Reproductive Technology Accreditation Committee

CERTIFICATION SCHEME

(RTAC Scheme)

Fertility Society of Australia

SUPPLEMENT 2

AUDIT REPORT – COMPLIANCE WITH RTAC CODE OF PRACTICE

(For use by Certification Bodies)

(February 2016)

ART Unit:

Date of Audit: / /

Date of Report: / /

Type of Audit: Primary ☐ Surveillance ☐

CRITICAL CRITERIA:

(COMPLETE REVIEW WITH EACH AUDIT (For Accreditation to the both the Full Australia & New Zealand Code and the International Code)

IN ACCORDANCE WITH THE RTAC SCHEME)

CRITICAL CRITERIA	MEASURE	COMPLIANT Yes / No COMMENTS:	CORRECTIVE ACTIONS	COMPLETED
1. Compliance				
The Organisation must comply with statutory and regulatory requirements.	Provide evidence of: • identification and communication of statutory and regulatory requirements. • how changes to external requirements are integrated into work practices. • communication, implementation, and review of all policies/procedures. • compliance with the RTAC Code of Practice. • records of current signed Deed of Agreement with the FSA. • all human research having been approved by a Human Research Ethics Committee (HREC) registered by the NHMRC Australian Human Ethics Committee or New Zealand equivalent. • compliance with the NHMRC Ethical Guidelines on the use of ART in clinical practice and research (2007) or New Zealand equivalent, except where specific alternate policies have been directed by a registered HREC affiliated to the Unit.			

CRITICAL CRITERIA	MEASURE	COMPLIANT Yes / No COMMENTS:	CORRECTIVE ACTIONS	COMPLETED
2. Key Personnel				
The Organisation must ensure access to competent staff. Staff must include: • **Medical director** • **Scientific director** • **Nurse manager** • **Senior counsellor**	Provide evidence of: • qualifications, training, education and experience of key personnel. (Refer to Attachment 1) • In a clinic where any of these personnel do not normally work on site, the clinic must be able to demonstrate regular involvement of those personnel in clinical and quality control review of the clinic's activities.			
3. Complaints Management				
The Organisation must acknowledge and investigate complaints.	Provide evidence of implementation and review of policies/procedures which include: • information on how patients make a complaint and how they receive feedback. • acknowledgement and investigation of complaints. • systematic recording, review and corrective action of complaints.			

CRITICAL CRITERIA	MEASURE	COMPLIANT Yes / No COMMENTS:	CORRECTIVE ACTIONS	COMPLETED
4. Adverse Events				
The Organisation must acknowledge and investigate adverse events.	Provide evidence of implementation and review of: • policies/procedures to systematically collect, analyse causal factors, review and act on all adverse, unplanned and untoward events. • Adverse events, including serious adverse events and serious notifiable adverse events are defined in Attachment 2. • Serious Notifiable Adverse Events, as defined in Attachment 2, must be reported to RTAC through its secretariat and to the appropriate Certifying Body to facilitate audit of responses to the Adverse Event.			

CRITICAL CRITERIA	MEASURE	COMPLIANT Yes / No COMMENTS:	CORRECTIVE ACTIONS	COMPLETED
5. Identification and Traceability				
The Organisation must ensure that gametes, embryos and patients are correctly identified and matched at all times.	Provide evidence of implementation and review of: • policies/procedures to identify when, how and by whom the identification, matching, and verification are recorded for gametes, embryos and patients at all stages of the treatment process. • the process that constitutes the traceability of gametes and embryos at all stages of the treatment cycle. • regular (at least annual) audit of the patient, gamete and embryo identification process. • where any part of the ART process occurs in a surgical facility remote from the clinic and/or laboratory, audit of ID processes in those facilities must form part of the audit. Clinics are referred to the RTAC Technical Bulletin #4 for good laboratory practice in gamete, embryo and patient identification and matching.			

CRITICAL CRITERIA	MEASURE	COMPLIANT Yes / No COMMENTS:	CORRECTIVE ACTIONS	COMPLETED
6. Medication Management				
The Organisation must ensure the safe management of drug storage, supply and administration.	Provide evidence of implementation and review of policies/procedures which include: • authorising orders for drugs that are to be supplied or administered to patients. • recording in the patient's individual file / record all drugs that are prescribed for, supplied or administered to patients by the ART Organisation. • maintenance of accurate records and audit of the drug management system where drugs are held • the safe procurement, storage and disposal of drugs where held. • management of returned drugs to ensure drugs are not reissued.			

CRITICAL CRITERIA	MEASURE	COMPLIANT Yes / No COMMENTS:	CORRECTIVE ACTIONS	COMPLETED
7. Multiple Pregnancy				
The Organisation must minimise the incidence of multiple pregnancy.	Provide evidence of implementation and review of policies/procedures that: • regularly audit (at least annually) multiple pregnancy rates and corrective actions that continuously attempt to reduce the incidence of multiple pregnancies in all treatment cycles, including artificial insemination and ovulation induction where these are performed within the clinic. The aim for multiple pregnancy rate should be less than 10%. • recommend to patients that no more than one embryo or oocyte is transferred in the first treatment cycle where the oocyte is obtained from a woman aged less than 35 years at the time of oocyte collection. • must ensure that no more than two embryos or oocytes are transferred in any one treatment cycle in a woman under the age of 40 years at the time of oocyte collection. • must ensure that no more than two embryos or oocytes are transferred to a recipient woman, of any age, in any one treatment cycle, where the oocytes are donated from a woman aged less than 40 years at the time of oocyte collection. • must ensure that patients receive information on the economic, medical, social and psychological hazards associated with multiple pregnancy.			

