

CODE OF PRACTICE FOR ASSISTED REPRODUCTIVE TECHNOLOGY UNITS

Fertility Society of Australia

Reproductive Technology Accreditation
Committee

(revised October 2017)





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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:

- a) Promote continuous improvement in the quality of care offered to people accessing fertility treatment.
- b) Provide a framework and set criteria for the auditing process that leads to accreditation of organisations that deliver fertility services.
- c) 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.

In addition to sections on establishing, renaming or closing an ART Unit, the Code of Practice has two sets of criteria as defined in the RTAC Certification Scheme, namely:

- a) Critical criteria. These are audited annually at the surveillance audits.
- b) Good Practice criteria. These are audited triennially.

These criteria are shown below, but are included in the text of the Code of Practice in an order that is intended to make them easier to relate to within an ART Unit:

Criteria	
Critical	Good Practice
<ol style="list-style-type: none">1. Compliance2. Personnel3. Disaster management4. Valid consent5. Management of infection risk6. Identification and traceability7. Donor and surrogacy requirements8. Cryostorage of gametes and embryos9. Adverse events10. Multiple pregnancy11. Data monitoring12. Data reporting	<ol style="list-style-type: none">1. Quality management system (QMS)2. Stakeholder feedback3. Medical management4. Information5. Medication management6. Emergency care7. Ovarian hyperstimulation syndrome

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 further revisions in 2010 and 2014.

In Australia, the *Research Involving Human Embryos Act 2002* 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 Units involved in the treatment of patients using ART.

RTAC Certification

An ART Unit's compliance with the RTAC Code of Practice must be reviewed on a regular basis. An ART Unit 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, and the RTAC Code of Practice should therefore 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 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.

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 ART Units involved in the treatment of patients with assisted reproductive technology including donated gametes or embryos, surrogacy 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) ART guidelines, and 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.

Technical Bulletins

From time to time RTAC will become aware of issues, questions or comments where it may consider assisting units to enhance the quality of their service to patients. A Technical Bulletin is an educational communication to all ART Units, and Bodies certifying units to the RTAC Code of Practice, offering advice and guidance. Technical Bulletins are not enforceable unless their content is incorporated into the Code of Practice. A current list of Technical Bulletins can be found at <https://www.fertilitysociety.com.au/rtac/technical-bulletins/>.

1. Structure and administration

1.1. Establishment of an ART Unit

The Unit 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 ART Unit prior to its opening and prior to its receiving a license from RTAC should include:

- a) Compliance with all aspects of the RTAC Code of Practice with the exception of treatment records and outcome data analysis,
- b) A fully documented ART Unit policy manual,
- c) A fully documented policy and procedure manual for each area of the organisation e.g. including but not limited to clinical, nursing and medication management, laboratory, counselling and administration,
- d) A fully documented Quality Management System,
- e) A fully documented Risk Assessment and Management policy and records of identified risks and their management strategies,
- f) Evidence that all proposed equipment for use in the ART Unit, in particular laboratory, drug storage, clinical and sterilisation equipment, has been validated,
- g) Records of an internal audit to verify compliance with these requirements performed by ART Unit personnel prior to the Certifying Body audit.
- h) RTAC must provide details of all newly established ART Units to the ANZARD custodian.

It is possible that the certifying body will require a further inspection after operational procedures have been performed.

1.2. Quality management system (QMS) (Good Practice Criterion 1)

The ART Unit must have a management system allowing planned, implemented, coordinated, and appropriate service delivery that meets the needs of all stakeholders. It must provide evidence of:

- a) A Quality Management policy that:
 - i) Demonstrates management commitment,
 - ii) Outlines the scope of services provided, including identification of key, outsourced personnel and services,
 - iii) Shows organisational objectives,
- b) Management review processes that review the scope, organisational objectives and relevance of the quality management system,

