ART POLICY GUIDELINES

Laboratory Guidelines for 2008 (1st edition)

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1. Definitions

ART encompasses a variety of clinical treatments and laboratory procedures which include the handling of human oocytes, sperm, or embryos, with the intent of establishing a pregnancy. This includes, but is not limited to, *in vitro* fertilization (IVF), gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT), embryo biopsy, preimplantation genetic diagnosis (PGD), embryo cryopreservation, oocyte or embryo donation, and gestational surrogacy.

2. General Standards

2.1 Personnel

High standards of integrity are required from those responsible for ART accredited activities – and from those taking part in those activities – in order to:

- Protect the interests and privacy of people seeking treatment
- Protect the interests and privacy of people considering donations
- Guard against the misuse of gametes and embryos
- Protect the welfare of couples and potential children born as a result of treatment and any other children who may be affected by the birth.

There should be a backup system in place for all personnel essential to a program. A single individual may fulfil the requirement for expertise in one or more areas. An ART program must include the following personnel:

- A designated overall practice director, medical director, and laboratory director. One individual may fulfil more than one of these positions, but the medical director must be a registered sub-specialist in Reproductive Medicine (with HPCSA).
- An individual who is a sub-specialist in Reproductive Medicine with training and experience in reproductive endocrinology, particularly in the use of ovulation-inducing agents and hormonal control of the menstrual cycle.
- An individual with experience in oocyte retrieval techniques.
- An individual with specialized training and experience in gynaecologic sonography who provides the monitoring of follicular development.
- An individual experienced in male reproduction (andrology) with special competence in semenology.
- An embryology laboratory director with personal experience in the organization and maintenance of a clinical embryology laboratory and in tissue culture techniques.
- Access to a mental health professional with expertise in reproductive issues.
- An individual with specialized training and experience in gamete and embryo cryopreservation techniques, when gamete and/or embryo cryopreservation is offered.
- An individual with specialized training in gamete biology and micro-operative techniques or access to such an individual, if oocyte and/or embryo micro-operative techniques are offered.
- Appropriate personnel to perform hormonal assays. An outside laboratory that has demonstrated adequate competence, quality control, and service, may be used for rapid assays of all the necessary reproductive hormones (including estradiol and

progesterone). Such hormone assays should be performed by a laboratory that meets Clinical Standards.

- Appropriate nursing support.
- An individual or consultant with specialized expertise in genetics or genetic counselling.

Where formal qualifications are insufficient, it is recommended that centres arrange for staff to take part in scientific, clinical, nursing or counselling training.

2.2 Facilities

The Person Responsible (i.e. the Medical Director) must ensure that proper equipment and suitable practices are used in all service provision and support to patients.

If a centre decides to use outside facilities, the Person Responsible is expected to be satisfied that those facilities are duly accredited.

Centres are expected to be fully aware of the microbiological hazards of handling gametes and embryos and comply with regulations regarding waste disposal and infection control.

The location used for egg collection for *in vitro* fertilisation is expected to be as close as is practical to the laboratory where fertilisation is to take place. The procedure room where conscious sedation is used should have adequate monitoring and resuscitation equipment.

Facilities for the cryopreservation of gametes and embryos are expected to be:

- Customised, secure and dedicated; and
- Adequate for the volume and types of activities to be carried out.

Appropriate emergency procedures are expected to be in place in all centres to respond to damage to storage vessels, embryo incubators etc.

Written procedures are expected to provide for the safe use of straws and to minimise the risk of sample losses or contamination.

Centres are expected to have written standard itemised operating procedures as follows:

- Cleaning vessels
- Filling vessels
- Securing vessels

- Freezing and thawing procedures
- Location and duration of storage
- Handling of contaminated samples.

Centres are expected to also take steps to minimise risks arising from the transfer of material between centres.

Centres with storage facilities are expected to provide secure, controlled access to gametes and embryos.

2.3 Maintaining and Improving Standards

Centres are expected to establish an effective system for monitoring and assessing laboratory practice.

Centres are expected to establish procedures for improving and updating laboratory practice.

