# SASREG ACCREDITATION APPLICATION AND SELF-ASSESSMENT CHECKLIST 2022-2025

**PRIVATE AND CONFIDENTIAL**

## Application

**Organization name:** _____

**Director(s):** _____

_____

_____

**Physical Address:** _____

_____

**Main tel. no.:** _____

**Main contact email:** _____

**Director(s) contact email:** _____

_____

_____

**Appointed Liaison for Accreditation:**_____

**Liaison Designation:** _____

**Liaison email:** _____

**I/We hereby declare that all information in this form is to the best of my knowledge correct.**

**Director (s) Signature:** _____

**Director (s) Signature:** _____

**Director (s) Signature:** _____

**Date:** _____

**New Application or Previously Accredited Clinic:**_____

## Application support documents

**Attach the application and submitting documents to this Self-Assessment Checklist.**

**The following documents must accompany this application electronically and need to be compliant in advance of the physical survey visit:**

- Approval of the facility safety by the local authority, as applicable:
  - Occupation Certificate for consultation, office and laboratory areas, and
  - Letter by sedation practitioner for procedure room, or
  - Department of Health license as Health Facility.
- Full staff list with positions.
- List of all medical and laboratory personnel with certified copies of highest qualifications and professional body registrations (e.g., HPCSA, SANC).
- Completed Self-Assessment document.

## Self-Assessment details

**Date of Self-Assessment completed:**_____

**Management Assessment:**_____ **Sign:**_____

**Clinical Assessment:** _____ **Sign:**_____

**Laboratory Assessment:**_____ **Sign:**_____

**Nursing Assessment:** _____ **Sign:**_____

**Counselling Assessment:** _____ **Sign:**_____

### Completing the Checklist tables

- Compliance Points

**The supporting information section from the Standards are converted to Compliance Points that need to be shown by the organization as evidence of complying to that Standard and thus is the specific aspects to be checked and surveyed.**

The organization will need to achieve 100% Full compliance to ROPs and >80% Fully and Largely Compliant ratings for non-ROPs for successful accreditation.

Although Non-ROP Standards are considered recommendations for implementation in future, these Standards should be assessed in the same manner as it will allow organizations to identify areas to improve the quality of their ART service. It will also give them preparation for future surveys when these may change to ROP Standards.

All applicable sections will contribute to the compliance score. In case a section is not applicable, e.g., Oncofertility, this section is excluded and will not impact the compliance score.

The bullet points in this section must be ticked (e.g., √) when evidence of compliance is seen during the survey. Any items with which the organization could not demonstrate compliance at time of the survey, should be clearly marked (e.g., X). Items to be submitted at a later stage by the organization to achieve accreditation should be discussed in the Comments section. Some sections and/or standards may be subject to relevancy and thus number of applicable ROPs vary (* in compliance summary).

- Compliance assessment interpretation:

**Fully compliant:** All aspects met according to supporting information and surveyor assessment.

**Largely compliant:** Minor aspects need attention, but no 'must' actions that need to be remedied.

**Partially compliant:** There is at least one "must" action recommendation that needs to be dealt with to be accredited.

**Non-compliant:** One or more "must" actions are required that must be resolved quickly in order for accreditation to be considered; if there are too many "non-compliant" items then accreditation could be withheld.

- Comments/Notes

**Notes or comments can be made by the assessing staff and can be inserted in this dedicated section.**

The electronic versions of the application, submitted documents, completed copies of this self-assessment checklist and the draft report will be submitted to the Surveyors, Accreditation Committee and kept on file by Turners.

## Compliance Summary

| | ROPs | | | | Total | Non-ROPs | | | | Total |
|---|---|---|---|---|---|---|---|---|---|---|
| | **Full** | **Largely** | **Partial** | **Non** | **Full** | **Full** | **Largely** | **Partial** | **Non** | **Full+ Largely** |
| **Facility Management:** | | | | | **/10** | | | | | **/5** |
| **Clinical Services:** | | | | | **/6** | | | | | **/6** |
| **Oncofertility*:** | | | | | **/5*** | | | | | **/3*** |
| **Nursing Services:** | | | | | **/6** | | | | | **/16** |
| **Laboratory Services:** | | | | | **/18** | | | | | **/38** |
| **Psychology & Counselling Services** | | | | | **/4** | | | | | **/6** |
| **Overall Outcome:** | | | | | **/** | | | | | **/** |

## Contents

## Table of tables

# I. FACILITY MANAGEMENT

## Assessors

**Director(s) and/or Management staff.**

**Assessor 1 Name: _____**

**Assessor 2 Name: _____**

**Assessor 3 Name: _____**

**Assessor 4 Name: _____**

## A. OVERALL MANAGEMENT

*Table I.1. Framework for standards: Facility Management.*

| MANAGEMENT | A: GENERAL FACILITY MANAGEMENT |
|---|---|
| **1. FACILITY, PLANNING & DESIGN** | 1. Building plan, structure, and installations compliance. ***ROP***<br>2. Design for efficient workflow and services.<br>3. Reception and waiting area(s). |
| **2. QUALIFICATIONS & STAFF STRUCTURE** | 4. Human resources. ***ROP*** |
| **3. EQUIPMENT & CONSUMABLE MANAGEMENT** | 5. Procurement, maintenance, and repairs. ***ROP***<br>6. Medication control and management. ***ROP***<br>7. Supply chain vendor contact list. |
| **4. PROCESSES & PROCEDURES** | 8. Quality control of specialized services. ***ROP*** |
| **5. INFORMATION, COMMUNICATION & FEEDBACK** | 9. Documents and records ***ROP***<br>10. General patient communication.<br>11. Informed consents for treatment and procedures. ***ROP***<br>12. ART data submission to national registries. ***ROP***<br>13. Complaints and feedback management. |
| **6. RISK & EMERGENCY MANAGEMENT** | 14. General Hygiene and Infection control. ***ROP***<br>15. Risk assessment and disaster plans. ***ROP*** |

| DEPARTMENT Management | | Sub-Department General |
|---|---|---|
| **A.1.1.** | **Standard name: Facility, planning & design:** Building plan, structure, and installations compliance. | **ROP: Yes** |

**Standard statement/Goal:**

**The facility must comply to local authority requirements, regulations and have the compliance approvals in place.**

**Intent:**

The facility must be structurally sound and safe for patients and staff and be fit to serve as a health facility to provide health services. It must have the essential basic services properly installed and maintained by authorized service providers.

**Compliance Points: *(indicate evidence seen)***

- Approved certificate of occupation from local building inspector or authority.
- Certificates of safety/compliance for installations by certified installers/providers of basic and additional services and systems.
- Repairs and support contractors for basic and additional services.

**Compliance assessment: *[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Management | | Sub-Department General |
|---|---|---|
| **A.1.2.** | **Standard name: Facility, planning & design:** Design for efficient workflow and services. | **ROP:** No |

**Standard statement/Goal:**

**The facility should be designed to be efficient in its operations when providing the services offered, with specific considerations to provide comfort for patients and occupational health and safety of the personnel.**

**Intent:**

The design and layout of the facility should be favorable to provide the ART service it offers efficiently and effectively, while including important considerations for the comfort of patients and occupational health of personnel.

**Compliance Points:** ***(indicate evidence seen)***

- Floor plans indicating efficient layout and considerations for patients and personnel.
- Occupational health considerations.
- Physical walk through for flow of patients and personnel.
- Access control system and/or policies.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Management | | Sub-Department General |
|---|---|---|
| **A.1.3.** | **Standard name: Facility, Design & Planning:** Reception and waiting area(s). | **ROP:** No |

**Standard statement/Goal:**

**The waiting and reception areas should have a comfortable atmosphere.**

**Intent:**

The reception area should ensure the patient is kept comfortable and secure while waiting, with sufficient comfortable seating for the number of patients.

**Compliance Points:** ***(indicate evidence seen)***

- Facility design and floorplan to show proper considerations for reception areas where needed.
- Summaries of patient satisfaction survey results.
- Booking diary to indicate capacity.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Management | | Sub-Department General |
|---|---|---|
| A.2.4. | Standard name: **Qualifications & Staff structure:** Human resources. | ROP: Yes |

**Standard statement/Goal:**

**The organization must have a human resource management system in place.**

**Intent:**

The organization must have a system for the management of the personnel they employ or have service contracts with. The system must be structured and comprehensive to include records of all relevant qualifications, registrations at professional bodies where applicable, and the contracts and agreements with all personnel performing duties and/or providing a service to patients at the facility regarding their expected responsibilities and job descriptions.

**Compliance Points:** ***(indicate evidence seen)***

- Staff structure organogram of whole facility.
- Policy on hiring appropriate personnel and filing system of personnel records.
- Backup staff agreement(s) where applicable.
- Written evidence/Minutes of staff meetings and staff feedback.
- Educational/Training system or policy.

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Management | | Sub-Department General |
|---|---|---|
| A.3.5. | Standard name: **Equipment & Consumable management:** Procurement, maintenance, and repairs. | ROP: Yes |

**Standard statement/Goal:**

**Proper management of all the equipment and consumables used within the facility to ensure optimal functioning.**

**Intent:**

An ART facility is highly reliant on the proper functioning of equipment and consumables to provide quality patient care and health services. There must be a system for the management and servicing of all the essential equipment, sterile contact materials, consumables, and accessory items. At a minimum, manufacturer's schedules, or instructions, or both must be used. The system must include policies regarding procurement of appropriate items, acceptance of deliveries, service and maintenance requirements, validations before clinical use and the repair and discontinuation of use processes. Current instruction on the use, safety and maintenance of equipment, including manuals and directions for use of the equipment must be readily available.

