CODE OF PRACTICE FOR ASSISTED REPRODUCTIVE TECHNOLOGY UNITS

INTERNATIONAL EDITION

Fertility Society of Australia and New Zealand

Reproductive Technology Accreditation Committee

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This document is adapted from the RTAC Code of Practice for Assisted Reproductive Technology Units October 2017 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 and New Zealand (FSANZ). 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 certification of Units 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. Units aspire to deliver services in a manner that recognises patients' cultural and individual values and beliefs, upholds patients' dignity and privacy, and supports the rights of offspring born through ART to know their genetic origins and to have optimal health outcomes.

Background

The code was first introduced in 1986 when the FSANZ 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 FSANZ. This initial code was revised in 1992, 1997, 2001 and 2005. It was fully rewritten in 2008 with revisions in 2010, 2014, 2017 and 2021.

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

a) Critical criteria. These are audited annually at the surveillance audits, or under national legislation/regulations.

b) Good Practice Criteria. These are audited at the initial certification audit and subsequently over three years of annual inspections, following the RTAC certification scheme. Where, under national legislation/regulations, assessments are less frequent than annually then all good practice criteria should be audited at each assessment.

Criteria	
Critical	**Good Practice**
CC 1. Compliance CC 2. Key personnel CC 3. Disaster management CC 4. Valid consent CC 5. Management of infection risk CC 6. Identification and traceability CC 7. Donor and surrogacy requirements CC 8. Cryostorage of gametes and embryos CC 9. Adverse events CC 10. Multiple pregnancies CC 11. Data monitoring CC 12. Data reporting	GPC 1. Quality management system (QMS) GPC 2. Stakeholder feedback GPC 3. Medical management GPC 4. Patient Information GPC 5. Medication management GPC 6. Emergency care GPC 7. Ovarian hyperstimulation syndrome

RTAC Certification

An ART Unit's compliance with the RTAC International Code of Practice must be reviewed regularly. 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) or the Fertility Society of Australia and New Zealand.

Assisted Reproductive Technology (ART)

For this Code of Practice, 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; intracytoplasmic sperm injection; embryo or gamete cryopreservation; surgical sperm recovery; oocyte, semen or embryo donation; embryo biopsy or non-invasive sampling 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 International Code of Practice

The International Code of Practice is to be observed in ART Units outside of Australia and New Zealand involved in the treatment of patients with assisted reproductive technology including donated gametes or embryos and IUI and desiring accreditation for compliance with the International 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.

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/technicalbulletins.

PART 1 CRITICAL CRITERIA

(AUDITED ANNUALLY OR UNDER NATIONAL LEGISLATION/REGULATIONS)

CC 1. Compliance

The ART Unit must comply with statutory and regulatory requirements.

It must provide evidence of:

a) Identification, communication of, and compliance with national statutory and regulatory requirements regarding ART treatment including donation and surrogacy,

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 International Code of Practice, and

e) A record of the current signed Deed of Agreement with the FSANZ.

CC 2. Key personnel

The Unit must ensure access to competent staff, and these must include a Medical Director, Scientific Director, Nurse Manager and Senior Counsellor

The ART Unit must provide evidence of qualifications, training, education and experience of key personnel, and the requirements and responsibilities of these personnel are given below. In a Unit 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 reviews of the clinic's activities.

CC2.1. Medical Director

The Medical Director is responsible for the clinical management within the Unit and the training, competency, and supervision of all clinicians involved in the Unit.
The Medical Director must be a specialist gynaecologist registered in the country of the clinic who has at least five years ART experience and must demonstrate continuing medical education in the field of reproductive endocrinology and infertility.

CC2.2. Scientific Director/Chief Embryologist

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

The Scientific Director must have a minimum of four years of ART clinical laboratory experience, as well as experience in the management of a clinical embryology or clinical andrology laboratory as appropriate to services offered with demonstrable knowledge of and continuing education in all laboratory aspects of the Unit. In addition, the Scientific Director must have a degree (PhD, Masters, Postgraduate diploma or a Bachelor of Science (BSc) in a relevant biological discipline) demonstrating a broadly-based scientific experience in reproductive biology, with expertise and/or specialised training in the physiology of reproduction, cell biology and biochemistry, statistics and problem-solving.

