CODE OF PRACTICE FOR ASSISTED REPRODUCTIVE TECHNOLOGY UNITS

Fertility Society of Australia

Reproductive Technology Accreditation Committee

(revised October 2010)

ISBN: 978-0-947285-03-6

This document replaces the Code of Practice for Assisted Reproductive Technology Units May2008.

For more information, contact:

Fertility Society of Australia
c/- Waldron Smith Management
61 Danks Street
Port Melbourne Victoria 3207
Telephone: +61 3 9645 6359
Website: http://www.fertilitysociety.com.au

CONTENTS

INTRODUCTION

The RTAC Code of Practice

This Code of Practice for Assisted Reproductive Technology (ART) Units has been developed by the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia (FSA). The purpose of the RTAC Code of Practice is to:

- Promote continuous improvement in the quality of care offered to people accessing fertility treatment.
- Provide a framework and set criteria for the auditing process that leads to accreditation of organisations that deliver fertility services.
- Ensure the auditing process is carried out in an independent, non-adversarial and constructive manner.

Fundamental to the delivery of ART services is that patients and their offspring remain the most important consideration in all decisions. Organisations aspire to deliver services in a manner that recognises patients' cultural and individual values and beliefs, upholds their dignity and privacy, and acknowledges the rights of children born through ART to know their genetic origins and health outcomes.

Background:

The code was first introduced in 1986, when the FSA produced a series of standards as a guide for ART units. In 1987, RTAC was established and added explanatory notes to many of the original standards drawn up by the FSA. This initial code was revised in 1992, 1997, 2001, 2005 and has been further developed and revised in 2008.

In Australia, the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* defines an accredited ART centre as a 'person or body accredited to carry out assisted reproductive technology by the Reproductive Technology Accreditation Committee of the Fertility Society of Australia'. Under this Act, a person commits an offence (imprisonment for 5 years), if the person 'intentionally uses, outside the body of a woman, a human embryo that is not an excess ART embryo; and the use is not for a purpose relating to the assisted reproductive technology treatment of a woman carried out by an accredited ART centre'. As a result, it is currently an offence in Australian Commonwealth law to use human embryos in any way without RTAC licensing. New Zealand has the HART Act 2004 which governs the delivery of ART services.

Therefore, compliance with the RTAC Code of Practice is mandatory for Organisations involved in the treatment of patients using ART.

RTAC Certification:

An ART organisation's compliance with the RTAC Code of Practice must be reviewed on a regular basis. An ART organisation includes associations, agencies, groups, independent practitioners and individuals accountable for the delivery of services to the patient**.**

The review is conducted as an audit by an independent Certification Body (CB) that is approved by the Joint Accreditation System of Australia and New Zealand (JAS-ANZ). The process for RTAC certification is defined in the RTAC Certification Scheme. Therefore, the RTAC Code of Practice should be used in conjunction with the RTAC Certification Scheme.

Assisted Reproductive Technology (ART)

ART involves clinical treatments; counselling services; and laboratory procedures for the assessment and preparation of human oocytes, sperm or embryos. ART includes IVF; gamete intrafallopian transfer; zygote intrafallopian transfer; intracytoplasmic sperm injection; embryo or gamete cryopreservation; surgical sperm recovery; oocyte, semen or embryo donation; blastomere biopsy for preimplantation genetic diagnosis; gestational surrogacy and intrauterine insemination (IUI).

An ART Unit is a facility with a laboratory that assesses and prepares human gametes and/or embryos for therapeutic service, possibly across a range of sites of clinical activity.

Scope of the Audit

The scope of the audit by a CB will include site visits to all ART units.

Certification Scheme

The RTAC Certification Scheme details the requirements and procedures for the certification of ART units to the Code of Practice. ART units holding a current RTAC Certification issued by a JAS-ANZ accredited RTAC Certification Body will be eligible for RTAC consideration for recognition as an RTAC accredited ART unit.