- c) Integration of all personnel and services:
 - i) Records confirming service integration.
- d) Records management:
 - i) Compliance with statutory and regulatory authorities,
 - ii) Document control system showing evidence of implementation, approval and review of internal and external documents,
 - iii) Systems of internal communication including copies of meeting minutes, emails and memos.
- e) Personnel training and competency:
 - i) Staff and/or contractors with appropriate and documented expertise to cover all aspects of the organisation's services,
 - ii) Management commitment to adequate staffing, training and ongoing education,
 - iii) Identification of training and education needs,
 - iv) Records of induction, training and ongoing education,
 - v) Records of relevant professional registration,
 - vi) Outline of responsibility and authority,
 - vii) Policies and procedures for training and ongoing competence assessment to cover aspects assessed, the frequency of assessment and the required achievement levels,
 - viii) Competency criteria including skill, education, training and experience,
 - ix) Records of each individual's competency for all services both internal and external.
- f) Buildings and facilities:
 - i) Assessment of requirements to meet organisational goals,
 - ii) Adequate facilities and equipment to meet objectives. Where any part of the ART process occurs in a surgical facility remote from the clinic and/or laboratory, audit of processes (including identification and traceability) and equipment in these facilities and during transport of reproductive tissues between facilities must form part of the audit,
 - iii) Records of QC validation, maintenance and service of equipment including the frequency of testing. In the absence of a policy the default policy will be that defined in the current NATA Medical Testing Field Application Document,
 - iv) Security, particularly to protect confidentiality of records and integrity of gametes and embryos,
 - v) All facilities where surgical procedures are conducted within an ART Unit need to provide evidence of policies and procedures to manage patient safety and assess risk.

- g) Risk management:
 - i) Assessment of risks,
 - ii) Review of risk,
 - iii) Incident reporting and response,
 - iv) Corrective and preventative action,
 - v) Workplace health and safety
- h) Key supplier management:
 - i) Records of service agreements with key contractors and key contracted service providers.
- i) Auditing:
 - i) Audit schedule,
 - ii) Internal audits in compliance with the audit schedule,
 - iii) Annual RTAC surveillance audits to be scheduled more than 30 days prior to expiry date of their RTAC licence.

1.3. Compliance (Critical Criterion 1)

The ART Unit must comply with statutory and regulatory requirements and provide evidence of:

- a) Identification and compliance with national and state-based statutory and regulatory requirements in regard to ART treatment including: statutory storage periods; donation of gametes or embryos; surrogacy; record keeping; and reporting requirements. This should be in the form of a risk assessment with clear pathways and evidence of discussion by top management, communication of any changes through documentation and staff training, and valid consent forms,
- b) How changes to external requirements are integrated into work practices,
- c) Communication, implementation, and review of all policies/procedures,
- d) Compliance with the RTAC Code of Practice,
- e) Records of current signed Deed of Agreement with the FSA,
- f) All human research having been approved by a Human Research Ethics Committee (HREC) registered with NHMRC, and operating in accordance with the *National statement on ethical conduct in human research* (2007 or more recent review), or the registered with the New Zealand equivalent,
- g) Compliance with the NHMRC *Ethical guidelines on the use of ART in clinical practice and research* (2017 or more recent review) or New Zealand equivalent, except where in conflict with legislation, or where alternative requirements have been directed by a registered and compliant HREC affiliated to the Unit.

1.4. Personnel (Critical Criterion 2)

The requirements for the senior positions are considered in two different situations, namely where the key personnel are (i) on-site, and (ii) off-site. Personnel in post prior to 1st October 2017, and fulfilling the RTAC Code of Practice requirements existing at that time, will be exempt.

1.4.1. Key personnel

The ART Unit must appoint, or ensure access to, a Medical Director, a Scientific Director, a Nurse Manager and a Senior Counsellor. Key personnel are expected to attend in person annual RTAC accreditation audits of ART Units or groups of ART Units. for which they are responsible. Where the Medical Director has clinical obligations on the day, he/she must make time available for discussions with the auditor. The ART Unit must provide evidence of qualifications, training, education and experience of key personnel.

1.4.1.1. Medical Director

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 Medical Director from January 2015 must be a recognised specialist gynaecologist or physician who;

- a) Has at least five years' experience in that role; or
- b) Can demonstrate substantial similar experience in the governance of an ART Unit and the management of patients with infertility; or
- c) Holds a Certificate of Reproductive Endocrinology and Infertility (CREI).