CRITICAL CRITERIA	MEASURE	COMPLIANT Yes / No COMMENTS:	CORRECTIVE ACTIONS	COMPLETED
8. Ovarian Hyperstimulation Syndrome				
The Organisation must minimise the incidence of Ovarian Hyperstimulation Syndrome (OHSS).	Provide evidence of implementation and review of policies/procedures: • for the identification and management of patients at risk of or experiencing OHSS. • that measure and attempt to minimise the incidence of OHSS. • that must ensure patients receive information on the risks, symptoms and management of OHSS. • that must ensure patients receive information on how to access help, advice or care out of normal hours or in the event of medical emergency.			
9. Emergency Care				
The Organisation must ensure access to emergency care.	Provide evidence of implementation and review of policies/procedures: • on emergency care. • that must ensure patients receive information on how to access emergency care including out of normal hours.			

CRITICAL CRITERIA	MEASURE	COMPLIANT Yes / No COMMENTS:	CORRECTIVE ACTIONS	COMPLETED
10. Data Monitoring				
The Organisation must undertake regular reviews of treatment outcomes.	Provide evidence of implementation and review of policies/procedures: • to identify, collect, analyse and review data to monitor treatments and treatment outcomes at planned intervals. • to benchmark the organisation's clinical outcomes against national standards • where clinical outcomes fall below the mean of the most recent ANZARD data, documented strategies be in place to improve results to above the mean. where clinical outcomes fall below the mean of the most recent ANZARD data, documented strategies be in place to improve results to above the mean.			

CRITICAL CRITERIA	MEASURE	COMPLIANT Yes / No COMMENTS:	CORRECTIVE ACTIONS	COMPLETED
11. Data Reporting				
The Organisation must provide the Australian and New Zealand Assisted Reproduction Database (ANZARD) with required data in the stipulated timeframe. **The Organisation must pay all FSA/RTAC fees.** **The Organisation must inform patients of the uses to which their medical information may be put**	Provide evidence of: • compliance with ANZARD data input. • 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. Provide at audit by the selected Certifying Body a list of cases submitted to ANZARD in the previous calendar year as having become pregnant as a result of the ART treatment. From this list the CB will randomly select ten for which the Organisation will be required to provide documentary evidence of testing verifying pregnancy.			

CRITICAL CRITERIA	MEASURE	COMPLIANT Yes / No COMMENTS:	CORRECTIVE ACTIONS	COMPLETED
12. Donor & Surrogacy Requirements				
The Organisation must ensure gametes, embryos and tissues are safe for donation and use in surrogacy arrangements and that appropriate counselling has been provided.	Provide evidence of compliance with: - NH&MRC Ethical Guidelines on the use of Assisted Reproductive Technology in Clinical Practice and Research (2007) or any subsequent revision. - Any applicable state or territory legislation. It is noted that counselling by a suitably qualified counsellor with training and experience in assisted reproductive technology is mandatory for all donors, recipients and surrogates. The Organisation must supply to the Certifying Body audit team a list of all file codes involving donation divided according to sperm, oocytes and embryos, and surrogacy, in the previous calendar year. The CB will select 3 (where available) from each category for full audit on the day.			

CRITICAL CRITERIA	MEASURE	COMPLIANT Yes / No COMMENTS:	CORRECTIVE ACTIONS	COMPLETED
13. Management of Infection Risk				
The Organisation must manage the risk of infection transmission.	The Organisation must have in place risk assessments, policies and procedures which ensure the minimisation of infection transmission risk: • Between donors of reproductive tissues and recipients or surrogate • Between partners in sero-discordant couples • Between patients and donors and staff handling their biological material to include infectious disease screening, required hygiene procedures, and the use of personal protective equipment Where applicable, policies should define quarantine periods and tests to be performed.			

CRITICAL CRITERIA	MEASURE	COMPLIANT Yes / No COMMENTS:	CORRECTIVE ACTIONS	COMPLETED
14. Informed Consent				
The Organisation must ensure that treatment only occurs with fully informed consent.	The Organisation must have a process whereby clinicians ensure that consent is obtained from all patients and/or donors (and, where relevant, their spouses or partners) before treatment commences. The Organisation must provide patients with information that is accurate, timely and in formats appropriate to the patient. The Organisation must provide evidence of implementation and review of policies/procedures: • which define the consenting process • to ensure that consent is informed, voluntary, competent, specific, documented and remains current			
15. Medical Management				
The Organisation must ensure that the medical management and care of patients with infertility is as defined in Part 4 of the Code of Practice.	The Organisation must provide evidence that doctors providing medical management and care of infertile patients comply with the requirements listed in Part 4 of the Code of Practice including: • qualifications and training. • continued medical education • appropriate supervision			