The Code of Practice is to be observed in units involved in the treatment of patients with assisted reproductive technology including donated gametes or embryos and IUI.

Certain ART units in Australia and New Zealand have also been designated by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) as training units for the subspecialty of reproductive endocrinology and infertility. The additional requirements of those units are beyond the scope of this Scheme.

Compliance:

ART units must also comply with relevant legislation and regulations. In rewriting the Code, RTAC has attempted to align it with the regulatory and legislative requirements. However, there may be differences in detail between this Code, National Health and Medical Research Council (NHMRC) guidelines, and the legislation and associated regulations relevant to ART that have been proclaimed by various governments. In such cases, as a general rule, national legislation overrides state legislation, and state legislation overrides regulations / guidelines.

PART 1 CRITICAL CRITERIA

(AUDITED ANNUALLY IN ACCORDANCE WITH THE RTAC CERTIFICATION SCHEME)

Following is a table of 12 **Critical Criteria**. Associated with each is a list of the types of evidence that a CB will consider to be **measures** that satisfy the criteria.

CRITICAL CRITERIA	MEASURE
1. Compliance **The Organisation must comply with statutory and regulatory requirements.**	Provide evidence of: • identification and communication of statutory and regulatory requirements. • how changes to external requirements are integrated into work practices. • communication, implementation, and review of all policies/procedures. • compliance with the RTAC Code of Practice. • records of current signed Deed of Agreement with the FSA. • all human research having been approved by a Human Research Ethics Committee (HREC) registered by the NHMRC Australian Human Ethics Committee or New Zealand equivalent. • compliance with the NHMRC Ethical Guidelines on the use of ART in clinical practice and research (2007) or New Zealand equivalent, except where specific alternate policies have been directed by a registered HREC affiliated to the Unit.
2. Key Personnel **The Organisation must ensure access to competent staff. Staff must include:** • **Medical director** • **Scientific director** • **Nurse manager** • **Senior counsellor**	Provide evidence of: • qualifications, training, education and experience of key personnel. (Refer to Attachment 1)

CRITICAL CRITERIA	MEASURE
3. Complaints Management **The Organisation must acknowledge and investigate complaints.**	Provide evidence of implementation and review of policies/procedures which include: • information on how patients make a complaint and how they receive feedback. • acknowledgement and investigation of complaints. • systematic recording, review and corrective action of complaints.
4. Adverse Events **The Organisation must acknowledge and investigate adverse events.**	Provide evidence of implementation and review of: • policies/procedures to systematically collect, analyse causal factors, review and act on all adverse, unplanned and untoward events.
5. Identification and Traceability **The Organisation must ensure that gametes, embryos and patients are correctly identified and matched at all times.**	Provide evidence of implementation and review of: • policies/procedures to identify when, how and by whom the identification, matching, and verification are recorded for gametes, embryos and patients at all stages of the treatment process • the process that constitutes the traceability of gametes and embryos at all stages of the treatment cycle including where transport is involved. • regular (at least annual) audit of the patient, gamete and embryo identification process.

CRITICAL CRITERIA	MEASURE
6. Drug Administration **The Organisation must ensure the safe management of drug storage, supply and administration.**	Provide evidence of implementation and review of policies/procedures which include: • authorising orders for drugs that are to be supplied or administered to patients. • recording in the patient's individual file / record, all drugs, including batch numbers where applicable, that are supplied or administered to patients by the ART Organisation. • maintenance of accurate records and audit of the drug management system. • the safe procurement, storage and disposal of drugs. • management of returned drugs to ensure drugs are not reissued.