CC2.3. Nurse Manager

The Nurse Manager is responsible for the nursing management within the Unit and the training, competency, and supervision of all nurses involved in the Unit.
The Nurse Manager must be a registered nurse or midwife in the country of the Unit with training in infertility nursing, must have three years of experience in the 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.

CC2.4. Senior Counsellor

A Senior Counsellor must be available for patients.

The Senior Counsellor must have tertiary qualifications in a clinical profession, recognised in the country of the unit, such as psychiatry, psychology or social work. In addition, the Senior Counsellor must be able to demonstrate current knowledge of infertility and infertility treatment and be able to demonstrate continuing education in the field of infertility.

CC 3. Disaster management

The Unit must minimise the risk of serious adverse outcomes following a disaster.

The ART Unit must:

a) Have contingency plans that address potential disaster and emergency scenarios including those specific 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 documented 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, emergencies and untoward events.

CC 4. Valid consent

The Unit must ensure that treatment only occurs with full valid consent.

The Unit 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 Unit must provide patients with information that is accurate, timely and in formats appropriate to the patient. It must provide evidence of implementation and review of policies/procedures that:

a) Define the consenting process,

b) Ensure that consent is informed, voluntary, competent, specific, documented and remains current.

c) Define the extent and use of information should there be any requirement for data reporting and external audits, and

d) Ensure the availability of a process to allow informed consent in situations where there is difficulty of understanding.

CC 5. Management of infection risk

The Unit must manage the risk of infection transmission for all clinical and laboratory procedures undertaken within the ART Unit.

The ART Unit 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 serodiscordant couples, between patients and donors, and

b) For staff handling biological material including infectious disease screening.

The policies and procedures in place must comply with any national requirements that exist in the country or region the Unit resides in.

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

CC 6. Identification and traceability

The ART Unit must ensure that gametes, embryos and patients are correctly identified and matched at all times.

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 the traceability of all persons and specimens unless national legislation in the country the Unit resides in only requires two (2) forms of identification. The patient's full name is deemed to be only one (1) identifier NOT two identifiers. When identifying patients, the three identifiers must be known to the person, for example name, date of birth, address, partners name and date of birth, national ID number and mobile / cell telephone.

CC 7. Donor and surrogacy requirements

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. Commercial surrogacy is not permitted.

The ART Unit must provide evidence of compliance with Attachment 1. It 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.

CC 8. Cryostorage of gametes and embryos

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. This must include, but is not limited to, location of and access to storage vessels, health and safety measures for staff accessing the vessels, monitoring vessel integrity sufficiently frequently so that contents of a vessel can be moved before the viability of the material is endangered, and retirement of old vessels. The unit must demonstrate traceability (date, location in the vessel, personnel performing) for every item (straw, vitrification carrier, ampoule) added to or removed from a vessel.

CC 9. Adverse events

The Organisations/ART Unit must acknowledge, investigate, report and review any serious adverse events and incidents (defined below). A serious adverse event is by definition reportable to RTAC and the Certifying Body.

The ART Unit must possess and show evidence of internal policies, and have governance mechanisms in place, to record and review any serious adverse events and incidents. If the internal or external review identifies a correctable action that the ART Unit needs to undertake to prevent recurrence of the event, the ART Unit needs to provide evidence that this is occurring.

a) Serious adverse events must be reported:

   1) As soon as practical, but no later than six weeks after the provider becomes aware of the incident. If the investigation has not been completed within this timeframe, the notification must still be submitted. A follow-up report can then be provided once the investigation has been finalised.

   2) Within two weeks for a potential or actual breach of legislation; or

   3) Within 48 hours for a sentinel event eg. death

   The serious adverse event must be reported to both RTAC and the Certifying Body

   The template form, ***Attachment 1,*** must be used for reporting.

b) A serious adverse event includes any event which:

   1) Causes a significant medical or surgical condition that occurs as a result of the ART treatment as defined in Section c) below.

   2) Results in the hospitalisation of the patient due to a complication of ART treatment as defined in Section c) below

   3) Results or may result in the transmission of a communicable disease

   4) Results in a breach or potential breach of legislation

   5) Arises from a gamete or embryo identification mix up

   6) Causes a loss of viability of gametes or embryos or suspected deterioration (beyond accepted laboratory standards) that renders them unsuitable for use.