The Medical Director must provide evidence of Fellowship of the Royal Australian and New Zealand College of Obstetrics and Gynaecology (RANZCOG) or the Royal Australian College of Physicians (RACP) and demonstrate continuing medical education in the field of reproductive endocrinology and infertility. For non-CREI holding Medical Directors, at least 50% of minimum required CME points in their College-mandated CME programmes must be obtained in the area of reproductive medicine and infertility.

1.4.1.2. Scientific Director

The Scientific Director is responsible for the scientific management within the ART Unit and the training, competency, and supervision of all scientists involved in the Organisation. 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:

- a) 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 and two years of experience in a managerial and/or supervisory role; OR
- b) Have a minimum of five years previous experience in a Scientific Director's role.

1.4.1.3. Nurse Manager

The nurse manager is responsible for the nursing management within the ART Unit and the training, competency, and supervision of all nurses involved in the Organisation. The Nurse Manager must be a Registered Nurse and/or Registered Midwife with experience and training in infertility nursing and:

- a) Be registered to practice in a state or territory of Australia or in New Zealand, and
- b) Have a minimum of three years' experience in management of patients with infertility, and
- c) Demonstrate continuing nursing education in the field of infertility.

1.4.1.4. Senior Counsellor

The senior counsellor is responsible for the counselling management within the ART Unit and the training, competency, and supervision of all counsellors involved in the Organisation. The Senior Counsellor must have, or be eligible for, full membership of the Australian and New Zealand Infertility Counsellors Association (ANZICA) and demonstrate continuing education in the field of infertility counselling.

1.4.2. Additional medical personnel

The ART Unit must provide evidence that medical practitioners providing medical management and care of patients have appropriate qualifications and training, continued medical education, and appropriate supervision, such that:

- a) The management and care of the patient within an ART Unit must be provided or supervised by a registered medical specialist who is a Fellow of the RANZCOG, or a Fellow of the RACP who has at least 20% of minimum required CME points in their College-mandated CME programmes obtained in the management of fertility.
- b) Supervision of trainees or general practitioners working within an ART Unit must be provided by a registered medical specialist who is a Fellow of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) or the Royal Australian College of Physicians (RACP) as above. Specialists, trainees and general practitioners must demonstrate evidence of training and competency in the management of fertility and continued medical education (CME) in this area.
- c) Where provision of care within an ART Unit is provided by a general practitioner or trainee, written delegation of the scope of clinical care undertaken by the general practitioner or trainee must be made by the supervising specialist, and agreed to by to the general practitioner or trainee. The nature and extent of this arrangement must be disclosed formally to the patient/s. Contingency arrangements in the event of an emergency must be in place.

1.4.3. Where key personnel are off-site

In the absence of an on-site Medical Director, Scientific Director, Nurse Manager, or Senior Counsellor, the day-to-day management of that area should be undertaken by a Clinical Director, Laboratory Supervisor, Nurse Co-ordinator or Counsellor respectively. The ART Unit must provide evidence of qualifications, training, education and experience of these personnel. In addition, the ART Unit must be able to demonstrate regular involvement of the Key Personnel in clinical and quality control review of the ART Unit and its activities through documented visits, meeting minutes, correspondence, or a combination of these.

1.4.3.1. Clinical Director

The Clinical Director is responsible for the day-to-day clinical management within the ART Unit and supports the Medical Director in the training, competency, and supervision of all clinicians involved in the Organisation. The Clinical Director must be a recognised specialist gynaecologist who;

- a) Has at least two years' experience in that role; or
- b) Can demonstrate substantial similar experience in the clinical management of an ART Unit and the management of patients with infertility; or
- c) Holds a Certificate of Reproductive Endocrinology and Infertility (CREI).

The Clinical Director must provide evidence of Fellowship of the FRANZCOG and demonstrate continuing medical education in the field of reproductive endocrinology and infertility. For non-CREI holding Clinical Directors, at least 20% of minimum required CME points in their College-mandated CME programmes must be obtained in the area of reproductive medicine and infertility.

1.4.3.2. Laboratory Supervisor

The Laboratory Supervisor must have experience in all aspects of a clinical embryology or clinical andrology laboratory, as appropriate to services offered, and must possess demonstrable knowledge of, and continuing education in, all aspects of the laboratory function.