CRITICAL CRITERIA	MEASURE
7. Multiple Pregnancy **The Organisation must minimise the incidence of multiple pregnancy.**	Provide evidence of implementation and review of policies/procedures that: • regularly audit (at least annually) multiple pregnancy rates and corrective actions that continuously attempt to reduce the incidence of multiple pregnancies in all treatment cycles, including artificial insemination and ovulation induction. • recommend to patients that no more than one embryo or oocyte is transferred in the first treatment cycle where the oocyte is obtained from a woman aged less than 35 years at the time of oocyte collection. • must ensure that no more than two embryos or oocytes are transferred in any one treatment cycle in a woman under the age of 40 years at the time of oocyte collection. • must ensure that no more than two embryos or oocytes are transferred to a recipient woman, of any age, in any one treatment cycle, where the oocytes are donated from a woman aged less than 40 years at the time of oocyte collection. • must ensure that patients receive information on the economic, medical, social and psychological hazards associated with multiple pregnancy.

CRITICAL CRITERIA	MEASURE
8. Ovarian Hyperstimulation Syndrome **The Organisation must minimise the incidence of Ovarian Hyperstimulation Syndrome (OHSS).**	Provide evidence of implementation and review of policies/procedures: • for the identification and management of patients at risk of or experiencing OHSS. • that measure and attempt to minimise the incidence of OHSS. • that must ensure patients receive information on the risks, symptoms and management of OHSS. • that must ensure patients receive information on how to access help, advice or care out of normal hours or in the event of medical emergency.
9. Emergency Care **The Organisation must ensure access to emergency care.**	Provide evidence of implementation and review of policies/procedures: • on emergency physical and psychological care. • that must ensure patients receive information on how to access emergency care including out of normal hours.
10. Data Monitoring **The Organisation must undertake regular reviews of treatment outcomes.**	Provide evidence of implementation and review of policies/procedures: • to identify, collect, analyse and review data to monitor treatments and treatment outcomes at planned intervals.

CRITICAL CRITERIA	MEASURE
11. Data Reporting **The Organisation must provide the Australian and New Zealand Assisted Reproduction Database (ANZARD) with required data in the stipulated timeframe.** **The Organisation must pay all FSA/RTAC fees.** **The Organisation must inform patients of the uses to which their medical information may be put**	Provide evidence of: • compliance with ANZARD data input. • compliance with FSA / RTAC fee payment. • implementation and review of policies/procedures for informing patients on the use of identifying and de-identified medical information that will be provided to statutory, regulatory and legislative authorities.
12. Donor Requirements **The Organisation must ensure gametes, embryos and tissues are safe for donation.**	Provide evidence of compliance with Attachment 2. Review recipient and donor files using ANZARD supplied file codes.
13. Reproductive health of infertility patients **The Organisation must ensure that it meets the reproductive health needs of the men and women under its care**	Provide evidence of implementation and review of policies/procedures so that: Infertile women undergo clinical evaluation for co-existing reproductive health or gynaecological problems, or those arising as a result of ART treatment Infertile men undergo clinical evaluation for co-existing reproductive health and related problems, or those arising as a result of ART treatment There are pathways of referral for endocrine and andrological expertise

PART 2 GOOD PRACTICE CRITERIA

AUDIT OF ALL GOOD PRACTICE CRITERIA AT THE INITIAL CERTIFICATION AUDIT AND SUBSEQUENTLY OVER A THREE YEAR PERIOD IN ACCORDANCE WITH THE RTAC CERTIFICATION SCHEME

Following is a table of **Good Practice Criteria**. Associated with each is a list of the types of evidence that a CB will consider to be **measures** that satisfy the criteria.

GOOD PRACTICE CRITERIA	MEASURE
1. Quality Management System (QMS) **The Organisation must have a management system allowing planned, implemented, coordinated, and appropriate service delivery which meets the needs of all stakeholders.**	Provide evidence of implementation and review of the following QMS elements. 1 - Quality Management policy that: • demonstrates management commitment. • outlines the scope of services provided, including identification of key outsourced personnel and services. • shows organisational objectives. 2 - Management review processes that review the scope, organisational objectives and relevance of quality management system. 3 - Integration of all personnel and services: • Records confirming service integration. • Records of service agreements with key contractors and key contracted service providers. 4 - Systems of internal communication: • copies of meeting minutes, emails, memos. 5 - Document control system: • evidence of implementation, approval and review of internal and external documents. 6 - Records management: • compliance with statutory and regulatory authorities. 7 - Personnel and training: • management commitment to adequate staffing, training and ongoing education. • Staff and/or contractors with appropriate and documented expertise to cover all aspects of