   7) Arises from a systematic failure in the validation/verification of a diagnostic test and/or technology that has resulted in misdiagnosis and/or significant potential harm or loss to patients, their gametes or embryos

c) Specific medical or surgical conditions that define a serious adverse event occurred

Scenario	Serious Reportable Adverse Event Document, analyse and report to RTAC and auditor within 6 weeks.	Serious Adverse Event Document, analyse and retain for auditor review at next audit.
OHSS Hospitalisation for observation and fluids after symptoms of OHSS	No	Yes
Presentation to a hospital for OHSS that included paracentesis or draining of pleural effusions	Yes	Yes
Hospitalisation for OHSS with permanent disability	Yes	Yes
Ovarian Torsion Hospitalisation after IVF treatment for ovarian torsion which required surgical intervention	Yes	Yes
Complication of ART Hospitalisation after OPU or surgical sperm retrieval for haemorrhage with or without blood transfusion, infection, thrombosis, or damage to tissues.	Yes	Yes
Drug Reaction Hospitalisation for an unexpected drug reaction to ART medications only	Yes	Yes
Transmission of a Communicable Disease	Yes	Yes
Incorrect Gametes or Embryos Potential use of incorrect gametes or embryos detected before use by the clinic's identification procedures	No	Yes
Actual use of incorrect gametes or embryos, no matter what the consequence (i.e. pregnant or not)	Yes	Yes
Complications directly attributable to ART Mental Health Event, death or permanent disability.	Yes	Yes
Ectopic Pregnancy	No	Yes
Breach of Legislation	Yes	Yes
Loss of Gametes or Embryos Inability to locate cryo stored bio items.	Yes	Yes
Loss of all gametes or embryos during the culturing and handling process.	Yes	Yes
Loss of some gametes or embryos during the culturing and handling process.	No	Yes

CC 10. Multiple pregnancies

The ART Unit must minimise the incidence of multiple pregnancies.

The ART Unit must provide evidence of implementation and review of policies/procedures that:

a) 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 even when the insemination is done offsite. The aim for multiple pregnancy rates should be less than 10%.

b) Ensure that patients receive information on the economic, medical, social and psychological hazards associated with multiple pregnancies.

CC 11. Data monitoring

The ART Unit must undertake regular reviews of treatment outcomes.

The ART Unit must provide evidence of implementation and review of policies/procedures to:

a) identify, collect, analyse and review data to monitor treatments and treatment outcomes at least annually.

b) benchmark the Unit's clinical outcomes against national and international standards

c) proactively follow up outcomes of treatment, including live births where possible

CC 12. Data reporting

The ART Unit must comply with national and institutional requirements for the provision of treatment data and must inform patients of the uses to which their medical information may be put.

The ART Unit must provide evidence of:

a) Compliance with national and institutional reporting requirements.

b) 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, certifying bodies, and any other relevant parties.

PART 2 GOOD PRACTICE CRITERIA

AUDIT OF ALL GOOD PRACTICE CRITERIA AT THE INITIAL CERTIFICATION AUDIT

AND SUBSEQUENTLY OVER -THREE YEARS OF ANNUAL INSPECTIONS, UNDER THE RTAC CERTIFICATION SCHEME

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

GPC 1. Quality management system (QMS)

The Unit 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.

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) 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.

d) 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,

e) 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, an audit of processes (including identification and traceability) and equipment in these facilities and during the 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.

iv) Security, particularly to protect the 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.

vi) Including records of service agreements with key contractors and key contracted service providers.

f) Risk management:

i) Assessment of risks,

ii) Review of risk,

iii) Workplace health and safety

g) Auditing:

i) Audit schedule;

ii) Internal audits in compliance with the audit schedule,

iii) All RTAC surveillance audits to be scheduled more than 30 days before the expiry date of their RTAC certification.

GPC 2. Stakeholder feedback

The Unit must undertake regular stakeholder feedback and acknowledge and investigate complaints.

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

GPC 3. Medical management

The Unit must ensure that it meets the reproductive health needs of the patients and partners under its care.

Provide evidence of implementation and review of policies/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) 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.

GPC 4. Patient Information

The ART Unit 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 that ensure:

a) Patients receive written and verbal information covering diagnosis, investigation and fertility treatment options.

b) The availability of a process to ensure information provision in comprehensible formats and language appropriate to the target audience.

c) Information is easy to understand and not misleading in any way.