**Compliance Points:** ***(indicate evidence seen)***

- Policy on equipment management, with service schedules and technical repair providers.
- Policy on consumable and contact material stock control and management.
- **Note: Compliance dependent on implementation compliance in each sub-section/area below: Clinical, Laboratory and Nursing services.**

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Management | | Sub-Department General |
|---|---|---|
| A.3.6. | Standard name: Equipment & Consumable management: Medication control and management. | ROP: Yes |

**Standard statement/Goal:**

**Medicines within the facility must be managed and controlled as according to national regulations and the manufacturers' instructions.**

**Intent:**

All pharmaceuticals and medications are to be controlled and managed according to Government regulations. Suitably stored pharmaceuticals and medications maintain shelf-life and ensure adequate efficacy when used correctly. There must be a stock control system for the medicine and medicinal supplies, including to ensure the availability of the medicines and medicinal supplies for the delivery of services according to demand.

**Compliance Points: *(indicate evidence seen)***

- Up to date drug register book.
- SOP and manufacturer's instructions for storage and use of medications, including reporting and feedback of adverse outcomes.
- Log sheets for the temperature monitoring.
- Soundalike vs lookalike SOP.
- Policy and designated responsible persons for medication management and access in the facility.
- Qualified responsible pharmacist for high scheduled drugs (where applicable).

**Compliance assessment: *[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Management | | Sub-Department General |
|---|---|---|
| **A.3.7.** | **Standard name: Equipment & Consumable Management:** Supply chain vendor contact list. | **ROP:** No |

**Standard statement/Goal:**

**The supply chain vendors for all equipment, consumables, and medication available to support the stock control system to ensure continuous patient care services.**

**Intent:**

The supply chain vendors for all equipment, consumables and medication should be listed and available to support the stock control system, for trouble shooting, stock shortage or faulty items, and ensure patient care is uninterrupted.

**Compliance Points: *(indicate evidence seen)***

- Supply chain vendors list available to designated staff.
- Procedure for supply chain problems and changes.
- Supplier contracts in place and backup suppliers where essential.

**Compliance assessment: *[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Management | | Sub-Department General |
|---|---|---|
| A.4.8. | Standard name: **Processes & Procedures:** Quality control of specialized services. | ROP: Yes |

**Standard statement/Goal:**

**The necessary specialized services and sterile supplies that are provided by external service providers is appropriately certified, validated and monitored for quality.**

**Intent:**

Specialized services by external providers are required by the organization as a supplement to the provision of ART services. The specialized services that may affect the quality of ART services especially those that may cause harm or risk to patients or staff, integrity of critical equipment, samples, or facility itself, must be provided by appropriately certified companies/organizations. The necessary agreements must be in place to ensure that the quality of their service is controlled and reliable.

**Compliance Points:** ***(indicate evidence seen)***

- List of certified specialized services, including their certificates, individual certifications of technicians (where applicable) and agreements of service provision, (e.g., biological waste removal, gas supplier, air quality technicians, sterilized surgical packs, specialized plumbing, specialized electrical power supply (UPS, Generator)).
- Records of services delivered (paper trail) and certificates received.
- Monitoring process by staff to confirm and report the quality of service/products.

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Management | | Sub-Department General |
|---|---|---|
| A.5.9. | Standard name: **Information, Communication & Feedback:** Documents and records. | ROP: Yes |

**Standard statement/Goal:**

**The organization must have an administrative system of managing all documents to ensure on-hand availability to relevant staff, and the proper use and, filing and storage of patient records and documents during provision of ART services.**

**Intent:**

ART services involve various types of important documents and records. A system must be in place to ensure proper use of relevant forms, protocols and consents, with current versions available at relevant locations, regular reviews and updates are done. Completed patient documents and records are safely filed and appropriately stored.

**Compliance Points:** ***(indicate evidence seen)***

- Outline of the document control management system/policy with review process.
- Accessibility control of current documentation.
- Back-up set-up for documents.
- Policy on electronic patient records and sharing on devices or groups.

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Management | | Sub-Department General |
|---|---|---|
| **A.5.10.** | **Standard name: Information, Communication & Feedback:** General patient communication. | **ROP:** No |

**Standard statement/Goal:**

**To ensure that all patients understand their treatment, regardless of a language barrier or disability.**

**Intent:**

The foundation of providing effective treatment and coordination is effective communication with the patient.

**Compliance Points: *(indicate evidence seen)***

- Polices and protocols on communication with patients with language barriers.
- Translations of information sheets.

**Compliance assessment: *[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Management | Sub-Department General | |
|---|---|---|
| A.5.11. | Standard name: **Information, Communication & Feedback:** Informed consents for treatment and procedures. | ROP: Yes |

**Standard statement/Goal:**

**There must be a consent form for treatments and procedure that the patient will undergo, to ensure patients are fully informed and consent to prevent litigation.**

**Intent:**

Patients must give and sign appropriate consent forms in advance of receiving ART treatment.

**Compliance Points:** ***(indicate evidence seen)***

- Consent documents for procedures and treatments.
- Policy for receiving consents (when and who) (can request a record at random, de-identified).
- Information and consent revisions.
- Example of Surrogacy case with High Court Approval and treatment plan (de-identified, and if applicable).

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Management | | Sub-Department General |
|---|---|---|
| A.5.12. | Standard name: **Information, Communication & Feedback:** ART data submission to national registries. | ROP: Yes |

**Standard statement/Goal:**

**The organization must have a process in place to ensure the data of ART services are submitted to operational national data registries including SARA/ANARA.**

**Intent:**

ART services involve various types of treatments and outcomes thereof should be recorded and submitted to active national ART data registries.

**Compliance Points:** ***(indicate evidence seen)***

- Policy or SOP on data entry into current data registries.
- Registration of organization on SARA/ANARA data capturing website.
- Evidence of current up to date data submission to SARA/ANARA.

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Management | | Sub-Department General |
|---|---|---|
| A.5.13. | Standard name: **Information, Communication & Feedback:** Complaints and feedback management. | ROP: No |

**Standard statement/Goal:**

**The organization should have a system to receive, report and act on complaints and feedback from patients and personnel to improve on the quality of the services they provide.**

**Intent:**

ART treatments involve a complex integration of several services and interactions between patients, personnel, suppliers, products, services and processes within the facility. Receiving and acting on feedback and complaints is an important part of monitoring quality of care and improving where the opportunity arises.

**Compliance Points:** ***(indicate evidence seen)***

- Complaints and feedback system.
- Meeting minutes to include feedback and action.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Management | | Sub-Department General |
|---|---|---|
| A.6.14. | Standard name: **Risk Management & Emergency Plans**: Hygiene and infection control. | ROP: Yes |

**Standard statement/Goal:**

**Cleaning and infection control measures in place and monitored for hygienic environment.**

**Intent:**

The facility, laboratories and office areas must be a clean and neat environment to provide healthy and safe spaces where both patients and staff are accommodated. There must be proper system of managing the cleaning for all the various types of areas and items and provide hand washing facilities where needed. General and medical waste must be managed appropriately.

**Compliance Points:** ***(indicate evidence seen)***

- Cleaning schedules, equipment, and storage.
- Cleaning logs and audits on hygiene and infection control.
- Staff and patient feedback and feedback surveys.
- Special infection control policy according to governmental notices when applicable.
- General and medical waste management plan with infection prevention.

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Management | | Sub-Department General |
|---|---|---|
| A.6.15. | Standard name: **Risk Management & Emergency Plans**: Risk assessment and disaster plans. | ROP: Yes |

**Standard statement/Goal:**

**Disaster and emergency plans based on risk assessments must be in place for the safety of personnel, patients, and reduction of detrimental effects to samples and critical and sensitive equipment.**

**Intent:**

Risk assessment of local probable disasters and emergency action plans must be in place for appropriate measures to be taken in emergency situations. In addition to local authorities' required emergency plans, additional risk assessment and emergency plans need to be in place according to the location and layout of the facility and the ART services it provides. All staff must be trained and knowledgeable of the emergency plans and measures for proper execution.

**Compliance Points:** ***(indicate evidence seen)***

- Approved Fire and evacuation plan (written and specify roles and responsibilities) with valid service and inspection certificates.
- Risk assessment report and resulting emergency plans including electrical back-up system.
- Logs of staff training in emergency plans, including formal competency certificates.

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

# II. CLINICAL SERVICES

## Assessors

**Fertility Specialist(s).**

**Assessor 1 Name: _____**

**Assessor 2 Name: _____**

**Assessor 3 Name: _____**

**Assessor 4 Name: _____**

## B. CLINICAL CONSULTATIONS AND TREATMENTS

*Table II.1. Framework for standards: Clinical Consultations and Treatments.*

| CLINICAL SERVICES | B: CLINICAL CONSULTATIONS AND TREATMENTS |
|---|---|
| **1. FACILITY, PLANNING & DESIGN** | 1. Sonar examination and consultation rooms. |
| **2. QUALIFICATIONS & STAFF STRUCTURE** | 2. Required qualifications and registration. ***ROP*** |
| **3. EQUIPMENT & CONSUMABLE MANAGEMENT** | 3. Equipment and consumables for gynecological examinations. |
| **4. PROCESSES & PROCEDURES** | 4. Treatment protocols and guidelines.<br>5. Consultation efficiency and records. |
| **5. INFORMATION, COMMUNICATION & FEEDBACK** | 6. Patient consent, information and feedback. |
| **6. RISK & EMERGENCY MANAGEMENT** | |

| DEPARTMENT Clinical Services | Sub-Department Clinical Consultations and Treatments | |
|---|---|---|
| B.1.1. | Standard name: **Facility, Planning & Design:** Sonar examination and consultation rooms. | ROP: No |

**Standard statement/Goal:**

**The consultation and examination room should ensure the privacy of the patient and have the appropriate facilities to perform required gynecological consultation and examinations.**

**Intent:**

The consultation and examination room should ensure the privacy and keep consultations confidential. The consultation room should ensure the patient is comfortable and safe for the duration of the consultation. The examination facilities should be clean and hygienic for safety of patients and staff.