GOOD PRACTICE CRITERIA	MEASURE
	the organisation's services. • identification of training and education needs. • records of induction, training and ongoing education. • records of relevant professional registration • outline of responsibility and authority.
1. QMS (continued)	8 - Competency of personnel: • competency criteria including skill, education, training and experience. • records of individual's competency for all services both internal and external. 9 - Buildings and facilities: • assessment of requirements to meet organisational goals. • adequate facilities and equipment to meet objectives. • records of validation, maintenance and service of equipment. • security, particularly to protect confidentiality of records and integrity of gametes and embryos. • management of risks. e.g. emergency equipment, power, gas. 10 - Risk management and infection control: • assessment of risks. • review of risk. • records of appropriate insurance for all staff • incident reporting and response. • corrective and preventative action.

GOOD PRACTICE CRITERIA	MEASURE
	11 - Key supplier management: • identification and review of key suppliers. 12 - Auditing: • audit schedule. • internal audits in compliance with the audit schedule. Note: The effect of the RTAC Scheme, Part 2, Clause 11.1, is that the organisation must complete an internal audit prior to certification.
2. Patient Information **The Organisation must provide patients with information that is accurate, timely and in formats appropriate to the patient.**	Provide evidence of implementation and review of policies/procedures: • to ensure patients receive written and verbal information covering diagnosis, investigation and fertility treatment options. Information must include but not be limited to: • processes, costs, risks and outcomes. • drugs and side effects. • availability of individual counselling and support groups. • patient rights and responsibilities. • availability of translation and interpreter services

GOOD PRACTICE CRITERIA	MEASURE
3. Consent Processes **The Organisation must have a process whereby clinicians ensure that consent is obtained from all patients and/or donors (and, where relevant, their spouses or partners).**	Provide evidence of implementation and review of policies/procedures: • which define the consenting process. • to ensure that consent is informed, voluntary, competent, specific, documented and remain current. Review patient records to show consent has been obtained.
4. Cryostorage of Gametes and Embryos **The Organisation must ensure the safe management of cryopreserved gametes, embryos and tissues.**	Provide evidence of implementation and review of policies/procedures: • to identify, locate, retrieve and maintain cryopreserved material. • to limit the time in storage. • to manage the disposal of cryopreserved material.
5. Stakeholder Feedback **The Organisation must undertake regular stakeholder feedback**.	Provide evidence of implementation and review of policies/procedures: • to collect, analyse, review and take relevant action on stakeholder feedback including patient stakeholders.

PART 3 ESTABLISHMENT OF AN ORGANISATION

ESTABLISHMENT OF AN ORGANISATION	MEASURE
Opening of an ART Unit **The Organisation must ensure compliance with the RTAC Certification Scheme and the RTAC Code of Practice.** **Refer also to the RTAC Certification Scheme.**	Provide evidence of: • compliance.

Closure of an ART Unit

(For Information Only – Not Part of the Auditable Standard)

The Organisation should ensure the ongoing safe storage of gametes, embryos, tissues and medical records.

The Organisation should inform the relevant statutory and regulatory authorities and all stakeholders.

ATTACHMENT 1

(AUDITED ANNUALLY)

Key Personnel

The Organisation must appoint, or ensure access to, a Medical Director, a Scientific Director, a Nurse Manager and a Senior Counsellor.

Responsibilities

The medical director is responsible for the clinical management within the Organisation and the training, competency, and supervision of all clinicians involved in the Organisation.

The scientific director is responsible for the scientific management within the Organisation and the training, competency, and supervision of all scientists involved in the Organisation.

The nurse manager is responsible for the nursing management within the Organisation and the training, competency, and supervision of all nurses involved in the Organisation.

