CODE OF PRACTICE FOR ASSISTED REPRODUCTIVE TECHNOLOGY UNITS

INTERNATIONAL EDITION

Fertility Society of Australia

Reproductive Technology Accreditation Committee

(March 2014)

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This document is adapted from the RTAC Code of Practice for Assisted Reproductive Technology Units March 2014 for application to Assisted Reproductive Technology clinics outside Australia and New Zealand.

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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 and 2005. It was fully rewritten in 2008 with revisions in 2010 and 2014.

The International Edition of the code was introduced in 2014 to facilitate its application in countries outside the jurisdiction of the regulatory laws of Australia and New Zealand.

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) or the Fertility Society of Australia.

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 that uses, assesses and/or 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.

Application of the Code of Practice

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 and desiring accreditation for compliance with the Code of Practice.

There are two levels of accreditation:

- Full accreditation with RTAC as required for Australian ART clinics.
  This requires:
  - A signed Deed of Agreement with the Fertility Society of Australia
  - Payment of the fee levied by the Fertility Society of Australia
  - Submission of de-identified treatment data to the Australian and New Zealand Assisted Reproduction Database (ANZARD)

- Accreditation against the International Edition of the RTAC Code of Practice

Compliance:

ART units must also comply with relevant national legislation and regulations in the countries where they are located. Where there are conflicts between legislation, regulations and this Code of Practice, national legislation overrides regulations, guidelines and this Code of Practice.

PART 1 CRITICAL CRITERIA

(AUDITED ANNUALLY OR IN ACCORDANCE WITH NATIONAL LEGISLATION/REGULATIONS)

Following is a table of 14 **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, communication of, and compliance with national statutory and regulatory requirements in regard to ART treatment including donation and surrogacy. • 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.
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) In a clinic where any of these personnel do not normally work on site, the clinic must be able to demonstrate regular involvement of those personnel in clinical and quality control review of the clinic's activities.

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. • Adverse events, including serious adverse events and serious notifiable adverse events are defined in Attachment 3. Where required by local legislation or guidelines they should be reported to the relevant body and/or institution. • For clinics with full RTAC accreditation, Serious Adverse Events, as defined in Attachment 3, must be reported to RTAC through its secretariat and to the appropriate Certifying Body to facilitate audit of responses to the Adverse Event.
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

CRITICAL CRITERIA	MEASURE
	• 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. Clinics are referred to the RTAC Technical Bulletin #4 for good laboratory practice in gamete, embryo and patient identification and matching.
6. Medication Management **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 that are supplied or administered to patients by the ART Organisation. Batch numbers of drugs used, where available, should be recorded in a drug register. Where drugs are dispensed through a pharmacy this is not a requirement. • 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. • management of drugs to ensure that they are always used within expiry date.

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 where these are performed within the clinic. The aim for multiple pregnancy rate should be less than 10%. • 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. • in the formation of embryo transfer number policies, there be documented consideration of available resources to manage the risks of multiple pregnancy and premature delivery. • must ensure that patients receive information on the economic, medical, social and psychological hazards associated with multiple pregnancy.

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. • to benchmark the organisation's clinical outcomes against national and international standards

11. Data Reporting **The Organisation must comply with national and institutional requirements for the provision of treatment data.** **Organisations with full RTAC accreditation must provide the Australian and New Zealand Assisted Reproduction Database (ANZARD) with de-identified treatment data in the nominated timeframe for benchmarking purposes.** **The Organisation must inform patients of the uses to which their medical information may be put.**	Provide evidence of: • compliance with national requirements and any ANZARD data input. • 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 and certifying bodies.
12. Donor & Surrogacy Requirements **The Organisation must ensure gametes, embryos and tissues are safe for donation and use in surrogacy arrangements and that appropriate counselling has been provided.**	Provide evidence of compliance with Attachment 2. The Organisation must supply to the Certifying Body audit team a list of all file codes involving donation divided according to sperm, oocytes and embryos, and surrogacy, in the previous calendar year. The Certifying Body audit team will select 3 (where available) from each category for full audit on the day.
13. Management of Infection Risk **The Organisation must manage the risk of infection transmission.**	The Organisation must have in place risk assessments, policies and procedures which ensure the minimisation of infection transmission risk: • Between donors of reproductive tissues and recipients or surrogates • Between partners in sero-discordant couples • Between patients and donors and staff handling their biological material to include infectious disease screening, required hygiene procedures, and the use of personal protective equipment. Where applicable, policies should define quarantine periods and tests to be performed.