**Compliance Points:** ***(indicate evidence seen)***

- Design and plans to show appropriate considerations for consultation and examination rooms to serve the purpose.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Clinical Services | | Sub-Department Clinical Consultations and Treatments |
|---|---|---|
| B.2.2. | Standard name: **Qualifications & Staff structure:** Required qualifications and registration. | ROP: Yes |

**Standard statement/Goal:**

**Optimizing patient safety during the assisted reproductive treatments and procedures.**

**Intent:**

The withdrawal of gametes from a person must only be performed by a reproductive specialist as defined by the Regulations of the National Health Act.

In the case of sperm, a qualified urologist is allowed to also perform the withdrawal procedure.

**Compliance Points:** ***(indicate evidence seen)***

- Copies of qualifications and HPCSA registrations of clinicians performing reproductive medicine treatments.

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Clinical Services | | Sub-Department Clinical Consultations and Treatments |
|---|---|---|
| **B.3.3.** | **Standard name: Equipment & Consumable Management:** Equipment and consumables for gynecological examinations. | **ROP:** No |

**Standard statement/Goal:**

**There should be an adequate standard of equipment and instrumentation available for conducting a gynecological examination including the necessary consumables.**

**Intent:**

The organization should ensure availability of an ultrasound machine with a vaginal probe capable of adequately and accurately visualizing the appropriate pelvic structures.

Adequate examination beds and equipment necessary for gynecological examination is required. All necessary consumables needed to perform gynecological examination should be easily accessible.

**Compliance Points:** ***(indicate evidence seen)***

- Working ultrasound with vaginal and abdominal probes.
- Suitable examination bed with lithotomy.
- Equipment and accessories for conducting gynecological examination, including light control
- Appropriate covering or gown provided to the patient for physical examination.
- Cleaning schedule/policy of the examination room between patients.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Clinical Services | | Sub-Department Clinical Consultations and Treatments |
|---|---|---|
| B.4.4. | Standard name: **Processes and Procedures:** Treatment protocols and guidelines. | ROP: No |

**Standard statement/Goal:**

**Fertility treatment procedures and diagnostic processes should be led by protocols and guidelines for patient risk management.**

**Intent:**

Specific risk reduction and management guidelines should be used as foundation for infertility treatment procedures and referral processes.

**Compliance Points:** ***(indicate evidence seen)***

- Clinical policies regarding reducing risks for hyper stimulation and multiple pregnancy.
- Information leaflets on above conditions.
- Recognized guidelines used as basis for clinical policies.
- Referral network and processes.
- Statistics on adverse events and multiple pregnancy rate

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Clinical Services | | Sub-Department Clinical Consultations and Treatments |
|---|---|---|
| B.4.5. | Standard name: **Processes and Procedures:** Consultation efficiency and records. | ROP: No |

**Standard statement/Goal:**

**To define processes and procedures to ensure that consultation and examinations are conducted safely and efficiently, and findings recorded sufficiently.**

**Intent:**

The consultation should be scheduled for a duration of time sufficient to address the needs of the patient. This should allow for a through history and clinical examination when indicated. Information collected from the consultation should be kept in a filing system or electronically. Clinical and sonar examination should be conducted in an appropriate fashion with adequate attention to necessary hygiene practices.

**Compliance Points:** ***(indicate evidence seen)***

- Supporting evidence of adequate consultation time to address the need of patients.
- Notes regarding the consultation should be structured
- Clinical notes should be recorded either written or electronically.
- Random review of patient records.
- POPI-compliant Quality systems should be in place.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Clinical Services | | Sub-Department Clinical Consultations and Treatments |
|---|---|---|
| B.5.6. | Standard name: **Information, Communication and Feedback:** Patient consent, information and feedback. | ROP: No |

**Standard statement/Goal:**

**The patient should have adequate access to information and timeous feedback on results and treatment planning, with clear channels to address complaints when they arise.**

**Intent:**

All relevant information should be shared freely with the patient.

The patient should be engaged in a manner or at a level of scientific complexity that ensures that they understand their diagnosis, treatment plan and prognosis.

Informed consent should be confirmed to be received before treatment commence and as treatment my change.

Results of special investigations should be communicated in a timeous and appropriate fashion. Clear channels for the patient to raise further questions or complaints should made available.

Feedback from the patients on their experience at the organization should be sought to identify any problem areas.

**Compliance Points: *(indicate evidence seen)***

- Standard operating procedures to document and facilitate communications.
- Visual aids to enhance understanding and knowledge.
- Complaints file and actions taken.
- Satisfaction Questionnaire.
- Quality control meeting minutes.

**Compliance assessment: *[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

## C. PROCEDURE ROOM

*Table II.2. Framework for standards: Procedure room.*

| CLINICAL SERVICES | C: PROCEDURE ROOM |
|---|---|
| **1. FACILITY, PLANNING & DESIGN** | 1. Procedure room design and layout. ***ROP*** |
| **2. QUALIFICATIONS & STAFF STRUCTURE** | 2. Qualifications, training and staff levels procedures under sedation. ***ROP*** |
| **3. EQUIPMENT & CONSUMABLE MANAGEMENT** | 3. Equipment and consumables for safe sedation practice. ***ROP***<br>4. Equipment and consumables for retrieval and transfer procedures. ***ROP*** |
| **4. PROCESSES & PROCEDURES** | |
| **5. INFORMATION, COMMUNICATION & FEEDBACK** | 5. Identification, records and informed consent. ***ROP*** |
| **6. RISK & EMERGENCY MANAGEMENT** | 6. Optimal hygiene standards and infection control. ***ROP*** |

| DEPARTMENT Clinical Services | Sub-Department Procedure room | |
|---|---|---|
| C.1.1. | Standard name: **Facility, Planning & Design:** Procedure room design and layout. | ROP: **Yes** |

**Standard statement/Goal:**

**The procedure room must have the appropriate facilities to perform required gamete retrievals and embryo transfers, with access to recovery area and provide patient privacy during operation.**

**Intent:**

The organization must provide dedicated procedure room(s) for gamete retrievals and embryo transfer, and all the necessary design and facilities to be able to perform the procedures adequately. The design must ensure patient privacy is secure during operation and adequate change and scrubbing facilities is available.

**Compliance Points:** ***(indicate evidence seen)***

- Design and plans to show appropriate installations and facility layout for the procedure room, change area and scrub basin.
- Temperature control.
- Access control measures.
- Policy for appropriate air quality control in procedural rooms with supporting evidence.
- Validation/Approval letter from the sedation practitioner confirming the suitability of facilities for sedation practice or DOH license where required.

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Clinical Services | | Sub-Department Procedure room |
|---|---|---|
| C.2.2. | Standard name: **Qualifications & Staff structure:** Qualifications, training and staff levels procedures under sedation. | ROP: Yes |

**Standard statement/Goal:**

**The physician and nurse(s) must be adequately trained in performing gamete retrievals and embryo transfers and the staff level sufficient to support the sedation process.**

**Intent:**

Sedation procedures must be done by qualified registered sedation practitioner(s) and supported by adequately trained nursing staff during assisted reproductive procedures.

**Compliance Points: *(indicate evidence seen)***

- List of all staff present during sedation procedures with qualifications, registrations and training/audit records.
- Policy on staff level and responsibilities during sedation procedures according to procedure, sedation patient class and sedation level.
- 3-person model vs. 2-person model – Evidence of documentation

**Compliance assessment: *(select one)***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Clinical Services | | Sub-Department Procedure room |
|---|---|---|
| C.3.3. | Standard name: **Equipment & Consumable Management:** Equipment and consumables for safe sedation practice. | ROP: Yes |

**Standard statement/Goal:**

**To ensure patient safety, it is required that the appropriate sedation and monitoring equipment, medication and consumables is available and confirmed to be sufficiently supplied in the procedure room by either the appointed sedation practitioner(s) or a Department of Health (DOH) license.**

**Intent:**

Equipment, medication, and consumables required for safe sedation must be confirmed to be available and sufficient by the sedation practitioner inducing sedation for retrieval and transfer procedures.

**Compliance Points: *(indicate evidence seen)***

- Validation letter from the sedation practitioner (confirming the appropriate facilities for sedation practice is in place) or DOH license of procedure room where applicable (provincial regulations).
- The DOH license in the case of the use of a theatre facility (separate to a procedure room set-up).

**Compliance assessment: *(select one)***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Clinical Services | | Sub-Department Procedure room |
|---|---|---|
| C.3.4. | Standard name: **Equipment & Consumable Management:** Equipment and consumables for retrieval and transfer procedures. | ROP: Yes |

**Standard statement/Goal:**

**An adequate standard of equipment and instrumentation for conducting a gamete retrievals and embryo transfers including the necessary consumables.**

**Intent:**

To ensure the availability and use of specialized required equipment for gamete retrievals and embryo transfers, including the appropriate consumables.

**Compliance Points:** ***(indicate evidence seen)***

- Sonar equipment and accessory list with validation records, user manuals for instructions of use and maintenance schedule with history logs.
- List of consumables and instruments used during these procedures.

**Compliance assessment:** ***(select one)***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Clinical Services | | Sub-Department Procedure room |
|---|---|---|
| C.5.5. | Standard name: **Information, Communication & Feedback:** Identification, records, and informed consent. | ROP: **Yes** |

**Standard statement/Goal:**

**Adequate and accurate identification, data collection and informed consent.**

**Intent:**

Accurate identification of patient and tissue sample is essential. Informed consent is to be obtained in advance of procedure commence.