The senior counsellor is responsible for the counselling management within the Organisation and the training, competency, and supervision of all counsellors involved in the Organisation.

Qualifications and training

The **medical director** must be a recognised specialist gynaecologist or physician who has experience in the governance of service to patients with infertility and must hold a Certificate of Reproductive Endocrinology and Infertility (CREI) or demonstrate continuing medical education in the field of reproductive endocrinology and infertility.

The **scientific director** must have experience in the management of a clinical embryology laboratory and must possess demonstrable knowledge of and continuing education in all laboratory aspects of the Organisation. The scientific director must:

- have a higher degree (PhD, Masters or Postgraduate diploma) demonstrating a broadly-based scientific experience in reproductive biology, with expertise and/or specialised training in the physiology of reproduction, cell biology and biochemistry, and experience in experimental design, statistics and problem solving; AND
- have a minimum of four years of ART clinical laboratory experience and two years of experience in a managerial and / or supervisory role; OR
- have a minimum of five years previous experience in a scientific director's role.

The **nurse manager** must be a registered nurse with training in infertility nursing, must have experience in management of patients with infertility, and must demonstrate continuing nursing education in the field of infertility.

The **senior counsellor** must meet the requirements for full membership by the Australian and New Zealand Infertility Counsellors Association (ANZICA), which means the counsellor must

- have at least a four year tertiary academic qualification from a recognised institution and be
    - registered to practise as a psychologist in a state of Australia or in New Zealand;

    OR

    - a member of, or eligible for membership of the Australian Association of Social Workers or the New Zealand Association of Social Workers (Bachelor of Social Work – 4 Years);

    OR

    - registered to practise as a psychiatrist in a state of Australia or in New Zealand;

    AND

- be counselling clients who are concerned about issues related to infertility; and
- have at least two years fulltime or equivalent supervised postgraduate counselling experience; and
- demonstrate current knowledge of infertility and infertility treatment; and
- demonstrate continuing education in the field of infertility counselling.

ATTACHMENT 2

(AUDITED ANNUALLY)

Donor Requirements

Provide evidence of implementation and review of policies/procedures to ensure:

- support of the offsprings' right to know their genetic origins.
- donors and recipients of gametes or embryos are informed they are required to meet with an infertility counsellor who meets the requirements of full ANZICA membership prior to any donation process commencing.
- service providers must not collect or use gametes, embryos or tissues for donation from a person who has not given consent to the collection or donation.
- the partners of the donor and recipient are included in the counselling and consenting process.
- patients undergoing fertility treatment are not coerced into donating gametes.
- patients are not approached to donate gametes or embryos whilst undergoing their own fertility treatment.
- records about donors and recipients are retained.
- the organisation explains the provisions, responsibilities and obligations associated with linking between donors, recipients and offspring.
- there is an outline of the criteria used for defining donor and recipient eligibility.
- the risk of transmission of infectious agents and genetic conditions between donors of gametes and/or embryos and recipients is minimised.
- there is a documented system for collection and retrieval of gametes which ensures the quality of the donation is not compromised.
- there is a limitation on the number of children and families created from one donor.
- potential donors and recipients (where relevant) are informed of:
    - the storage and potential use of their gametes or embryos, and the processes involved in donation.
    - the procedures involved in collecting gametes, and any risks to the person.

- the screening to be carried out and the practical implications of having an HIV antibody test.
- the purposes for which the gametes or embryos might be used.
- the legislation defining the legal status of children born as a result of the procedure.
- the information that service providers collect and the extent to which that information may be disclosed to people born as a result of the donation.
- the process for the disclosure of identifying information.
- the possibility that a child born with a disability as a result of a donor's failure to disclose abnormalities is a legal responsibility of the donor.
- the fact that a woman donating eggs must not incur any financial or other penalty if she withdraws her consent at any stage, including after preparation for oocyte recovery has begun.
- the fact that donated gametes, and embryos created from those donated gametes, must not be used for treatment after the maximum number of children born, or the family limit specified in the relevant legislation or guidelines, has been reached.
- the options of placing boundaries, subject to any relevant legislation, on the use of their gametes and that the donor's wishes are carried out by the service provider.
- the right of donors and recipients to withdraw or vary the terms of their consent and specify limits, subject to any relevant legislation, at any time until the donated gametes or embryos are used.
- the fate of their gametes if the donor dies.
- the fact that donors will receive no financial gain, consideration or similar benefit for their donation.