14. Informed Consent	
The Organisation must ensure that treatment only occurs with full informed consent.	The Organisation must have a process to ensure that consent is obtained from all patients and/or donors (and, where relevant, their spouses or partners) before treatment commences. The Organisation must provide patients with information that is accurate, timely and in formats appropriate to the patient. The Organisation must provide evidence of implementation and review of policies/procedures: • which define the consenting process. • to ensure that consent is obtained and is informed, voluntary, competent, specific, documented and remain current. • that define the extent and use of information included in data reporting. • that ensure the availability of a process to ensure informed consent in situations of illiteracy

PART 2 GOOD PRACTICE CRITERIA

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

(WHERE, IN ACCORDANCE WITH NATIONAL LEGISLATION/REGULATIONS, ASSESSMENTS ARE LESS FREQUENT THAN ANNUALLY, ALL GOOD PRACTICE CRITERIA SHOULD BE AUDITED AT EACH ASSESSMENT)

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 the organisation's services.

GOOD PRACTICE CRITERIA	MEASURE
	• 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: • policies and procedures for training and ongoing competence assessment to cover aspects assessed, the frequency of assessment and the required achievement levels. • 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 QC, validation, maintenance and service of equipment including the frequency of testing and servicing. • security, particularly to protect confidentiality of records and integrity of gametes and embryos. • management of risks. e.g. emergency equipment, power, gas.

GOOD PRACTICE CRITERIA	MEASURE
	10 - Risk Management • assessment of risks. • review of risk. • records of appropriate insurance for all staff • incident reporting and response. • corrective and preventative action. • workplace health and safety 11 - Key supplier management: • identification and review of key suppliers and contractual arrangements. 12 - Auditing: • audit schedule. • internal audits in compliance with the audit schedule. • An Organisation being certified for the first time must complete an internal audit of its Quality Management System prior to the certification inspection by the Certifying Body.
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. • that ensure the availability of a process to ensure information provision in situations of illiteracy Information must include but not be limited to: • processes, costs, risks and outcomes. • drugs and side effects.

GOOD PRACTICE CRITERIA	MEASURE
	• availability of individual counselling and support groups. • patient rights and responsibilities consistent with national policy. • availability of translation and interpreter services
3. 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 • Preconceptual advice should be provided to couples, including the consequences of abnormal weight, smoking, adverse environmental exposure and other relevant factors. This should be incorporated into referral pathways to ensure optimal health before fertility treatment.

GOOD PRACTICE CRITERIA	MEASURE
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.**	The primary audit conducted by a Certifying Body on a new clinic prior to it's opening and prior to it's receiving a license from RTAC should include: - there be compliance with all aspects of the RTAC Code of Practice with the exception of treatment records and outcome data analysis - there be a fully documented clinic policy manual - that there be fully documented policy and procedure manual for each area of the clinic e.g. including but not limited to clinical, nursing and medication management, laboratory, counselling and administration - there be a fully documented Quality Management System - there be a fully documented Risk Assessment and Management policy and records of identified risks and their management strategies - that ALL proposed equipment for use in the clinic, in particular laboratory, drug storage, clinical and sterilisation equipment, be installed and validated - that there be records of an internal audit to verify compliance with these requirements performed by clinic personnel prior to the Certifying Body audit. The certifying body has the right to require a further inspection after procedures have been performed.