**Compliance Points:** ***(indicate evidence seen)***

- Protocols on patient and sample identification.
- Data capturing protocol.
- Sedation consent forms.
- Procedure and monitoring forms.

**Compliance assessment:** ***(select one)***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Clinical Services | Sub-Department Procedure room | |
|---|---|---|
| C.6.6. | Standard name: **Risk & Emergency Management:** Infection incidents, power back-up and emergency trolley. | ROP: Yes |

**Standard statement/Goal:**

**There must be appropriate protocols in place to handle infection incidents and medical emergencies including power back-up to emergency equipment is available.**

**Intent:**

It is required that the procedures and recovery process provide a safe environment for staff and patients. The proper infection control measures and emergency protocols must be in place. Power back-up must supply critical and emergency equipment.

**Compliance Points:** ***(indicate evidence seen)***

- Training and monitoring logs of power back-up and functioning of emergency and critical equipment for procedure room while on power back-up.
- Records of emergency trolley supplies and monitoring.
- Protocols for disinfection, cleaning and handling of biohazardous waste in procedure room.

**Compliance assessment:** ***(select one)***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

## D. ONCOFERTILITY

**This section is only applicable to organizations performing female fertility preservation for oncological reasons. Specific Processes & procedures standards *(tables D.4.3, D.4.4. & D.4.6.)* further subject to facility relevancy.**

**Select relevancy:**

☐ Section applicable ☐ Section not applicable

*Table II.3. Framework for standards: Oncofertility.*

| CLINICAL SERVICES | D: ONCOFERTILITY |
|---|---|
| **1. FACILITY, PLANNING & DESIGN** | 1. Services. ***ROP*** |
| **2. QUALIFICATIONS & STAFF STRUCTURE** | 2. Oncofertility knowledge. |
| **3. EQUIPMENT & CONSUMABLE MANAGEMENT** | |
| **4. PROCESSES & PROCEDURES** | 3. Oocyte Cryopreservation. ***ROP***<br>4. Ovarian tissue cryopreservation. ***ROP***<br>5. Timeline. ***ROP***<br>6. Financial support. ***ROP*** |
| **5. INFORMATION, COMMUNICATION & FEEDBACK** | 7. Clinical notes.<br>8. Informed consent. |
| **6. RISK & EMERGENCY MANAGEMENT** | |

| DEPARTMENT Clinical Services | | Sub-Department Oncofertility |
|---|---|---|
| D.1.1. | Standard name: **Processes & Procedures:** Services. | ROP: Yes |

**Standard statement/Goal:**

**An Oncofertility Clinic should be able to offer a range of fertility preservation options to their oncology patients.**

**Intent:**

The treatment option for an oncofertility patient is highly case specific. Treatment should be individualized, after considering all the relevant clinical factors.

**Compliance Points:** ***(indicate evidence seen)***

- Evidence of appropriate stimulation protocols.
- The contingency plan, as who they refer to should the full spectrum of options not be available or if the clinician is on leave.

**Compliance assessment:** ***(select one)***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Clinical Services | | Sub-Department Oncofertility |
|---|---|---|
| **D.2.2.** | **Standard name: Qualifications & Staff Structure:** Oncofertility knowledge. | **ROP:** No |

**Standard statement/Goal:**

**The fertility specialist must understand the basic principles in fertility preservation.**

**Intent:**

The intended Fertility preservation option is determined by multiple clinical factors. A basic understanding of cancer treatment and its effect on future fertility is paramount in understanding and treating these patients. Treatment must be individualized, after considering all the relevant clinical factors.

**Compliance Points: *(indicate evidence seen)***

- Evidence of Oncofertility training and courses attended.

**Compliance assessment: *(select one)***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Clinical Services | | Sub-Department Oncofertility |
|---|---|---|
| D.4.3. | Standard name: Processes & Procedures: Oocyte Cryopreservation. | ROP: Yes |

**Standard statement/Goal:**

**The procedure of Oocyte Cryopreservation is an essential step in the preservation of a patient's fertility potential.**

**Intent:**

Optimization of future clinical outcomes.

**Compliance Points: *(indicate evidence seen)***

- Supportive documentation of lab KPI's on cryo-survival rates and pregnancy outcomes in vitrified oocyte treatment cycles.

**Compliance assessment: *(select one)***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

☐ **Not applicable (procedure not performed)**

**Comments / Notes**

| DEPARTMENT Clinical Services | | Sub-Department Oncofertility |
|---|---|---|
| D.4.4. | Standard name: **Processes & Procedures:** Ovarian tissue cryopreservation. | ROP: Yes |

**Standard statement/Goal:**

**Ovarian Tissue Cryopreservation (OTC) is a novel fertility preservation strategy which creates both opportunities and challenges.**

**Intent:**

Ovarian tissue banking is an acceptable fertility-preservation technique. It is no longer considered experimental. Ovarian tissue banking is the only method to preserve fertility for pre-pubertal girls and in aggressive cancers. However, this fertility preservation technique is novel for most South African clinics and should therefore only be performed under guidelines and ethical practices.

**Compliance Points: *(indicate evidence seen)***

- Evidence exposure and training in ovarian tissue cryopreservation.

**Compliance assessment: (*select one*)**

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

☐ **Not applicable (procedure not performed)**

**Comments / Notes**

| DEPARTMENT Clinical Services | | Sub-Department Oncofertility |
|---|---|---|
| D.4.5. | Standard name: **Processes & Procedures:** Timeline. | ROP: Yes |

**Standard statement/Goal:**

**Rapid access to fertility preservation counselling must be provided.**

**Intent:**

To prevent delaying time sensitive oncology treatment, potentially impacting on the long-term prognosis of the patient.

**Compliance Points: *(indicate evidence seen)***

- Evidence of identifiable Oncofertility contact person/s must be provided.
- The organization's day sheet reflecting these emergency consultations.
- Verbal feedback from the receptionist to confirm this standard operating procedure.

**Compliance assessment: (*select one*)**

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Clinical Services | | Sub-Department Oncofertility |
|---|---|---|
| D.4.6. | Standard name: **Processes & Procedures:** Financial support. | ROP: Yes |

**Standard statement/Goal:**

**Oncofertility care may contribute further to the financial burden on the oncology patient.**

**Intent:**

Financial support and counselling to be offered to the oncology patient requiring fertility preservation.

**Compliance Points: *(indicate evidence seen)***

- Evidence of a reduced fee structure in the organization must be provided (private organizations only).

**Compliance assessment: (*select one)***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

☐ **Not applicable (government facility)**

**Comments / Notes**

| DEPARTMENT Clinical Services | | Sub-Department Oncofertility |
|---|---|---|
| D.5.7. | Standard name: **Information, Communication & Feedback:** Clinical notes. | ROP: No |

**Standard statement/Goal:**

**Standardized clinical notes highlight the multifaceted factors involved in decision making.**

**Intent:**

Standardization of record keeping, serves as conformation of a multi-disciplinary approach and individualization of care.

**Compliance Points: *(indicate evidence seen)***

- Documentation of clinical notes recorded.

**Compliance assessment: (*select one*)**

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Clinical Services | | Sub-Department Oncofertility |
|---|---|---|
| D.5.8. | Standard name: Information, Communication & Feedback: Informed consent. | ROP: No |

**Standard statement/Goal:**

**Consent forms are important in all oncofertility procedures and the cryo storage of specimens.**

**Intent:**

Clinicians treating oncofertility patients has the responsibility of ensuring the patients clearly understands their treatment options, and the advantages and limitations thereof. There are many unknowns in the field of oncofertility and patients should be counselled accordingly.

**Compliance Points: *(indicate evidence seen)***

- Consent forms for Fertility preservation, usage, and post mortem disposition.

**Compliance assessment: (*select one*)**

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

# III. NURSING SERVICES

## Assessors

**Nurse(s) and Fertility Specialist(s).**

**Assessor 1 Name: _____**

**Assessor 2 Name: _____**

**Assessor 3 Name: _____**

**Assessor 4 Name: _____**

## E. NURSING AND COORDINATION

*Table III.1. Framework for standards: Nursing and Coordination.*

| NURSING SERVICES | E: NURSING AND COORDINATION |
|---|---|
| **1. FACILITY, PLANNING & DESIGN** | 1. Coordination station/office. |
| **2. QUALIFICATIONS & STAFF STRUCTURE** | 2. Qualifications and training of nursing staff. ***ROP***<br>3. Nursing staff levels.<br>4. Training and competency in third party coordination.<br>5. Training and management of medications for ART. ***ROP*** |
| **3. EQUIPMENT & CONSUMABLE MANAGEMENT** | 6. Equipment for nursing and coordination.<br>7. Stock control of consumables, contact materials and medications at nursing stations. |
| **4. PROCESSES & PROCEDURES** | 8. Demonstration of medication use.<br>9. Management of donors and donor treatments.<br>10. Management of surrogacy treatments. |
| **5. INFORMATION, COMMUNICATION & FEEDBACK** | 11. General patient communication.<br>12. Reporting of results. |
| **6. RISK & EMERGENCY MANAGEMENT** | 13. Infection control and medical emergency protocols. ***ROP***<br>14. Power back-up and monitoring. |

| DEPARTMENT Nursing Services | | Sub-Department Nursing & Coordination |
|---|---|---|
| E.1.1. | Standard name: **Facility, Design & Planning:** Coordination station/office. | ROP: No |

**Standard statement/Goal:**

**The IVF coordinator or nurse's consultation room should ensure the privacy of the patient, be sufficient for patient load and have a comfortable and informative atmosphere.**

**Intent:**

The consultation room/station/office should provide safety, privacy and adequate comfort and space to provide a room favorable to coordination discussions. To ensure sufficient nurses' rooms/stations/offices for the patient load.