Patient information must include but not be limited to:

i) Processes, costs, risks and outcomes.

ii) Drugs and side effects.

iii) Availability of individual counselling and support groups.

iv) Patient rights and responsibilities that are consistent with national policy.

v) Availability of translation and interpreter services.

vi) Preconception advice that includes the consequences of abnormal weight, smoking, adverse environmental exposure and other relevant factors.

GPC 5. Medication management

The Unit must ensure the safe management of drug storage, supply and administration.

Provide evidence of implementation and review of policies/procedures which include:

a) Authorising orders for drugs that are to be supplied or administered to patients.

b) Recording in the patient's file/record, all drugs that are supplied or administered to patients by the ART Unit. Batch numbers of drugs used, where available, should be recorded in a drug register. Where drugs are dispensed through a pharmacy or equivalent this is not a requirement.

c) Maintenance of accurate records and monitoring of the drug management system.

d) The safe procurement, storage, including temperature monitoring and disposal of drugs.

e) Management of returned drugs to ensure drugs are not reissued.

f) Management of drugs to ensure that they are always used within the expiry date.

GPC 6. Emergency care

The Unit must ensure access to emergency care.

Provide evidence of implementation and review of policies/procedures:

a) On emergency physical and psychological care.

b) That must ensure patients receive information on how to access emergency care including out-of-normal hours.

GPC 7. Ovarian hyperstimulation syndrome

The Unit must minimise the incidence of Ovarian Hyperstimulation Syndrome (OHSS).

Provide evidence of implementation and review of policies/procedures:

a) For the identification and management of patients at risk of, or experiencing, OHSS.

b) That measure and attempt to minimise the incidence of OHSS.

c) That must ensure patients receive information on the risks, symptoms and management of OHSS.

d) That must ensure patients receive information on how to access help, advice or care outside of normal hours or in the event of a medical emergency.

PART 3 ESTABLISHMENT AND CLOSURE OF AN ART UNIT

Initial Certification of an ART Unit

The Unit must ensure compliance with the RTAC Certification Scheme and the RTAC International Code of Practice.

The primary audit conducted by a Certifying Body on a clinic applying for certification, and before its receiving a license from RTAC should include:

a) Compliance with all aspects of the RTAC International Code of Practice except for treatment records and outcome data analysis

b) A fully documented clinic policy manual

c) A 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

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) Installation and validation of ALL proposed equipment for use in the clinic, in particular laboratory, drug storage, clinical and sterilisation equipment.

g) Records of an internal audit to verify compliance with these requirements performed by clinic personnel before the Certifying Body audit.

A Unit being certified for the first time must complete an internal audit of its Quality Management System and patient, gamete and embryo identification processes before the certification inspection by the Certifying Body.

RTAC has the right to require a further inspection after procedures have been performed.

Closure or Discontinuation of Certification of an ART Unit

The ART Unit should ensure the ongoing safe storage and accessibility of gametes, embryos, tissues and medical records. It must inform the relevant statutory and regulatory authorities, RTAC and the Certifying bodies, and all stakeholders of the processes carried out to ensure this safe storage and accessibility. This is for information only and is not part of the auditable standard.

ATTACHMENT 1

Donor & Surrogacy Requirements

The ART Unit must provide evidence of implementation and review of policies/procedures to ensure:

a) compliance with national legislation and/or guidelines on the donation of biological tissues, the donation of gametes and embryos, and the provision of services for surrogacy agreements;

b) commercial surrogacy is not undertaken;

c) support of the donors' offspring's right to know their genetic origin and to have in place policies and procedures for donor-offspring linking. Where legislation dictates anonymity, records linking the donor and recipient must be maintained in case of changes to legislation allowing identification. Donors must be counselled as to future legislative changes or applications for linking;

d) 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 arrangement including any financial arrangements and the rights of the donor/surrogate with regard to withdrawal from the arrangement;

e) that there be documented clinic-determined criteria for eligibility for donors and surrogates;

f) comprehensive identifying and non-identifying information is collected about each donor and/or surrogate including the last known address and relevant medical history of immediate family;

g) records about donors, recipients and surrogates are retained indefinitely;

h) that donors, recipients and/or the surrogate have attended a counselling process that includes (but is not limited to);

   i) the advantages of telling any resulting child of its genetic origin

   ii) local legislation defining the legal status of any child born as a result of the procedure

   iii) any genetic or infectious disease screening to be carried out and the implications of having a positive result.

   iv) Implications of donating or receiving donated gametes or embryos, or participating in surrogacy

i) the partners of the donor, the recipient and/or the surrogate must be included in the counselling and consenting process;

j) policies and procedures are in place, which have been developed in conjunction with the senior counsellor, about these treatment arrangements. For known donation, an additional joint session involving all parties must be undertaken before the signing of consents;

k) that counselling has been undertaken by trained personnel;

l) valid and 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;

m) 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 after donating;

n) there is a limitation on 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;

o) donors are required to declare if they have donated at other clinics to ensure that the family limit is maintained.

