these were nonetheless very serious incidents that happened despite clinics believing that their procedures were safe.

The occurrence of two such incidents in a relatively short space of time is extremely concerning. We are therefore issuing with this letter revised Directions on Witnessing of Clinical and Laboratory Procedures to replace the existing Directions D2002/1 which were issued with the Chair's letter CH(02)01 on 29 August 2002. These Directions also supersede the requirements in Chapter 15 of the 6<sup>th</sup> edition of the Code of Practice. The revised Directions strengthen the existing procedures by requiring the use of **Unique Patient Identifiers** for all patients, including donors and recipients. In particular, your attention is brought to point 7 'Gamete/Embryo Freezing' where 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).

All licensed Centres are reminded of the requirement to have procedures in place to double-check the identification of:

- the individuals undergoing treatment,
- the sperm and eggs at the time of insemination;
- the embryos and the patient at the time of embryo transfer;
- the gametes and embryos at the time of cryopreservation and thawing.

Centres are also asked to review key administrative procedures so that primary data (e.g. Patient Records) should be available for verification against patient name, date of birth and **one Unique Patient Identifier**.

Centres should introduce as a matter of urgency, if they have not already done so, the following procedures in their witnessing protocols:

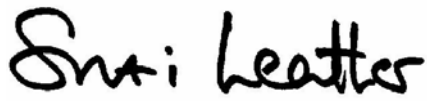
- (i) Each stage of the witnessing paper trail should be checking the same two methods of identification.
- (ii) A system of active identification of patients should be introduced, for example to avoid confusion where two patients on a clinic's register have the same name and date of birth. This should include the use of a further piece of information to ensure that the patient being treated is the same as the patient in the notes.
- (iii) A training programme for new staff, and refresher training, should be in place to ensure that the principles of witnessing procedures are fully understood and that the

- centre specific protocols are followed.
- (iv) Protocol compliance should be checked regularly, including at the time of the centre's internal annual audit.

Centre's compliance with these Directions will be followed up at inspections. Centres are reminded that under S18(1)(c) of the Human Fertilisation & Embryology Act 1990, a licence committee may revoke a centre's licence if the person responsible has failed to comply with Directions issued under the Act.

If you have any queries with regard to this new policy please contact Mr Charles Lister, Head of Policy on 020 7291 8230, e-mail [charles.lister@hfea.gov.uk](mailto:charles.lister@hfea.gov.uk) or Dr Christina Panton, Policy Manager on 020 7291 8232, email [Christina.panton@hfea.gov.uk](mailto:Christina.panton@hfea.gov.uk).

Yours faithfully,

A handwritten signature in black ink that reads "Suzi Leather". The signature is written in a cursive, slightly slanted style.

Suzi Leather  
Chair HFEA

**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:

*Sm. Leathes*

**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</p>	

	<b>Clinical / Laboratory Activity</b>	<b>Core Witnessing Procedure Required</b>	<b>Checked</b>
		<p>appropriate person.</p> <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>	

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

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