**Compliance Points:** ***(indicate evidence seen)***

- Facility design or floorplan to show proper considerations for coordination and nurses' stations where needed.
- Summaries of patient satisfaction survey results.

**Compliance assessment:** ***(select one)***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Nursing Services | Sub-Department Nursing & Coordination | |
|---|---|---|
| E.2.2. | Standard name: **Qualifications & Staff Structure:** Qualifications and training of nursing staff. | ROP: Yes |

**Standard statement/Goal:**

**Nurses performing the ART coordination functions and roles to assist in clinical services for patient care throughout treatment to be appropriately qualified and trained.**

**Intent:**

The organization must ensure nurses assisting in clinical services during ART treatment receive the quality care by appropriately qualified, trained, and registered nursing staff to manage the specific nursing role with appropriate authority, accountability, and responsibility.

**Compliance Points:** ***(indicate evidence seen)***

- Facility organogram pertaining to nursing roles.
- Records of nursing qualifications and registrations with reference to responsibilities.
- Attendance certificates of ART related workshops/presentations.
- Meeting minutes for multi-disciplinary collaboration.

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Nursing Services | | Sub-Department Nursing & Coordination |
|---|---|---|
| **E.2.3.** | **Standard name: Qualifications & Staff Structure:** Nursing staff levels. | **ROP:** No |

**Standard statement/Goal:**

**To ensure sufficient nursing staff are employed to according to the patient load, type and complexity of treatments to be coordinated, number of clinicians, range of services provided and level of training of nurses in the team.**

**Intent:**

The nursing staff level should be sufficient to provide the expected quality care for the workload considering the patient load, treatment services, number of clinicians, coordination responsibilities and complexity of ART cycles.

**Compliance Points:** ***(indicate evidence seen)***

- Organogram indicating communication, functions and integration model.
- Records of nursing staff meetings.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Nursing Services | Sub-Department Nursing & Coordination | |
|---|---|---|
| E.2.4. | Standard name: **Qualifications & Staff Structure:** Training and competency in third-party coordination. | ROP: No |

**Standard statement/Goal:**

**To ensure nursing staff are appropriately trained and competent in the care and coordination of third-party ART treatments.**

**Intent:**

ART cycles and treatments are more complex when a third-party is involved, i.e., donor and/or surrogate. Therefore, additional training and a level competency should be in place for the nursing staff in the role of coordinating third-party treatments.

**Compliance Points:** ***(indicate evidence seen)***

- Policy on training for nursing staff new to third party coordination and expected competency levels.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Nursing Services | Sub-Department Nursing & Coordination | |
|---|---|---|
| E.2.5. | Standard name: **Qualifications & Staff Structure:** Training and management of medications for ART. | ROP: Yes |

**Standard statement/Goal:**

**Nursing staff to be appropriately trained and competent in the management and administration of medications involved during ART.**

**Intent:**

It is imperative that the nursing staff is properly trained and competent in the administration and management of the medications used for ART, which include stimulation drugs and specialized drugs related to the sedation procedures.

**Compliance Points:** ***(indicate evidence seen)***

- Policies and SOPs for medication administration and management and training.

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Nursing Services | | Sub-Department Nursing & Coordination |
|---|---|---|
| E.3.6. | Standard name: Equipment & Consumable Management: Equipment for nursing care and coordination. | ROP: No |

**Standard statement/Goal:**

**The necessary patient care and cold storage equipment is available, sufficient, and working properly at nursing stations.**

**Intent:**

Nursing needs specific pieces of equipment to perform patient care, communication and monitoring, and keep cold chain medications under required storage conditions to ensure patients receive the care to support quality ART treatment. The necessary equipment should be working properly, sufficient, and readily available to nursing staff at their stations according to the service provided.

**Compliance Points: *(indicate evidence seen)***

- List of relevant equipment at stations.
- Equipment manuals and service logs with calibration/validation logs where applicable.

**Compliance assessment: *[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Nursing Services | | Sub-Department Nursing & Coordination |
|---|---|---|
| **E.3.7.** | **Standard name: Equipment & Consumable Management:** Stock control of consumables, contact materials and medications at nursing stations. | **ROP:** No |

**Standard statement/Goal:**

**An effective stock control system in place and effectively managed to ensure traceability and sufficient supply of patient care consumables at nursing stations.**

**Intent:**

Nursing stations are usually stocked with the various patient consumables and medication for proper patient care. A proper and effective stock control system should ensure that careful attention be paid to ordering, using, and billing of patient consumables.

**Compliance Points: *(indicate evidence seen)***

- Storage locations and cold chain storage monitoring.
- Stock control system organogram with responsible persons and roles.
- Traceability system of contact materials.
- Monitoring and checking lists.
- Necessary SOPs and manufacturer's inserts/instructions.
- Documentation of all standing orders and rotating stock agreements.

**Compliance assessment: *[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Nursing Services | | Sub-Department Nursing & Coordination |
|---|---|---|
| **E.4.8.** | **Standard name: Process & Procedures:** Demonstration of medication use. | **ROP:** No |

**Standard statement/Goal:**

**To ensure that the use of medication is demonstrated in such a way that the patient can comfortably and effectively self-administer their stimulation medication.**

**Intent:**

Patients may need to administer their stimulation medication at home between monitoring sonar examinations to reduce the need of daily visits to the facility. Nursing staff need to be able and have the necessary aids to provide sufficient demonstration and communication to instruct patients to perform the self-administration effectively.

**Compliance Points: *(indicate evidence seen)***

- Patient feedback after demonstrating how to administer medication.
- Patient satisfaction surveys or feedback.

**Compliance assessment: *[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Nursing Services | Sub-Department Nursing & Coordination | |
|---|---|---|
| E.4.9. | **Standard name: Process & Procedures:** Management of donors and donor treatments. | **ROP:** No |

**Standard statement/Goal:**

**To ensure donors and donor cycles are managed appropriately to ensure quality care for donors and recipients.**

**Intent:**

Donors and donor treatment cycles require additional care measures during coordination and protocols to ensure that donor identity is protected throughout treatment.

**Compliance Points:** ***(indicate evidence seen)***

- Policy of donor treatment management.
- Process in place to ensure all relevant information(results) are recorded (e.g., family history, medical history, physical examination, blood tests.)

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Nursing Services | Sub-Department Nursing & Coordination | |
|---|---|---|
| E.4.10. | Standard name: **Process & Procedures:** Management of surrogacy treatments. | ROP: No |

**Standard statement/Goal:**

**To ensure that surrogates and commissioning parents are well informed of the entire process before and during treatment.**

**Intent:**

Surrogates and surrogacy treatment cycles require additional care measures during coordination and protocols to ensure that surrogates and commissioning parents are properly informed regarding their treatment.

**Compliance Points:** ***(indicate evidence seen)***

- Policy on surrogacy cycle management
- Information sheets and documentation of information discussions.
- Paperwork in file (e.g., tests that have been performed on both the intended parents and surrogates).

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Nursing Services | | Sub-Department Nursing & Coordination |
|---|---|---|
| E.5.10. | Standard name: **Information, Communication & Feedback:** Information relay of medical procedures. | ROP: No |

**Standard statement/Goal:**

**To ensure that the patient receives accurate information regarding the process/procedure they are going to undertake.**

**Intent:**

Communicating and explaining the stimulation processes and medical procedures to patients in advance of and during their treatment is essential.

**Compliance Points:** ***(indicate evidence seen)***

- Policy and protocols of information relay from treating doctor to nurse to patient.
- Information sheets, leaflets and documentation used for explaining all the different procedures and processes.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Nursing Services | Sub-Department Nursing & Coordination | |
|---|---|---|
| E.5.12. | Standard name: **Information, Communication & Feedback:** Reporting of patient results. | ROP: No |

**Standard statement/Goal:**

**To ensure patient results are being conveyed in a timely manner, to enhance coordination process, treatment, and communication with the patient.**

**Intent:**

Timeous and effective communication with the patient is a core function of coordination during ART treatment. Patient results and the implication thereof on their treatment is essential.

**Compliance Points:** ***(indicate evidence seen)***

- Process of patient results reporting and documentation of communication.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Nursing Services | Sub-Department Nursing & Coordination | |
|---|---|---|
| E.6.13. | Standard name: **Risk & Emergency Management:** Infection control and medical emergency protocols. | ROP: Yes |

**Standard statement/Goal:**

**The appropriate infection control measures and safety protocols are in place at nursing stations and nursing staff is well trained in the emergency protocols.**

**Intent:**

Nursing staff have essential roles in the protocols and measures for infection control and health emergency procedures. All nurses should be properly trained and have easy access to the safety manual at their stations.

**Compliance Points:** ***(indicate evidence seen)***

- Safety manual and location pertaining to nursing.
- Hazardous waste and Infection control policy pertaining to nursing including information update process.
- Training logs and updated emergency course completion (CPR, etc.)

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Nursing Services | | Sub-Department Nursing & Coordination |
|---|---|---|
| E.6.14. | Standard name: **Risk & Emergency Management:** Power back-up and monitoring. | ROP: No |

**Standard statement/Goal:**

**Critical and sensitive equipment located in nursing stations on back-up power supply for medical emergencies.**

**Intent:**

The critical, medical emergency and sensitive equipment at nursing stations should be on battery power back-up to ensure continuous availability.