Donor – Recipient Counselling Checklist

The following checklist must be used as the basis for implications counselling for donors and recipients. All donors and recipients and their partners must undertake counselling prior to commencing treatment. Trained staff may facilitate the session using the checklist outlined below. Additional topics may be added to the list.

Donor:		**Donor's Partner** ***(If applicable)***	
Date of Donor Counselling:		Date of Partner's Counselling *(If applicable):*	
Recipient:		**Recipient's Partner** ***(If applicable)***	
Date of Recipient Counselling:		Date of Partner's Counselling *(If applicable):*	
Date of Joint Counselling Date if known donation:		Date of Joint Counselling Date if known donation:	
Counsellor:			

	Checklist for Gamete or Embryo Donor / Partner (if applicable)	**Discussed – Yes / No**
1	Information relating to legislation or guidelines on the donation or receipt of biological tissues.	
2	Local legislation defining the legal status of any child born as a result of the procedure.	
3	Support of the donor-offspring's right to know their genetic origin and procedures for donor-offspring linking. Options for offspring to make contact in the future if requested.	
4	Motivations of the donor in the context of their family and social history.	
5	Short and long-term consequences for all parties concerned, including that the donation may result in an adverse outcome.	
6	Support systems.	
7	Cultural, religious and moral issues to be addressed.	
8	Thoughts about disclosure to donor-conceived person about their donor conception.	
9	Expectations regarding contact/relationship with donor conceived child/ren.	
10	Consideration that any children they have/may have in the future will be genetically related to donor-conceived offspring.	
11	Donor's or Recipient's right to withdraw from the arrangement.	
12	Disclosure of relevant medical history of immediate family.	
13	The advantages of telling any resulting child of its genetic origin	
14	Any genetic or infectious disease screening to be carried out and the implications of having a positive result.	
15	Implications of donating or receiving donated gametes or embryos for themselves and their current and future families	
16	The consenting process and discussion about coercion.	
17	The limitation on the number of families from one donor, to comply with national regulations/guidelines and to minimise the potential risk of future consanguinity.	

18	Online DNA testing and the possibility of uncontrolled release of identifying information.	
19	Donors must be counselled as to future legislative changes or applications for donor linking.	

	Checklist for Recipient / Partner (if applicable)	**Discussed – Yes / No**
1	Information relating to legislation or guidelines on the donation or receipt of biological tissues.	
2	Local legislation defining the legal status of any child born as a result of the procedure.	
3	Support of the donor-offspring's right to know their genetic origin and procedures for donor-offspring linking.	
4	Motivations of the recipients in the context of their family and social history.	
5	Recipients' feelings about non-genetic parenting. Issues associated with the use of donated embryos and any siblings. Arrangements with embryo donors.	
6	Short and long-term consequences for all parties concerned, including that the donation may result in an adverse outcome.	
7	Support systems.	
8	Cultural, religious and moral issues to be addressed.	
9	Thoughts about disclosure to donor-conceived person about their donor conception.	
10	Expectations regarding contact/relationship between donor and offspring.	
11	Consideration that any child conceived may have half siblings that are genetically related.	
12	Donor's or Recipient's right to withdraw from the arrangement.	
13	Process for donation and receipt of gametes or embryos.	
14	The advantages of telling any resulting child of its genetic origin.	
15	Any genetic or infectious disease screening to be carried out and the implications of having a positive result.	
16	Implications of donating or receiving donated gametes or embryos for themselves, their donor-conceived child and extended families.	
17	The limitation on the number of families from one donor, to comply with national regulations/guidelines and to minimise the potential risk of future consanguinity.	
18	Online DNA testing and the possibility of uncontrolled release of identifying information.	

I / we declare that the information included in the checklist was discussed with my partner *(if applicable)* and I, and any questions have been answered to my/our satisfaction.