2.4 Advertising

Centres may wish to circulate information about the variety of treatments they offer. Publicity materials are expected to conform to the guidelines of the HPCSA. Publicity materials are expected to also be designed and written with regard to the particularly sensitive issues involved in recruiting donors.

3. Liability / Errors

3.1 Conscientious Objection

Prospective employees at an accredited centre are expected to be provided with full descriptions of the centre's activities.

3.2 Adverse Incidents

Each treatment centre is expected to have a written policy and procedure for dealing with adverse incidents.

Adverse incidents are defined as any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to patients, their embryos and/or gametes, or to staff of an accredited centre.

Where an adverse incident has occurred, centres are expected to:

- Review relevant procedures in order to minimise the risk of any reoccurrence of the incident.

4. Storage and Handling of Gametes and Embryos

4.1 General Obligations

Treatment centres are expected to ensure that the highest possible standards are maintained in the storage and handling of gametes and embryos.

4.2 Screening

All patients placing gametes, embryos and ovarian or testicular tissue in storage are expected to be screened for Hepatitis B, Hepatitis C and HIV.

It is expected that screened samples will be kept in a separate cryostore from unscreened samples. Unscreened samples include:

- Any samples stored before comprehensive screening of all patients was introduced; and
- Any samples in temporary storage while the results of screening test are obtained.

4.3 Security

It is expected that gametes and embryos will be stored in a designated security area with controlled access.

The Medical Director is expected to permit access to the designated security area only to the treatment centre's named individuals for whom access is essential in the course of their work. No other people are expected to have access to gametes and embryos.

In order to minimise the amount of handling required in retrieving gametes and embryos, their storage location is expected to be recorded in detail. Each and every occasion when gametes or embryos are handled is expected to be recorded.

There is expected to be an effective monitoring system to ensure high standards of security wherever gametes and embryos are handled or stored.

4.4 Identification

The sources of gametes and embryo are expected to be accurately recorded and labelled in a way that is not susceptible to unauthorised or undetectable alteration.

Records are expected to enable authorised staff to trace what happens to an individual embryo, egg or sperm sample from the date of collection. This also applies to fresh embryos and frozen embryos once thawed.

4.5 Storage Review

Storage centres are expected to carry out reviews, at least annually, of the status of stored gametes and embryos. The purposes of these reviews are expected to be:

- To reconcile the centre's records with the genetic material stored; and
- To review the purpose and duration of storage; and
- To identify action that needs to be taken.

Storage centres are expected to endeavour to maintain contact with the providers of stored gametes and embryos to inform them when the terminal storage date for their gametes and embryos is approaching as agreed by mutual consensus. Centres are expected to inform providers of the importance of keeping the centres informed of a change in contact details.

4.6 Contamination

It is expected that gametes and embryos intended for treatment will not be placed in close proximity to radioactive material or any known potential source of infection, chemical or atmospheric contamination.

4.7 Transfer of Gametes and Embryos

Where gametes or embryos are transferred between sites, adequate arrangements are expected to be made to protect their quality and security. All storage, treatment and research centres are expected to operate a fail-safe mechanism to ensure that correct gametes and embryos are transferred.

5. Research

5.1 General Standards

Research projects in ART should be approved by the relevant bona fide Research Ethics Committee and in accordance with the National Health Act.

6. Records

6.2 Confidentiality

Centres must ensure that information provided in confidence is kept confidential and only disclosed in the circumstances permitted by law. It is expected that patients will not have access to any other person's records (including those of a patient's spouse or partner) without that other person's prior consent.

6.3 Access to Health Records

Centres are expected to establish written procedures for considering applications for access to confidential records.

Centres are expected to allow all donors and clients who provide information about themselves to the centre access to the record of that information and an opportunity to correct it.

POST SCRIPT

Certain points are yet to be debated and finalized in these guidelines. Areas with question marks will be finalized once opinions are heard from SASRSS members"

7. Use of Gametes and Embryos

7.1 Obtaining Gametes and Embryos

Centres may only import and export gametes and embryos in accordance with the regulations in the National Health Act.