**Compliance Points:** ***(indicate evidence seen)***

- Monitoring logs of battery or UPS supply to critical, medical emergency and sensitive equipment at nursing stations.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

## F. PROCEDURES AND RECOVERY

*Table III.2. Framework for standards: Procedures and Recovery.*

| NURSING SERVICES | F: PROCEDURES AND RECOVERY |
|---|---|
| **1. FACILITY, PLANNING & DESIGN** | 1. Recovery area design, equipment and access control.<br>2. Sluice or dirty utility area. |
| **2. QUALIFICATIONS & STAFF STRUCTURE** | 3. Training for nurses in ART sedation procedures and recovery. ***ROP*** |
| **3. EQUIPMENT & CONSUMABLE MANAGEMENT** | |
| **4. PROCESSES & PROCEDURES** | 4. Patient identification for admission & discharge. ***ROP*** |
| **5. INFORMATION, COMMUNICATION & FEEDBACK** | 5. Consents and documentation for procedures and recovery. ***ROP*** |
| **6. RISK & EMERGENCY MANAGEMENT** | 6. Cleaning and infection control in recovery.<br>7. Power back-up and emergency trolley. ***ROP*** |

| DEPARTMENT Nursing Services | Sub-Department Procedures & Recovery | |
|---|---|---|
| F.1.1. | Standard name: **Facility, Design & Planning:** Recovery area design, equipment and access control. | ROP: No |

**Standard statement/Goal:**

**The recovery area should be a restricted access area and provide a safe, calm, and private space to provide quality recovery processes.**

**Intent:**

The procedure room and recovery area should be favorable for all the recovery processes before and after ART procedures after sedation. It should be so planned and equipped that control can be exercised over all persons and materials that enter it.

**Compliance Points:** ***(indicate evidence seen)***

- Facility design and plans to show proper considerations for procedure room and recovery area with access control measures.
- Recovery monitoring equipment including number and locations.
- Temperature and ventilation control.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Nursing Services | Sub-Department Procedures & Recovery | |
|---|---|---|
| F.1.2. | Standard name: **Facility, Design & Planning:** Sluice or dirty utility area. | ROP: No |

**Standard statement/Goal:**

**There should be a well-kept sluice/dirty utility area or sterilization station available.**

**Intent:**

The Sluice/dirty utility area should allow for all soiled linen and instruments to be discarded or cleaned. This is to ensure effective infection control is always maintained. This area requires a defined unidirectional workflow for instruments from dirty to clean or sterile and then to the clean/sterile store.

**Compliance Points:** ***(indicate evidence seen)***

- Facility design and plans to show proper considerations for CSSD and Sluice areas where needed.
- Evidence of up-to-date service certificate of the autoclave.
- Evidence of the quality control logs for the autoclave – testing kits, run logs (indicating temperature and pressure for each run).
- Copy of 3rd party agreements where necessary.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Nursing Services | Sub-Department Procedures & Recovery | |
|---|---|---|
| F.2.3. | **Standard name: Qualifications & Staff Structure:** Training for nurses in ART sedation procedures and recovery. | ROP: Yes |

**Standard statement/Goal:**

**The nursing staff expected to perform duties during sedation procedures and recovery processes on-site, must have the appropriate training, competency, and experience.**

**Intent:**

Nursing staff to assist in sedation procedures and recovery need to have the appropriate proper training and be knowledgeable to perform their functions and provide the expected quality patient care during these services.

**Compliance Points:** ***(indicate evidence seen)***

- Policy of nurse training for sedation and recovery procedures, including any additional procedures outside scope of practice where applicable.

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Nursing Services | | Sub-Department Procedures & Recovery |
|---|---|---|
| F.4.4. | Standard name: **Processes & Procedures:** Patient identification for admission & discharge. | ROP: Yes |

**Standard statement/Goal:**

**All patients being admitted for the on-site procedures must be identified with their recognizing information.**

**Intent:**

Positive identification of patients before procedures is essential including during recovery and for discharge processes.

**Compliance Points:** ***(indicate evidence seen)***

- Identification protocols for admissions and discharges for procedures.

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Nursing Services | Sub-Department Procedures & Recovery | |
|---|---|---|
| F.5.5. | Standard name: **Information, Communication & Feedback:** Consents and documentation for procedures and recovery. | ROP: Yes |

**Standard statement/Goal:**

**There must be informed consent from the patient and medical documentation completed for all procedures performed.**

**Intent:**

Patients must give and sign appropriate medical consent forms in advance of undergoing procedures in the procedure room and all the relevant medical documentation regarding admission, procedures, recovery and discharge processes must be completed for all patients and procedures.

**Compliance Points:** ***(indicate evidence seen)***

- Consents and medical documentation for procedures, including random patient record (de-identified).

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Clinical Services | | Sub-Department Procedure room |
|---|---|---|
| F.6.6. | Standard name: **Risk and Emergency Management:** Cleaning and infection control in recovery. | ROP: No |

**Standard statement/Goal:**

**Optimal hygiene standards and infection control in recovery area surrounding the procedure room.**

**Intent:**

To provide adequate hygienic and clean conditions in the recovery area and hallways surrounding the procedure room to prevent infections, including active cleaning and linen and consumable replacement measures between changing of patients.

**Compliance Points:** ***(indicate evidence seen)***

- Cleaning, consumable replacement and disinfection policy for recovery room.
- Linen and patient attire management.
- Waste management and signage for recovery area including in ablution facility.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Nursing Services | | Sub-Department Procedures & Recovery |
|---|---|---|
| F.6.7. | Standard name: **Risk & Emergency Management:** Power back-up and emergency trolley. | ROP: Yes |

**Standard statement/Goal:**

**There must be appropriate protocols and equipment in place to handle medical emergencies including power back-up to critical equipment is supplied and monitored.**

**Intent:**

It is important to provide the recovery area with the necessary emergency equipment for proper emergency care and power back-up is supplied to the critical and emergency equipment.

**Compliance Points:** ***(indicate evidence seen)***

- Location, training and monitoring logs of power back-up and functioning of emergency and critical equipment in recovery while on power back-up.

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

# IV. LABORATORY SERVICES

## Assessors

**Embryologist(s) and Fertility Specialist(s).**

**Assessor 1 Name: _____**

**Assessor 2 Name: _____**

**Assessor 3 Name: _____**

**Assessor 4 Name: _____**

## G. GENERAL LABORATORY

*Table IV.1. Framework for standards: General Laboratory.*

| LABORATORY SERVICES | G: GENERAL LABORATORY |
|---|---|
| **1. FACILITY, PLANNING & DESIGN** | 1. Construction, design, and layout of laboratories.<br>2. Cleanrooms and workstations for therapeutic procedures.<br>3. Storage facilities and accessibility for laboratory supplies. |
| **2. QUALIFICATIONS & STAFF STRUCTURE** | 4. Required qualifications and registrations. ***ROP***<br>5. Staff structure and levels.<br>6. Training and Credentials. |
| **3. EQUIPMENT & CONSUMABLE MANAGEMENT** | 7. Laboratory equipment management and maintenance.<br>8. Consumables and mediums management. |
| **4. PROCESSES &**<br>**5. PROCEDURES** | 9. Policies and standard operating procedure management system.<br>10. Traceability and identification of patient samples. ***ROP*** |
| **6. INFORMATION, COMMUNICATION & FEEDBACK** | 11. Documents, reports, and consents. ***ROP*** |
| **7. RISK MANAGEMENT & EMERGENCY PLANS** | 12. Medical waste, infection, and contamination control. ***ROP***<br>13. Power back-up for laboratories. ***ROP***<br>14. Adverse events, emergency, and disaster planning. |

| DEPARTMENT Laboratory Services | | Sub-Department General |
|---|---|---|
| G.1.1. | Standard name: **Facility, planning & design:** Construction, design, and layout of laboratories. | ROP: No |

**Standard statement/Goal:**

**Laboratory sections should be constructed using appropriate materials with sufficient ventilation and light. Design should provide sufficient space with designated administrative areas and clean rooms for therapeutic processing, including consideration for operator comfort and efficiency.**

**Intent:**

The laboratory construction should be using appropriate materials for walls, floors, and work surfaces. There should be adequate ventilation and light and ensure safe and comfortable working conditions for operators. The design should provide efficient work areas appropriate to the services provided and designated work areas separating procedures and administration, including access control to authorized persons.

**Compliance Points: *(indicate evidence seen)***

- Identification of different workspaces and facilities allocated according to type of procedures, i.e., chemical workspaces, diagnostics, data etc.
- Materials used in construction.
- Light, ventilation, and temperature controls.
- Layout of laboratory workspaces to achieve efficiency and comfort during operation.
- Access control method.

**Compliance assessment: *[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department General |
|---|---|---|
| G.1.2. | Standard name: **Facility, Planning & Design:** Cleanrooms and workstations for therapeutic procedures. | ROP: No |

**Standard statement/Goal:**

**Laboratory areas for therapeutic processing should be within designated clean room areas constructed with appropriate materials and air quality control systems.**

**Intent:**

Air quality affect quality of gametes and embryos thus samples should be safeguarded against external influences, such as the introduction of bacteria, viruses, or VOCs, to ensure uncompromised sperm to be used for therapeutic assisted reproductive procedures. Clean rooms for therapeutic processing should be constructed with appropriate materials and minimal VOC release. Workstations for therapeutic processing should achieve acceptable levels of air flow and filtering capacity.

**Compliance Points:** ***(indicate evidence seen)***

- Air quality filtrations system and positive pressure validation and certification (indicating ISO level particle counts and air changes)
- Types of workstations according to laboratory services with ISO certificates.
- Laboratory attire for clean room areas and change room location.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department General |
|---|---|---|
| G.1.3. | Standard name: **Facility, planning & design:** Storage facilities and accessibility for laboratory supplies. | ROP: No |

**Standard statement/Goal:**

**Laboratory supplies and consumables should be stored appropriately, media and chemicals according to manufacturers' instructions. Designated storage should facilitate use and stock control.**

**Intent:**

Quality of laboratory supplies may be affected by inappropriate storage and manufacturers' instructions should be followed for proper storage. Designated storage facilities should be accessible for use by operators and stock control processes.