GOOD PRACTICE CRITERIA

(COMPLETE REVIEW AT LEAST ONCE IN EVERY THREE YEARS (For Full Accreditation to the Australian & New Zealand Code)

AND WITH EACH AUDIT (For Accreditation to the International Code) IN ACCORDANCE WITH THE RTAC SCHEME)

GOOD PRACTICE CRITERIA	MEASURE	COMPLIANT Yes / No COMMENTS:	CORRECTIVE ACTIONS	COMPLETED
1. Quality Management System (QMS) **The Organisation must have a management system allowing planned, implemented, coordinated, and appropriate service delivery which meets the needs of all stakeholders.**	Provide evidence of implementation and review of the following QMS elements. 1 - Quality Management policy that: • demonstrates management commitment. • outlines the scope of services provided, including identification of outsourced services e.g. External consultants, Pathology, Ultrasound. • shows organisational objectives. 2 - Management review processes that review the scope, organisational objectives and relevance of quality management system.			

GOOD PRACTICE CRITERIA	MEASURE	COMPLIANT Yes / No COMMENTS:	CORRECTIVE ACTIONS	COMPLETED
1.QMS (continued)	3 - Integration of all personnel. 4 - Systems of internal communication: • copies of meeting minutes, emails, memos. 5 - Document control system: • evidence of implementation, approval and review of internal and external documents. 6 - Records management: • compliance with statutory and regulatory authorities. 7 - Personnel and training: • management commitment to adequate staffing and training. • identification of training needs. • records of training. • outline of responsibility and authority.			

GOOD PRACTICE CRITERIA	MEASURE	COMPLIANT Yes / No COMMENTS:	CORRECTIVE ACTIONS	COMPLETED
1. QMS (continued)	8 - Competency of personnel: • competency criteria including skill, education, training and experience. • records of individual's competency for all services both internal and external. 9 - Buildings and facilities: • assessment of requirements to meet organisational goals. • adequate facilities and equipment to meet objectives. • records of validation, maintenance and service of equipment. • security, particularly to protect confidentiality of records and integrity of gametes and embryos. • management of risks. e.g. emergency equipment, power, gas.			

GOOD PRACTICE CRITERIA	MEASURE	COMPLIANT Yes / No COMMENTS:	CORRECTIVE ACTIONS	COMPLETED
1.QMS (continued)	10 - Risk management and infection control: • assessment of risks. • review of risk. • incident reporting and response. corrective and preventative action 11 - Key supplier management: • identification and review of key suppliers. 12 - Auditing: • audit schedule. • internal audits in compliance with the audit schedule.			

GOOD PRACTICE CRITERIA	MEASURE	COMPLIANT Yes / No COMMENTS:	CORRECTIVE ACTIONS	COMPLETED
2. Patient Information **The Organisation must provide patients with information that is accurate, timely and in formats appropriate to the patient.**	Provide evidence of implementation and review of policies/procedures: • to ensure patients receive written and verbal information covering diagnosis, investigation and fertility treatment options. Information must include but not be limited to: • processes, costs, risks and outcomes. • drugs and side effects. • availability of counselling and support groups. • patient rights and responsibilities. • availability of translation and interpreter services			

GOOD PRACTICE CRITERIA	MEASURE	COMPLIANT Yes / No COMMENTS:	CORRECTIVE ACTIONS	COMPLETED
3. Reproductive Health of Infertility Patients The Organisation must ensure that it meets the reproductive health needs of the men and women under its care	Provide evidence of implementation and review of policies/procedures so that: • Infertile women undergo clinical evaluation for coexisting reproductive health or gynaecological problems, or those arising as a result of ART treatment • Infertile men undergo clinical evaluation for coexisting reproductive health and related problems, or those arising as a result of ART treatment. • There are pathways of referral for endocrine and andrological expertise • Preconceptual advice should be provided to couples, including the consequences of abnormal weight, smoking, adverse environmental exposure and other relevant factors. This should be incorporated into referral pathways to ensure optimal health before fertility treatment.			

GOOD PRACTICE CRITERIA	MEASURE	COMPLIANT Yes / No COMMENTS:	CORRECTIVE ACTIONS	COMPLETED
4. Cryostorage of Gametes and Embryos **The Organisation must ensure the safe management of cryopreserved gametes, embryos and tissues.**	Provide evidence of implementation and review of policies/procedures: • to identify, locate, retrieve and maintain cryopreserved material. • to limit the time in storage. • to manage the disposal of cryopreserved material.			
5. Stakeholder Feedback **The Organisation must undertake regular stakeholder feedback**.	Provide evidence of implementation and review of policies/procedures: • to collect, analyse, review and take relevant action on stakeholder feedback including patient stakeholders.			

Summary:

Noncompliance List:	Corrective Action List:	Satisfactory Corrective Action: Yes / No
1.		
2.		
3.		
4.		

Recommendation: Certification Yes ☐ No ☐

Comments:

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Auditor: _____ **Signature:** _____ **Date:** _____/_____/_____