7.2 Clinical Use

It is expected that eggs, sperm or embryos created from the patient/s will not be used for treatment where there are reasonable grounds for believing that procedures to which the eggs or sperm have been subject carry an actual, or reasonable theoretical risk of harm to their developmental potential.

Similarly, it is expected that embryos will not be used for treatment where there are reasonable grounds for believing that procedures to which the embryos themselves have been subject carry an actual or a reasonable theoretical risk of harm to their development, or a theoretical risk of harm to their developmental potential.

It is expected that attempts to produce embryos *in vitro* will not be made unless there is an intention to store or use the resulting embryos(s) or unless there is a specific reason why it is necessary to do so in connection with the provision of treatment services for a particular woman. On each such occasion:

- It is expected that the reason will be explained to the woman
- It is expected that counselling relating to the implications of the treatment is offered to her
- The written consent of each person providing the gametes must have been obtained.

Frozen embryo transfer is a regulated activity. Where a woman has had an embryo stored and subsequently wishes to have treatment transferring the embryos to her, the treatment centre must:

- Consider her for treatment in the usual manner
- Check that the treatment is in accordance with the terms of the consent given by both parties.

It is expected that gametes or embryos that have been exposed to a material risk of contamination and which might cause harm to recipients or to resulting children will not to be

used for treatment. If in any doubt about these risks, treatment centres are expected to seek expert advice.

Treatment centres are expected not to:

- ??Select the sex of embryos for social reasons (to be debated or discussed further by SASRSS executive)

7.3 Termination and Disposal

Where consent to continued storage has been withdrawn by only one gamete provider, centres are expected to take steps to ensure that the other gamete provider (unless that person is a donor) is informed of the centre's obligation to dispose of the embryos. Where the women/partner to be treated is not one of the gamete providers, the centre is expected to take similar steps to ensure that she is informed of the obligation to dispose of the embryos.

7.4 People Seeking Treatment

Additional information

It is recommended that sperm is produced at the accredited facility. In the event that the sperm sample is produced outside of the facility, this should be documented as such.

7.5 Transfer of Eggs and Embryos

It is recommended that women will not be treated with gametes, or with embryos derived from gametes, of more than one man or woman during any treatment cycle.

In all cases it is expected that the appropriate number of eggs or embryos to be transferred, and the reasons for this (Including the risks of multiple pregnancy) will be assessed and discussed with the woman and her partner and her consent placed in the medical records.

Use of patient's own egg or embryos (fresh or frozen)

7.6 Donor Insemination

Before commencing treatment by donor insemination, the treatment centre is expected to discuss with the patient the number of treatment cycles to be attempted in the event of failure to conceive, before further investigation takes place and thereafter, and review this situation at regular intervals.

7.7 People Providing Gametes and Embryos for Donation

If embryo donation is being considered where an embryo has been created using partner sperm produced at home, the treatment centre must take that fact into consideration.

Where a donor of gametes or embryos has, as a result of such donations achieved the maximum limit of live births as prescribed by the National Health Act, it is expected that the donor's gametes or embryos will not be used on a subsequent occasion (for deliberation by SASRSS).

A 'live birth event' is the birth of a live child or children. This means that the birth of twins or triplets is expected to be considered a single 'live birth event' (for deliberation by SASRSS).

- Issues of siblings, and frozen embryos (for deliberation by SASRSS)

7.8 Export of Gametes

Gametes from donors who have reached the maximum number of live birth events should not be exported. The export of gametes should be done in accordance with the regulations of the National Health Act.

7.9 Posthumous Use

Insemination of a woman at an accredited treatment centre using her late husband or partner's sperm is regulated under the National Health Act.

9. Intra-Cytoplasmic Sperm Injection (ICSI)

9.2 Definitions

ICSI is the type of IVF treatment that involves the injection of a single sperm straight into an egg.

The ICSI practitioner is defined as the person who injects the spermatozoon into the egg. An ICSI practitioner should fulfil the requirements as per the SASRSS accreditation guidelines.

Compilation of these guidelines

These guidelines were modelled on the "HFEA. *Code of Practice*. 6th Edition" and adapted for South African practitioners in the Sub-Speciality of Reproductive Medicine.

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