SASRSS ACCREDITATION OF INFERTILITY SERVICES (Updated 2008)

GUIDELINES AND MINIMUM STANDARDS:

Minimum Standards for In Vitro Fertilization, Gamete Intra Fallopian Tube Transfer and related Procedures:

INTRODUCTION:

Treatment of the infertile couple is evolving rapidly. Perhaps no area in this speciality better exemplifies the advances of technology than assisted reproductive technology. (ART) The document is not designed to cover all clinical situations or practices, but rather should be reviewed by ART program and laboratory directors to be certain that their programs' practice reflects current recommendations. It includes sections on ethical and experimental procedures, record keeping, and informed consent, all of which are areas of increased importance in contemporary ART practice. This document is intended to enhance the already high standards practised by ART programs.

PERSONNEL:

An ART program must include, as a minimum, personnel with the following expertise.
A single individual may fulfil the requirement for expertise in one or more areas. There should be a backup system in place for all personnel essential to a program. There must be a minimum of one full-time specialist Gynaecologist and another gynaecologist available as a back up person. There should be one embryologists working in the unit and another embryologist available as a back up person. All these full-time personnel must be qualified and experienced as specified in the section on "Specialised Training and Experience".

Each program must have:

1. A designated overall practice director, medical director or laboratory director.
   One individual may fulfil more than one of these positions; however the medical director must be a registered specialist Reproductive Medicine Sub-Specialist Gynaecologist.

2. An individual with training or experience in reproductive endocrinology, particularly in the use of ovulation - inducing agents and hormonal control of the menstrual cycle.

3. An individual with the expertise in pelvic reparative (infertility) surgery as well as experience in laparoscopic and ultrasound guided oocyte retrieval techniques.

4. An ultrasonographer or medical practitioner with specialised training and experience in gynaecologic sonography that provides the monitoring of follicular development.

5. An individual experienced in male reproduction (andrology) with special competence in semenology and testicular sperm retrieval techniques. If this individual is not an urologist, then there also should be an available consultant urologist with expertise in reproductive surgery.

6. An embryology laboratory director. This laboratory director must have personal experience in the organisation and maintenance of a basic or clinical embryology laboratory ,as well as in tissue culture techniques.

7. If gamete and or embryo cryopreservation is offered, there should be an individual with specialised training and experience in the gamete and embryo cryopreservation techniques.

8. If oocyte microoperative techniques are offered, there should be an individual with specialised training in gamete biology and experience in microoperative techniques.

9. Rapid assays of all the necessary reproductive hormones (including estrodial, LH, and Progesterone) should be available as required. A program may utilise outside laboratories which demonstrate adequate competence, quality control, and service.

SPECIALISED TRAINING AND EXPERIENCE:

1. It is recommended that a specialist gynaecologist with experience in reproductive endocrinology and infertility direct the follicular recruitment phase of the ART cycle.

2. Each gynaecologist performing oocyte retrievals should have performed at least 20 follicular aspirations under the direct supervision within a practice that meets these standards. Satisfactory completion of this training should be documented by a signed letter by the practice director. Each gynaecologist should continue performing a minimum of 30 aspirations and transfers per year. It is recommended that the gynaecologist involved in the supervision of the follicular recruitment and oocyte retrieval procedures be responsible for the ultrasound monitoring of follicular development and that an ultrasound scanner be available in the clinical area for this purpose.

3. The embryo laboratory director should be an individual with demonstrated knowledge of all laboratory aspects of ART. To be acceptable as an embryo laboratory director, an applicant should fulfil both of the following requirements.

    a. Hold an earned doctorate degree (Ph.D.) from an accredited institution in a chemical, physical, or biological science as the major subject or a medical degree from an accredited institution or have qualified as a laboratory director or supervisor for at least five years. The laboratory director should have the expertise and or special training in biochemistry, cell biology, and physiology of mammalian reproduction with experience in experimental design, statistics and problem solving/ troubleshooting. The laboratory director should be responsible for formulating laboratory policies and protocols and should communicate regularly with the medical director regarding patient progress and protocols as they affect the laboratory aspects of treatment.

    b. Have 5 years of documented pertinent experience in a program performing IVF related procedures. This experience should include:

        1) Familiarity with the laboratory quality control, inspection and accreditation procedures.

        2) Detailed knowledge of cell culture, ART and andrology procedures performed in mammalian systems.

If the medical director is also the laboratory director, there should be a qualified, designated laboratory supervisor: The embryo laboratory supervisor should have a Bachelors or Masters degree in a chemical, physical, or biological science as a major subject.

The laboratory supervisor should have had a period of training of at least 6 months and completed at least 80 ART procedure in a program that performs at least 100 IVF procedures per year with the minimum annual 20% IVF pregnancy rate per transfer cycle.

A procedure is defined as a combination of the examination of follicular aspirates, insemination, documentation of fertilization and preparation of embryo transfer. Satisfactory completion of this period of training should be documented by a signed letter from the laboratory director of the training practice. In lieu of formalised training, a similar experience within the directors own practice is sufficient, provided the practice has performed at least a total of 100 retrievals and has had at least an annual 20% pregnancy rate per transfer cycle.