The Laboratory Supervisor:

- a) Is responsible for the training and competency of all clinical scientists working in that laboratory.
- b) Must have a BSc degree or equivalent demonstrating a broadly-based scientific experience in reproductive biology, with expertise and/or specialised training in the physiology of reproduction, cell biology and biochemistry.
- c) Must also have a minimum of two years of ART clinical laboratory experience following completion of their formal training in the services provided. Solo competent embryologists in remote geographical locations may be exempt providing that policies and procedures, together with evidence of on-going communication, exist to ensure clear and effective support from the Scientific Director.

1.4.3.3. Nurse Co-ordinator

The Nurse Co-ordinator is responsible for the nursing management within the ART Unit and supports the Nurse Manager in the training, competency, and supervision of all nurses involved in the ART Unit. The Nurse co-ordinator must be a Registered Nurse and/or Registered Midwife with experience and training in infertility nursing and:

- a) Be registered to practice in a state or territory of Australia or in New Zealand; and
- b) Have a minimum of 2 years of experience in management of patients with infertility, and
- c) Demonstrate continuing nursing education in the field of infertility.

If no permanent Nurse Co-ordinator is available, the Nurse Manager must be in regular and on-going contact, and communication records be kept, to assist with training, policy and procedure implementation and any other accreditation requirements. The Nurse Manager must also be contactable by staff at satellite centres in the absence of a Nurse Co-ordinator.

1.4.3.4. Counsellor

The Counsellor must have, or be eligible for, full membership of the Australian and New Zealand Infertility Counsellors Association (ANZICA) and demonstrate continuing education in the field of infertility counselling.

In addition, the ART Unit must ensure that proper systems are in place for record keeping and maintaining confidentiality in keeping with ANZICA and NHMRC ART guidelines.

1.5. Stakeholder feedback (Good Practice Criterion 2)

The ART Unit must undertake regular stakeholder feedback. It must provide evidence of implementation and review of policies and procedures to collect, analyse, review and take relevant action on stakeholder feedback including patient stakeholders.

The ART Unit must acknowledge and investigate complaints, and provide evidence of implementation and review of policies and procedures which include:

- a) Information on how patients make a complaint and how they receive feedback,
- b) Acknowledgement and investigation of complaints,
- c) Systematic recording, review and corrective action of complaints.

1.6. Disaster management (Critical Criterion 3)

In order to minimise the risk of serious adverse outcomes following a disaster, the ART Unit should:

- a) Have contingency plans that address potential disaster scenarios including those unique to their location,
- b) Ensure access to emergency equipment, power, and gas that is shown to work in critical areas such as surgical procedures and maintenance of embryo culture conditions,
- c) Show evidence of working through scenarios,
- d) Identify the principal components of the plans, and show them to be feasible and to work.

The ART Unit should have a policy, where possible, of open disclosure with patients adversely affected by disasters that align with the Australian Open Disclosure Framework from the Australian Commission on Safety and Quality in Health Care.

1.7. Renaming or Closure of an ART Unit

1.7.1. Renaming of an ART Unit

In the event of renaming, the ART Unit must notify within 30 days RTAC, the Certifying Body, the ANZARD custodian, and statutory and regulatory authorities where applicable.

1.7.2. Closure of an ART Unit

In the event of closure, the ART Unit must:

- a) Notify within 30 days RTAC, the Certifying Body and the ANZARD custodian.
- b) Ensure the ongoing safe storage and accessibility of gametes, embryos, tissues and medical records, and
- c) Inform the relevant statutory and regulatory authorities and all stakeholders.

2. Patient management and treatment

2.1. Medical management (Good Practice Criterion 3)

The ART Unit must ensure that it meets the reproductive health needs of the patients and partners under its care. It must provide evidence of implementation and review of policies and procedures so that:

- a) Women undergo clinical evaluation for co-existing reproductive health or gynaecological problems, or those arising as a result of ART treatment,
- b) Men undergo clinical evaluation for co-existing reproductive health and related problems, or those arising as a result of ART treatment,
- c) There are pathways of referral for endocrine and andrological expertise,
- d) Preconception advice should be provided to patients, 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.