Donor: _____ Date:

Donor's Partner *(if applicable):* _____ Date:

Recipient: _____ Date:

Recipient's Partner *(if applicable):* _____ Date:

Counsellor: _____ Date:

ATTACHMENT 2

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, and 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 within 6 weeks to relevant local authorities, RTAC and the Certifying Body, along with a summary of the investigation of the event and any actions taken.
Appoint	When the Unit 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.
Counselling	Provision of professional assistance and guidance in resolving personal or psychological problems. For donors, recipients and surrogates counselling includes a discussion relating of the implications of treatment.
Deed of Agreement	A current signed agreement with the FSANZ to comply with the RTAC Code of Practice is required prior to each certification audit.
Facility	The physical location, site or building within or from which the service is provided.
FSANZ	Fertility Society of Australia and New Zealand
Governance	Taking responsibility for the overall direction of the Unit, including determination of the purpose and goals of the service.
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 Unit.
Must	Where it is mandatory in every circumstance to perform the required task with no exception.
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 a Unit.
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 a Unit 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 a Unit, service provider or the patient/donor themselves. This also includes documented information determined by the organisation as being necessary for the effectiveness of the business and management.
Review	A formal process of updating, amending, or replanning that is based on the evaluation of outcomes.
Risk	The chance of something happening that will harm patients, staff and the unit.
Risk management	The culture, processes and structures that are directed towards realising potential opportunities whilst managing adverse effects.
Sero-discordant	Where one partner is infected with a sexually transmitted disease and the other is not.
Service provider	An individual who is responsible for providing the service either independently or on behalf of a Unit. 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 a Unit, 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, and IUI. It does not include diagnostic procedures e.g. semen analysis.
Valid Consent	For consent to be valid: • 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, • the consent must be specific and is effective only concerning the treatment or procedure for which information has been given.

ATTACHMENT 3

Adverse Events Reporting

Please supply the following information about any serious adverse event to the RTAC secretariat and your Certifying Body as required in CC9 Adverse Section c) of the RTAC Code of Practice.

ART Unit name, site and RTAC licence number	
ART Unit reference number (if applicable)	
Type of event (Clinical, Laboratory, Regulatory, Compliance, Patient, other)	
Other authorities notified	
Date of Incident (This is the date the incident became apparent, for re-hospitalisation events it is the date the patient was first re-admitted to the hospital.)	
ART procedure (IVF, etc)	
Date of notification (This is the date this report was sent to RTAC and the CB)	
Date of OPU, ET (if FET), or procedure start date if there was no OPU or ET.	
Incident description (Please include cause, how identified, severity, staff involved (not names, eg. 2 embryologists) and dates. See additional notes for OHSS incidents)	
Number of eggs collected (if applicable)	
Pregnancy outcome (Include if the patient returned a positive test and is the pregnancy is ongoing)	

Patient outcome	
Analysis of causes and or contributing factors to the incident. (This must include any corrective action that was recommended.)	
Date of conclusion of the event	
The total number of days the patient was hospitalised. (Multiple re-admissions must be recorded separately and include a total)	
OHSS reporting only (The following extra information is requested if the event is OHSS)	
1) Type of stimulation (Agonist, Antagonist, Clomid	
2) Drug and dose of trigger used	
3) E2 level before the trigger	
4) Paracentesis (Y/N)	
5) Embryo Transfer (Y/N)	
6) Pregnancy (Y/N)	
Attached documentation (indicate if extra documentation has been included in the submission.)	
Member of Key Personnel reviewing the case, and date of the review	

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

ATTACHMENT 4

Best Practice Recommendations

The following recommendations have been made. At the moment these are not auditable but at some time in the future some or all of these recommendations will enter the Code as auditable standards.

CC3 - Disaster Management

a) It is recommended that all incubators used for gamete/embryo culture be alarmed and the alarms monitored 24/7.

b) It is recommended that all cryostorage devices (LN_2 tanks) be alarmed and the alarms monitored 24/7.

CC8 - Cryostorage

It is recommended that records must be kept of temperature movements within the vessel that may affect the viability of any stored genetic material.

CC10 - Multiple Pregnancies

It is recommended:

a) 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.

b) 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.

c) 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.

d) That single embryo transfer is mandatory for a gestational carrier in surrogacy arrangements.

e) In the formation of embryo transfer number policies, there be documented consideration of available resources to manage the risks of multiple pregnancies and premature delivery.