Closure of an ART Unit

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

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

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

ATTACHMENT 1

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 specialist gynaecologist registered in the country of the clinic who has at least five years ART experience. The medical director must 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 or clinical andrology laboratory as appropriate to services offered 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. Must also have a minimum of four years of ART clinical laboratory experience.

The **nurse manager** must be a registered nurse in the country of the clinic with training in infertility nursing, must have five years experience in management of patients with infertility, and must demonstrate continuing nursing education in the field of infertility. In the absence of this period of experience there must be a well-documented orientation/training/supervision programme.

The **senior counsellor** must have tertiary qualifications in Psychiatry, Psychology or Social Work, be able to demonstrate current knowledge of infertility and infertility treatment, and be able to demonstrate continuing education in the field of infertility counselling.

ATTACHMENT 2

Donor & Surrogacy Requirements

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

- compliance with national legislation and/or guidelines on the donation of biological tissues, the donation of gametes and embryos, the provision of services for surrogacy agreements.
- support of the offsprings' right to know their genetic origin and to have in place policies and procedures for donor-offspring linking.
- where there is no relevant donation or surrogacy legislative requirements, clinics must develop policies and procedures to ensure agreements are in place to outline the medical and legal consequences of the agreements including any financial arrangements and the rights of the donor/surrogate with regards to withdrawal from the arrangement.
- that there be documented clinic-determined criteria for eligibility for donors and surrogates.
- comprehensive identifying and non-identifying information is collected about each donor and/or surrogate including last known address and relevant medical history of immediate family.
- records about donors, recipients and surrogates are retained indefinitely.
- that donors, recipients and/or the surrogate have attended a counselling process that includes (but is not limited to):
    - the advantages of telling any resulting child of its genetic origin
    - local legislation defining the legal status of any child born as a result of the procedure
    - any genetic or infectious disease screening to be carried out and the implications of having a positive result.
- the partners of the donor, the recipient and/or the surrogate are included in the counselling and consenting process.
- fully informed consent, including acknowledgment of risks to the donor, has been obtained without coercion for the collection and donation and/or the surrogacy and the final point at which consent can be withdrawn without financial penalty defined.
- the risk of transmission of infectious agents and genetic conditions between donors of gametes and/or embryos is minimised. It is a requirement that donors inform the clinic of any known genetic condition that they or close family members are diagnosed with prior or subsequent to donating.
- there is a limitation of the number of families from one donor, to comply with national regulations/guidelines and to minimise the potential risk of future consanguinity. In the absence of regulations or guidelines there must be documented clinic-determined family limits for donors and evidence of monitoring these family limits.
- donors are required to declare if they have donated at other clinics to ensure that the family limit is maintained.

ATTACHMENT 3

Definitions

Adverse Events	A Serious Adverse Event is any event associated with ART treatment: - which causes or potentially causes harm, loss or damage to patients or their reproductive tissues - which results in hospitalisation following, and as a result of, the treatment. Serious adverse events must be investigated, fully documented, and corrective actions put in place for review by the Certifying Body at the next scheduled inspection A Serious Notifiable Adverse Event is an abnormal unintended outcome associated with ART treatment which: - might result in the transmission of a communicable disease - might result in death or a life-threatening, disabling, or incapacitating condition - arises from a gamete or embryo identification error or mix-up. Serious Reportable Adverse Events must be reported immediately to relevant local authorities, RTAC and the Certifying Body, along with a summary of investigation of the event and any actions taken.
ANZARD	Australian and New Zealand Assisted Reproduction Database
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 that uses, assesses and/or prepares 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 19011:2011).
Competent	Having the required ability, knowledge or authority.
Deed of Agreement	A new signed agreement with the FSA to comply with the RTAC Code of Practice is required annually for clinics wishing full FSA RTAC accreditation.
Facility	The physical location, site or building within or from which the service is provided.
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.
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.
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.