2.2. Information (Good Practice Criterion 4)

2.2.1. Patient information

The Unit must provide patients with information that is accurate, timely, in formats and language appropriate to the patient, and consistent with the NHMRC ART guidelines. It must provide evidence of implementation and review of policies and procedures to ensure patients receive written and verbal information covering diagnosis, investigation and fertility treatment options. Information must include but not be limited to:

- a) Processes, costs, risks and outcomes,
- b) Drugs and side effects,
- c) Availability of individual counselling and support groups,
- d) Patient rights and responsibilities,
- e) Availability of translation and interpreter services,
- f) Preconception advice including the consequences of abnormal weight, smoking, adverse environmental exposure and other relevant factors.
- g) A statement that donor and surrogacy arrangements are likely to require multiple counselling sessions.

2.2.2. Public information

Information presented in the public domain must be in language that can be understood by the lay public and ensure the overall conclusion is not misleading in any way. Information must be consistent with the following requirements:

- a) Success rates must:
 - i) be divided by age,
 - ii) specify live birth rates for fresh and frozen embryo transfers separately. Use of clinical pregnancy rates in advertised success rates may be permissible provided that the live birth rates are also available for comparison in the same communication,
 - iii) be accompanied with the following clarifying information: the time period during which the advertised data was collected and unambiguous details of the population group from which they are derived (e.g. whether they relate to IVF, ICSI, PGS/PGD or FET, and age group),
 - iv) be accompanied by a qualifying statement of broad factors that affect success rates e.g. age, weight, and cause of infertility, and that individual results will vary with individual circumstances,
 - v) be accompanied by a statement that not every treatment cycle will result in an egg collection, an embryo transfer or embryo cryopreservation,
 - vi) be accompanied by a reference and/or hyperlink to the FSA statement on “Interpreting Pregnancy Rates: a consumer guide”
 - vii) ensure that any clarification, qualifying statement or reference be clear and prominent and not hidden in a disclaimer.
- b) Media announcements of scientific or clinical “breakthroughs” in the field of ART should only be made after a peer review process such as presentation of an abstract for a scientific meeting or a manuscript publication in an appropriate scientific journal.
- c) ART Units must not incorporate patient comments on social media that promote their practice or service,
- d) ART Units must have appropriate governance in place to ensure that all public information complies with the requirements of the Australian Consumer Law, as well as AHPRA and ACCC guidance, and should only release information to the public domain once its accuracy has been verified and approved by the Medical Director.
- e) Any RTAC accredited unit receiving a notification from the ACCC or a Department of Fair Trading of a complaint in relation to advertising by the ART clinic or one of its registered health practitioners must advise the Chair of RTAC to enable monitoring of complaints by RTAC.
- f) ART Units must ensure their websites comply with the above requirements, and document this through regular internal audits.

2.3. Valid consent (Critical Criterion 4)

The ART Unit must:

- a) Ensure that treatment only occurs with valid consent, as defined by the NHMRC *Ethical guidelines on the use of ART in clinical practice and research* (2017 or more recent review).
- b) Have a process whereby clinicians ensure that valid consent is obtained from all patients, donors and/or surrogates (and, where relevant, their spouses or partners) before treatment commences,

- c) Provide patients with information that is accurate, timely and in formats appropriate to the patient,
- d) Provide evidence of implementation and review of policies and procedures which define the consenting process.

2.4. Management of infection risk (Critical Criterion 5)

The ART Unit must manage the risk of infection transmission for all clinical and laboratory procedures undertaken within the ART Unit. It must have in place risk assessments, policies and procedures which ensure the minimisation of infection transmission risk:

- a) Between donors of reproductive tissues and recipients or surrogates, between partners in sero-discordant couples, and between patients and donors,
- b) For staff handling biological material, including infectious disease screening.

Where applicable, policies should define quarantine periods and tests to be performed.

2.5. Medication management (Good Practice Criterion 5)

Where the ART Unit issues medications without pharmacy involvement the unit must provide evidence of implementation and review of policies and procedures to ensure the safe management of drug storage, supply and administration.

2.6. Identification and traceability (Critical Criterion 6)

The ART Unit must ensure that gametes, embryos and patients are correctly identified and matched at all times and, in particular, ensure that men providing a semen sample confirm in writing on each occasion that the sample is theirs.