**Compliance Points:** ***(indicate evidence seen)***

- Designated storage facilities in accordance with the types of consumables, media and chemicals and manufacturers' instructions.
- Accessibility of storage areas to stock control processes and laboratory areas.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department General |
|---|---|---|
| G.2.4. | Standard name: **Qualifications & staff structure:** Required qualifications and registrations. | ROP: Yes |

**Standard statement/Goal:**

**ART laboratory services may only be performed by qualified embryologists (Clinical Technologists and/or Medical Biological Scientists in Reproductive Biology) with relevant HPCSA registration.**

**Intent:**

Embryology and andrology procedures must be done by laboratory staff that hold the relevant reproductive biology qualifications and registered as such with the HPCSA.

**Compliance Points:** ***(indicate evidence seen)***

- Copies of qualifications and HPCSA registrations of laboratory staff.
- Staffing organogram.

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department General |
|---|---|---|
| G.2.5. | Standard name: **Qualifications & staff structure:** Staff structure and levels. | ROP: No |

**Standard statement/Goal:**

**Laboratory staff should be structured according to responsibilities. Staff levels should be sufficient to provide services offered and accommodate witnessing and supervision as needed during laboratory procedures.**

**Intent:**

Laboratory staff should be clearly and appropriately structured according to level of responsibility. Sufficient staff should be available according to laboratory procedures provided. The team structure should provide supervision where training is done and witnessing at critical steps.

**Compliance Points:** ***(indicate evidence seen)***

- Laboratory staff structure organogram with responsibility levels and job descriptions.
- Staff levels and rotations according to laboratory services and patient/sample loads.
- Staff structure providing supervision for training and witnessing at all crucial stages of therapeutic procedures.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department General |
|---|---|---|
| G.2.6. | Standard name: **Qualifications & staff structure:** Training and Credentials. | ROP: No |

**Standard statement/Goal:**

**Laboratory procedures should be performed by personnel with appropriate training and credentials to ensure competency.**

**Intent:**

Proper handling, analyses and processing of reproductive fluids, gametes or embryos is an essential part of quality service in assisted reproduction. The execution of procedures should be done by or under supervision of adequately trained personnel. The laboratory should have a KPI monitoring, and competency benchmark system is in place to confirm competency per operator.

**Compliance Points:** ***(indicate evidence seen)***

- Evidence of staff training and competency analyses.
- Policies on training expectations for performing methods by staff in the laboratory.
- Policies on KPIs and benchmarks for monitoring procedures that also includes operator competency.
- Schedule of KPI reviews and discussions regarding competency and recommendations made.
- Show attendance records of workshops and educational activities.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department General |
|---|---|---|
| G.3.7 | Standard name: **Equipment & consumable management:** Laboratory equipment management and maintenance. | ROP: No |

**Standard statement/Goal:**

**Laboratory equipment should be properly procured, maintained, and validated for clinical use to ensure optimum function and performance during use for laboratory services and procedures.**

**Intent:**

Laboratory equipment should be properly procured, maintained according to prescribed service intervals, validated to be fit for purpose before clinical use and continuously monitored to ensure proper function.

**Compliance Points:** ***(indicate evidence seen)***

- Procurement processes for laboratory equipment.
- Equipment manufacturer manuals with instructions of use.
- Equipment service schedule and history including service agreements with support contact information.
- Validation records before clinical use.
- Logs of equipment monitoring.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department General |
|---|---|---|
| G.3.8. | Standard name: **Equipment & consumable management:** Consumables, mediums, and reagents. | ROP: No |

**Standard statement/Goal:**

**Laboratory procedures should be performed using proper consumables and appropriate mediums.**

**Intent:**

Processing and handling of reproductive fluids, gametes or embryos should be performed using appropriate consumables and mediums specifically manufactured for such purposes that has not expired. Therapeutic processes should include sterile contact consumables with additional safety analyses and media specifically manufactured for the procedures.

**Compliance Points: *(indicate evidence seen)***

- Reference to and descriptions of consumables required in laboratory SOPs/guidelines including product inserts for manufactures' instructions of use.
- Documentation on cold chain, storage, sterility, and batch analyses of consumables and media to indicate fit for purpose.
- List of suppliers and contact details.
- Stock management systems of mediums and consumables including records of levels, batches, dates used and expiration dates.

**Compliance assessment: *[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department General |
|---|---|---|
| G.4.9. | Standard name: **Processes & procedures: Policies and standard operating procedure management system.** | ROP: No |

**Standard statement/Goal:**

**The laboratory should have a system of policy manuals and standard operating procedures (SOPs) in place relating to all the procedures offered and processes involved.**

**Intent:**

The policy manuals should describe and guide all major decisions, actions, principals, and SOPs instructions for processes of procedures.

**Compliance Points:** ***(indicate evidence seen)***

- Outline of all policies and SOPs relating to services offered.
- Policies an SOPs, with copies of updated versions (hardcopy or electronic) present in the laboratory areas where required.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department General |
|---|---|---|
| G.4.10. | Standard name: **Processes & Procedures:** Traceability & Identification of samples. | ROP: Yes |

**Standard statement/Goal:**

**A system must be in place to ensure accurate traceability of patient samples with their identifiers throughout the laboratory service provided.**

**Intent:**

It is a requirement for a laboratory to ensure accurate clear identification of patient samples from entering the service until completion and must use unique identifiers. Identification and direct verification via a witness of patient details and labelled containers must be done at critical steps during analytical and therapeutic processes.

**Compliance Points:** ***(indicate evidence seen)***

- Identification and traceability System/Policy

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department General |
|---|---|---|
| G.5.11. | Standard name: **Information, communication & Feedback:** Documents, reports, and consent control. | ROP: No |

**Standard statement/Goal:**

**The laboratory should have an organizational system of document control to ensure proper documentation for all laboratory services.**

**Intent:**

Laboratory services involves several types of important documentation. A system should be in place to ensure proper use of appropriate documents, current versions are used, regular updates are done, the documents pertaining to the laboratory service is available to responsible staff where required and a back-up is in place.

**Compliance Points: *(indicate evidence seen)***

- Document control management system/policy with review process.
- Consents and laboratory records management.
- Accessibility control of current documentation.
- Back-up set-up for laboratory document system.

**Compliance assessment: *[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department General |
|---|---|---|
| G.6.12. | Standard name: **Risk Management & Emergency Plans**: Medical waste, infection, and contamination control. | ROP: Yes |

**Standard statement/Goal:**

**All laboratory procedures and protocols must include measures to be taken to reduce risk of cross-contamination and promote safety of staff. A safety manual must readily available and all personnel familiar with safety and protective measures.**

**Intent:**

All laboratory procedures entail handling of potentially infectious biological material and fluids, posing the potential hazard of transmitting diseases to personnel and contamination of other biological samples, consumables, and equipment. Medical waste must be managed appropriately. Safety processes must be in place for staff safety and reduce risk of cross-contamination.

**Compliance Points:** ***(indicate evidence seen)***

- Policies and SOPs of aseptic techniques and contamination reduction measures.
- SOPs for handling processes (fluids, gametes, culture, cryopreservation, storage) of seropositive patient samples including additional protective and contamination reduction measures.
- Disinfectants in use with corresponding compatibility and efficacy labeling or similar as applicable.
- Protection and disinfection procedures at workstations.
- Certified medical waste bins and removal protocols for laboratories.

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department General |
|---|---|---|
| G.6.13. | Standard name: **Risk Management & Emergency Plans**: Emergency back-up power supply to critical laboratory equipment. | ROP: Yes |

**Standard statement/Goal:**

**A regulated back up power supply must be available for and connected to all critical and sensitive laboratory equipment to prevent detrimental power failures, interruptions of optimal embryo culture conditions and damage to sensitive instruments.**

**Intent:**

There must be an uninterrupted back-up power supply to provide and regulate electrical power to all critical equipment related to sample processing, cold storage, incubation, and visibility (light) to prevent interruptions, ensure continuation of laboratory services, and protect embryo culture conditions and sensitive instrumentation. The back-up power supply must be checked and monitored to be in working order.

**Compliance Points: *(indicate evidence seen)***

To be checked for every laboratory area (e.g., andrology, embryology, cryopreservation) as applicable:

- System and set-up of back-up power supply within laboratories, including provided length of supply.
- Equipment and critical items identified to be connected to back-up power supply.
- Alarm/Notification system for power supply connections to incubators used for embryo culture.
- Additional emergency power supply points.
- Logs of monitoring checks and service records.
- SOPs and management plan of the back-up power supply system with technical support details.

**Compliance assessment: *[select one]***

**Andrology:** ☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Embryology:** ☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Cryopreservation:** ☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant** ☐ **Not applicable (no separate cryo lab/area)**

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department General |
|---|---|---|
| G.6.14. | Standard name: Risk Management & Emergency Plans: Adverse event, emergency and disaster planning. | ROP: Yes |

**Standard statement/Goal:**

**The laboratory must have a risk assessment with protocols in place to manage adverse events, emergencies and possible disasters that may put the laboratory services, staff and samples at risk of failure.**

**Intent:**

The safety of all personnel, patients and samples must be ensured by an up-to-date system of laboratory risk management with emergency SOPs in case of adverse events and probable disasters. This system must be described in a risk management or safety manual that is readily available even in disaster situations. Regular training of staff in emergency procedures to done and documented.

**Compliance Points:** ***(indicate evidence seen)***

- Fire escape plan and equipment close to laboratory areas.
- Outline/Index of safety manual.
- The original safety manual, policies and protocols must be safely filed, with copies of updated versions off all policies and protocols present in the laboratory.
- Training logs for emergency protocols.