ATTACHMENT 3

Definitions

ANZARD	Australian and New Zealand Assisted Reproduction Database
ANZICA	Australian and New Zealand Infertility Counsellors Association
Appoint	When the Organisation employs, hires, contracts with, chooses, or arranges for a particular individual to provide a certain role.
ART	Assisted Reproductive Technology
Artificial Insemination	The controlled and planned ART process by which sperm is introduced into the female genital tract with or without hormonal stimulation.
ART Unit	A facility with a laboratory collecting or preparing human gametes and/or embryos for therapeutic service, possibly across a range of sites of clinical activity. Where the collection of gametes/embryos takes place at a different site to the preparation, the two sites are considered to be a single Unit.
Audit	A systematic, independent examination and review to determine whether actual activities and results comply with planned arrangements.
Authority	The proper powers to carry out an action whether granted directly or delegated.
Certification	A third party assessment of the quality system of the service provider with respect to published quality system standards and any supplementary documentation required under the system (for example ISO 19011:2002).
Competent	Having the required ability, knowledge or authority.
CREI	Certificate of Reproductive Endocrinology and Infertility
Deed of Agreement	Signed agreement with the FSA to comply with the RTAC Code of Practice. A new agreement is required annually.
Facility	The physical location, site or building within or from which the service is provided.
FNA	Fertility Nurses of Australasia
FSA	Fertility Society of Australia
Governance	Taking responsibility for the overall direction of the organisation, including determination of the purpose and goals of the service.
HIV	Human immunodeficiency virus
Integration	When the Organisation involves, assimilates, incorporates or amalgamates individuals into its day to day activities.
Management	Implementing the policy determined by the governing body and coordinating the day to day service activity which achieve the purpose and goals of the organisation.

Must	Where it is mandatory in every circumstance to perform the required task with no exception.
Organisation	An entity that is accountable for the delivery of services at one or more ART Units.
Ovulation Induction	The controlled and planned ART process whereby hormonal stimulation is employed to induce the process of ovulation.
Patient	A user or participant in the service including donors.
Policy	Overall intentions and directions of an organisation.
Procedure	A specific way to carry out an activity.
Process	A set of interrelated or interactive activities which are planned and carried out under controlled conditions.
Quality Policy	Overall intentions and direction of an organisation related to quality as formally expressed by top management.
Records	A description of the healthcare provided for an identifiable patient/donor. May be a single file, multiple files, hard copy or electronic and be held by an organisation, service provider or the patient/donor themselves.
Review	A formal process of updating, amending, or replanning that is based on evaluation of outcomes.
Risk	The chance of something happening which will have an adverse impact on objectives.
Risk management	The culture, processes and structures that are directed towards realising potential opportunities whilst managing adverse effects.
Service provider	An individual who is responsible for providing the service either independently or on behalf of an organisation. This includes all staff and management who are employed, self employed, visiting, honorary, sessional, contracted or volunteer.
SIRT	Scientists in Reproductive Technology
Stakeholders	Person or group having an interest in the performance or success of an organisation, including but not limited to staff, patients, owners, major suppliers, funding organisations and community
Supervision	An activity that aims to enable the supervisee to achieve, sustain and develop a high quality practice through the means of focused support and development.
Therapeutic Service	Service aimed at treating patients, such as IVF, IUI. It does not include diagnostic procedures e.g. semen analysis.

ATTACHMENT 4

Reference Material

Please refer to the FSA website (www.fsa.au.com) for factual information which may assist.