The ART Unit must provide evidence of implementation and review of:

- a) Policies and 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 including digital and manual record keeping,
- b) The process that constitutes the traceability of gametes and embryos at all stages of the treatment cycle and associated digital and manual records including where transport is involved,
- c) Regular (at least annual) audit of the patient, gamete and embryo identification process and associated digital and manual records,
- d) A minimum of three forms of identification should be used to ensure traceability of all persons and specimens.

2.7. Emergency care (Good Practice Criterion 6)

The ART Unit must ensure access to emergency care. It must provide evidence of implementation and review of policies and procedures on emergency physical and psychological care, and ensure patients and their partners receive information on how to access emergency care including out of normal hours. The ART Unit must have a policy for dealing with emergency after hours psychological care for patients which has been developed in consultation with the Senior Counsellor.

2.8. Donor and surrogacy requirements (Critical Criterion 7)

The ART Unit must ensure gametes, embryos and tissues are safe for donation and use in surrogacy arrangements and that appropriate counselling has been provided. It must provide evidence:

- a) Of compliance with NHMRC *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* (2017 or more recent review) or any subsequent revision,
- b) Of compliance with any applicable national, state or territory legislation,
- c) That the Unit will obtain a declaration from the recipient patient / couple prior to the initiation of the treatment cycle saying that the recipient patient / couple will provide information about the treatment cycle outcome,
- d) That counselling has been undertaken by a counsellor who is eligible for membership of ANZICA. For donor and surrogacy arrangements, counselling is mandatory for all donors, partners, recipients and surrogates and their partners,
- e) That policies and procedures are in place, which have been developed in conjunction with the senior counsellor, in relation to these treatment arrangements. For known donation, an additional joint session involving all parties must be undertaken prior to the signing of consents.

The ART Unit 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 CB will select three (where available) from each category for full audit on the day.

2.9. Cryostorage of gametes and embryos (Critical Criterion 8)

The ART Unit must provide evidence of implementation and review of policies and procedures to ensure the safe management of cryopreserved gametes, embryos and tissues in accordance with national, state or territory legislation and the NHMRC ART guidelines.

3. Outcomes

3.1. Ovarian hyperstimulation syndrome (Good Practice Criterion 7)

The ART Unit must minimise the incidence of Ovarian Hyperstimulation Syndrome (OHSS). It must provide evidence of implementation and review of policies and procedures that:

- a) Enable identification and management of patients at risk of or experiencing OHSS,
- b) measure and attempt to minimise the incidence of OHSS,
- c) must ensure patients receive information on the risks, symptoms and management of OHSS,
- d) must ensure patients receive information on how to access help, advice or care out of normal hours or in the event of a medical emergency.

3.2. Adverse events (Critical Criterion 9)

The ART Unit must acknowledge and investigate adverse events, and provide evidence of implementation and review of:

- a) Policies and procedures to systematically collect, analyse causal factors, review and act on all adverse, unplanned and untoward events,
- b) Adverse events, including serious adverse events and serious notifiable adverse events are defined in Section 4.
- c) Serious Notifiable Adverse Events, as defined in Section 4, must be reported to RTAC through its secretariat to facilitate audit of responses to the Adverse Event, and to the appropriate Certifying Body. The information indicated in Attachment 1 must be provided.

3.3. Multiple pregnancy (Critical Criterion 10)

The ART Unit must minimise the incidence of multiple pregnancy. It must provide evidence of implementation and review of policies and procedures that:

- a) Ensure a regular audit (at least annually) of multiple pregnancy rates and corrective actions that continuously attempt to reduce the incidence of multiple pregnancies in all treatment cycles, including artificial insemination even when the insemination is done offsite,
- b) 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,
- c) 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,
- d) 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,

- e) Ensure single embryo transfer is mandatory for a gestational carrier in surrogacy arrangements,
- f) Ensure that patients receive information on the economic, medical, social and psychological hazards associated with multiple pregnancy.

3.4. Data monitoring (Critical Criterion 11)

The ART Unit must undertake regular reviews of treatment outcomes. It must provide evidence of implementation and review of policies and procedures to:

- a) Identify, collect, analyse and review data to monitor treatment procedures and practices and treatment outcomes at least annually.
- b) Benchmark the ART Unit's clinical outcomes against the most recent ANZARD report, and identify areas and opportunities for improvement. Where clinical outcomes fall below the 25th percentile, the clinic is required to study why its results fall in this range, and implement an improvement plan where it is deemed necessary.