The embryo laboratory technologist should have an earned Bachelors degree from an accredited institution with a chemical, physical or biological science as the major subject. The technologist should have documented pertinent experience in cell culture and sterile technique with evidence of completion of 30 complete IVF procedures under continuous supervision of the laboratory director and supervisor. Experience and documented training in cell culture, sperm egg interaction, or related areas in animal reproduction are desirable. The embryology laboratory technologist works under the supervision of the laboratory director. Programs for the appropriate training of the embryo technologist should in place for each program with documentation of completion of each employee.

Each staff embryologist (including the embryology laboratory director or supervisor) should perform at least 20 IVF procedures a year. At least 20% of the procedures must be ICSI procedures.

Among the embryology laboratory staff there should be one or more persons with knowledge and experience in the following fields:

1. Preimplantation Embryology
2. Andrology
3. Prefertilizaiton and postfertilization events

GIFT AND RELATED PROCEDURES:

Because technical consideration at the time of oocyte recovery may prevent tubal transfer, it is recommended that GIFT only be performed in a facility that is accredited to carry out IVF, as an alternative or in addition, in the event that the GIFT procedure turns out not to be feasible and or excess oocytes are recovered. Accordingly GIFT program must have an embryo laboratory and personnel capable of fertilizing non transferred oocytes and freezing the resulting embryos if they are of good quality. That is not to say that GIFT is not an appropriate treatment choice for selected patients, but only that the embryo laboratory equipment, procedures, quality control and personnel must be capable of successfully performing IVF and ICSI.

QUALITY ASSURANCE:

The quality of the embryo laboratory is recognised as one of the most important components of a successful ART program. However there are inherent difficulties involved in evaluating the " quality " of any laboratory system. It is therefore necessary to allow flexibility in the interpretation of any standards of the quality to accommodate different methods of maintaining laboratory quality.

The following quality control procedures should be considered as guidelines, subject to reasonable amendment:

1. Laboratory " contact materials" are defined as those items (disposable or recycled) that come into direct physical contact with gametes, embryos, or their supporting culture media.

2. Assays need to be applied to cell culture media and contact materials to rule out toxins, inappropriate ionic concentration, microbial contamination, or other potential hazards to human gametes or embryos.

3. Each laboratory should design its individual quality control procedures and protocols about these quality control procedures should be available for accreditation purposes.

4. All media used for ART procedures should have the following information available for each batch: Lot # of media, date prepared, bioassays, osmolality, pH, method of sterilisation, and expiration date.

LABORATORY FACILITIES:

Embryo laboratories should have the standard features of a " clean room" including controlled temperature and humidity and filtered air with an appropriate number of air changes per hour. Walls and floors should be composed of materials easily wash and disinfected and the use of carpeting should be avoided. Aerosols and toxic pest control substances should not be used in the embryo laboratory.

The embryo laboratory should be adjacent to the oocyte collection / procedure room. The presence of a general access hallway between the embryo laboratory and the procedure room is not recommended. As and alternative, oocyte identification and isolation can be performed in the procedure room using self contained, temperature - controlled and enviromental controlled microscope / incubator unit. Oocytes can then be transported within this unit (or in a portable incubator) to the embryo laboratory at the conclusion of the procedure. Subsequent handling of gametes and embryos should be performed in a specified clean area or in the portable microscope/ incubator unit described above.

EQUIPMENT AND MAINTENANCE:

All major equipment items should be adequately maintained and have a written schedule of preventative maintenance and / or certification services. Large laboratory items (e.g. Laminar flow hoods) should be certified by on - site inspection on a regular (6 -12 months) basis with appropriate record keeping. Equipment such as balances, pipettes, thermometers, pH meters, centrifuges, and refrigerators should be calibrated on a regular basis with the appropriate records kept of these.

Routine quality assurance of equipment should include daily checks of refrigerator, freezer, and incubator humidity level; external verification of the gaseous environment in the incubators; level of liquid nitrogen in any embryo or gamete storage container; and the status of gas cylinders and / or liquid nitrogen reservoir supplies. Written records of these checks should be maintained. There should be regular preventative maintenance schedule for complete cleaning and decontamination of incubators, laminar flow hoods, and related items.

Power backup must be available in the laboratory for at least a 24 hour period. Backup systems with for the gas supply to incubators also need to be catered for.

EMBRYO AND GAMETE CRYOPRESERVATION:

Because human embryos cannot be replaced, programs should have freezing equipment power failure backup systems. Embryo freezers should be calibrated against an external thermometer or thermocouple.

Duplicate records on frozen embryos should include as a minimum, the developmental stage at which frozen, freezing protocol is used, recommended thawing procedures, and the physical location of each embryo within a storage container should be kept in the laboratory and with the practice director. Embryo containers should be labeled with the patient's name, identification number and the date of cryopreservation.

The same record keeping and backup systems should be in place for gamete cryopreservation.

SAFETY:

Embryologist are advised to wear non-toxic (non-powdered) gloves while handling gametes and embryos, in addition to other safety measures as appropriate. These conditions are recommended for both the protection of the embryologist as well as to maintain optimal quality of the culture conditions.

Written procedures should be established for the double-checking and verification of patient identity and the identification of the gametes and embryo samples. These procedures should be performed before insemination, embryo thawing, or embryo transfer procedures.

RECORD KEEPING:

Documentation of the proper identification, outcome and disposition of all oocytes and embryos is of utmost importance. This documentation should identify all clinic and laboratory personnel who have handled gametes and embryos during each procedure.