In addition, the RTAC Chair will notify the Unit when the clinical outcomes as reported to ANZARD fall below the 3rd standard deviation in a funnel plot taking into account potentially confounding factors such as the size of the ART Unit, female patient age and parity. If this occurs on two consecutive years then the ART Unit will be required to submit to the RTAC Chair an improvement plan, and its implementation will be audited by the Unit's Certifying Body at six monthly intervals, at the Unit's cost, until there is a sustained improvement.

3.5. Data reporting (Critical Criterion 12)

The ART Unit must (a) provide the Australian and New Zealand Assisted Reproduction Database (ANZARD) with required data in the stipulated timeframe, and (b) inform patients of the uses to which their medical information may be put. It must provide evidence of:

- a) Compliance with ANZARD data input,
- b) Accuracy of ANZARD data, including the definition of pregnancy outcome as specified in the current ANZARD data dictionary, through an internal audit prior to submission to the agency collecting the data, and
- c) Implementation and review of policies and procedures for informing patients and obtaining valid consent on the use of identifying and de-identified medical information that will be provided to statutory, regulatory and legislative authorities including ANZARD, and that their de-identified ANZARD information may be used for population analysis and research projects.

In addition, the ART Unit must provide at the RTAC audit a list of all cases submitted to ANZARD in the previous calendar year, and all ART treatment cycles undertaken in the current year where the final outcome is known. This should include those having become pregnant and with a range of pregnancy outcomes. From this list, the CB will randomly select ten (10) for which the ART Unit will be required to provide documentary evidence of testing verifying pregnancy outcome.

4. Definitions

ACCC	Australian Competition and Consumer Commission
Adverse Events	<p>A Serious Adverse Event is any event associated with ART treatment which:</p> <ul style="list-style-type: none"> • causes harm, loss or damage to patients or their reproductive tissues • causes a significant medical or surgical condition to arise directly from ART treatment • results in hospitalisation following, and as a result of, the ART treatment. <p>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.</p> <p>A Serious Notifiable Adverse Event is an abnormal unintended outcome associated with ART operations which:</p> <ul style="list-style-type: none"> • 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. • might impact safety of people, gametes, embryos, equipment or facilities as a result of a disaster • results in a potential or actual breach of legislation <p>Serious Notifiable Adverse Events must be reported within 6 weeks of the event to RTAC and the Certifying Body, along with a summary of investigation of the event and any actions taken.</p>
AHPRA	Australian Health Practitioner Regulation Agency
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 ART 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.
Disaster	A disaster is a sudden, calamitous event that seriously disrupts the functioning of a community or society and causes human, material, and economic or environmental losses that exceed the community's or society's ability to cope using its own resources. Though often caused by nature, disasters can have human origins.
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 ART Unit 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.
NHMRC	National Health and Medical Research Council
NHMRC ART guidelines	<i>Ethical guidelines on the use of assisted reproductive technology in clinical practice and research (2017 or more recent review) issued by NHMRC</i>
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.
Satellite Unit	Satellite unit is a unit which does not have a resident laboratory or laboratory facilities.
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.
Valid Consent	For consent to be valid: <ul style="list-style-type: none"> • the person giving consent must be considered to have the capacity to provide consent, • the decision to consent to the treatment or procedure must be made without undue pressure, • all relevant requirements regarding the provision of information and counselling requirements in Chapter 4 of the NHMRC ART guidelines must be satisfied, • the consent must be specific, and is effective only in relation to the treatment or procedure for which information has been given.

ATTACHMENT 1

Please supply the following information about any serious adverse event to the RTAC secretariat and your Certifying Body as required in Section 3.2 of the RTAC Code of Practice.

ART Unit name	
Type of event as per Code of Practice	
Clinical presentation and intervention (with dates)	
Patient outcome	
Corrective action taken	
Date of conclusion of event	
Member of Key Personnel reviewing the case, and date of review	

Return to:

FSA Secretariat, Waldron Smith Management, 119 Buckhurst Street, South Melbourne VIC 3205
(e-mail: kimo@wsm.com.au)