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

## H. ANDROLOGY

*Table IV.2. Framework for standards: Andrology Laboratory.*

| LABORATORY SERVICES | H: ANDROLOGY |
|---|---|
| **1. FACILITY, PLANNING & DESIGN** | 1. Semen collection room. |
| **2. QUALIFICATIONS & STAFF STRUCTURE** | 2. Competency and team structure. |
| **3. EQUIPMENT & CONSUMABLE MANAGEMENT** | 3. Equipment for andrology services. |
| **4. PROCESSES & PROCEDURES** | 4. Andrology procedure manuals or standard operating procedures. ***ROP*** |
| **5. INFORMATION, COMMUNICATION & FEEDBACK** | 5. Information and instruction leaflets.<br>6. Documents and forms.<br>7. Reporting of results. |
| **6. RISK & EMERGENCY MANAGEMENT** | |

| DEPARTMENT Laboratory Services | | Sub-Department Andrology |
|---|---|---|
| **H.1.1.** | **Standard name: Facility, planning & design:** Semen collection room. | **ROP:** No |

**Standard statement/Goal:**

**Semen samples should be collected in a private room near the laboratory, to limit the exposure of the semen to fluctuations and to control the time between collection and analysis.**

**Intent:**

A suitable semen collection room (SCR) is an important aspect of quality care for the Andrology. The SCR should be located near the laboratories to control environmental effects.

Washing facilities for before and after collection should be available in the SCR. If a toilet is not located in the room, a bathroom should be available close by.

**Compliance Points: *(indicate evidence seen)***

- Instruction leaflet on producing a semen sample by means of the various acceptable methods (masturbation, special condom etc.).
- Posted instructions in the SCR with hand washing instructions.

**Compliance assessment: *[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Andrology |
|---|---|---|
| **H.2.2.** | **Standard name: Qualifications & staff structure:** Competency and team structure. | **ROP:** No |

**Standard statement/Goal:**

**Laboratory staff performing andrological procedures should be adequately trained, and the number of andrology laboratory staff and their skills should be appropriate for the workload.**

**Intent:**

Competency assessment should be in place for andrological procedures. The andrology team should consist of sufficient staff to provide the andrology services offered and workload in a timely manner with back-up staff in place.

**Compliance Points:** ***(indicate evidence seen)***

- Organogram of andrology team structure including indication of back-up Andrologist/Embryologist where relevant.
- Logbook of various andrology procedures done per operator.
- Competency assessment records and yearly reviews.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Andrology |
|---|---|---|
| H.3.3. | Standard name: **Equipment & consumable management:** Equipment for andrology services and procedures. | ROP: No |

**Standard statement/Goal:**

**Andrology laboratories should maintain and have access to appropriate equipment necessary to properly and consistently perform the Andrology services provided.**

**Intent:**

The Andrology laboratory should have access to required equipment to perform all procedures listed in the procedure manual. Equipment should be validated to be fit for purpose and in a good working condition with operator's instructions.

**Compliance Points:** ***(indicate evidence seen)***

- Equipment list and back-up items.
- Equipment SOPs and instructions for use.
- Validation records.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Andrology |
|---|---|---|
| H.4.4. | Standard name: **Processes & procedures:** Andrology procedure manuals or standard operating procedures. | ROP: Yes |

**Standard statement/Goal:**

**The Andrology laboratory must have current versions of the procedure manual of Standard Operating Procedure (SOP) documents available in the laboratory pertaining to all the services offered.**

**Intent:**

Andrology services must be guided by complete instructions of processes and procedures. The procedure manual of SOPs, for all procedures listed in the laboratory's policy manual must describe all the procedures in sufficient detail to assure reproducibility and competence in performing all andrology services offered including quality control processes.

**Compliance Points:** ***(indicate evidence seen)***

- Outline/Index of procedure manual or SOPs available
- Original SOPs safely filed, with copies of updated versions off all SOPs present in the laboratory.

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Andrology |
|---|---|---|
| H.5.5. | Standard name: **Information, Communication & Feedback:** Information and instruction leaflets. | ROP: No |

**Standard statement/Goal:**

**The Andrology laboratory should have updated versions of patient instruction leaflets available.**

**Intent:**

The information and instruction leaflets should clearly state what is expected of the patient under the specific circumstances. The documents should be concise, and easy to understand and follow. Instructions should also provide for specialized tests, and distinct patient needs.

**Compliance Points:** ***(indicate evidence seen)***

- Original information and instruction leaflet available should be filed, with electronic and hardcopy copies of updated versions available.
- Provisions in place to accommodate specialized diagnostics and different patient requirements.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Andrology |
|---|---|---|
| H.5.6. | Standard name: **Processes & procedures:** Documentation and forms. | ROP: No |

**Standard statement/Goal:**

**Andrology laboratory services should use updated versions of all the documents, procedural and consent forms needed for the services offered.**

**Intent:**

Andrology procedures should be well documented using appropriate documents, procedural and consent forms which should be easily accessible and updated with current versions readily available.

**Compliance Points: *(indicate evidence seen)***

- Outline/Index of document, procedural forms, and consent forms
- Original forms filed, with electronic and hardcopy copies of updated versions of all forms and consent forms available where applicable.

**Compliance assessment: *[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Andrology |
|---|---|---|
| H.5.7. | Standard name: **Information, Communication & Feedback:** Reporting of results. | ROP: No |

**Standard statement/Goal:**

**Reporting of results should be sympathetic to the category of patients under examination and give clear diagnostic information and overview to the clinical user who will interpret the report.**

**Intent:**

Reporting should be clear with internationally accepted reference values where applicable. Insightful interpretative comments and summary of results are important according to the clinical interpreter, i.e., expert fertility clinicians may require a low level of commentary, but a higher level may be required for other health care provider.

**Compliance Points:** ***(indicate evidence seen)***

- Example of report and interpretive commentary.
- Policy on reporting of results.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

# I. EMBRYOLOGY

*Table IV.3. Framework for standards: Embryology laboratory.*

| LABORATORY SERVICES | I: EMBRYOLOGY |
|---|---|
| **1. FACILITY, PLANNING & DESIGN** | 1. Embryology laboratory construction and air quality. ***ROP***<br>2. Embryology laboratory workspace and design. ***ROP***<br>3. Accessibility to procedure room. ***ROP*** |
| **2. QUALIFICATIONS & STAFF STRUCTURE** | 4. Training and Competency monitoring.<br>5. Staff structure and levels. |
| **3. EQUIPMENT & CONSUMABLE MANAGEMENT** | 6. Equipment for embryology procedures.<br>7. Embryology consumables and media. |
| **4. PROCESSES &**<br>**5. PROCEDURES** | 8. Embryology standard procedures (SOPs) and manuals. ***ROP***<br>9. Quality management for embryology procedures.<br>10. Traceability & Identification of embryology samples. ***ROP*** |
| **6. INFORMATION, COMMUNICATION & FEEDBACK** | 11. Documentation and reporting of embryology procedures.<br>12. Patient information and consents for ART. ***ROP*** |
| **7. RISK MANAGEMENT & EMERGENCY PLANS** | 13. Contingency plans for embryology equipment and records. |

| DEPARTMENT Laboratory Services | | Sub-Department Embryology |
|---|---|---|
| I.1.1. | Standard name: **Facility, planning & design:** Embryology laboratory construction and air quality. | ROP: Yes |

**Standard statement/Goal:**

**The Embryology laboratory must be a stable clean room environment with specific attention to VOC release of materials used and with stringent air quality control, temperature control appropriate for gamete handling, embryo culturing and manipulation techniques.**

**Intent:**

The Embryology laboratory (EL) is the most important area for assisted reproductive techniques (ART). A stable clean room environment constructed with materials with low VOC release adhering to stringent air quality and temperature control is required to optimize environmental conditions for gamete and embryo handling and aseptic techniques.

**Compliance Points: *(indicate evidence seen)***

- Design plans with materials used for EL
- Air handling unit/Positive pressure unit and HEPA filtration certification and validation, and ongoing re-certification schedule.

**Compliance assessment: *[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Embryology |
|---|---|---|
| I.1.2. | Standard name: **Facility, planning & design:** Embryology laboratory workspace and design. | ROP: Yes |

**Standard statement/Goal:**

**The Embryology laboratory msut be a stable clean room environment with stringent air quality control, temperature control and humidity monitoring appropriate for gamete handling, embryo culturing and manipulation techniques.**

**Intent:**

Ergonomic emphasis must be placed on the laboratory space design and workflow to ensure efficiency, minimize risk of accidents whilst optimizing protection of the biological samples and achieving optimal embryo culture outcomes. The space must be sufficient for the number of procedures and comfortable for staff.

**Compliance Points:** ***(indicate evidence seen)***

- Design and floor plan to demarcate layout of lab and working ergonomics.
- Indications of number of procedures and staff and workflow.

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Embryology |
|---|---|---|
| I.1.3. | Standard name: **Facility, planning & design:** Accessibility to procedure room. | ROP: Yes |

**Standard statement/Goal:**

**Gametes and embryos must be protected against exposures to detrimental environmental factors (temperature and air quality) during transit between the embryo laboratory and the procedure room as required for retrieval and transfer procedures.**

**Intent:**

The exposure of gametes and embryos to detrimental environmental factors must be minimized during transit between the embryology laboratory and the procedure room for oocyte retrieval and embryo transfer procedures. The procedure room for embryo transfers and follicle aspirations must either be adjacent to the embryology laboratory, or the procedure room and laboratory must have appropriate equipment to enable safe and optimum transport of gametes or embryos.

**Compliance Points:** ***(indicate evidence seen)***

- Design plans indicating location and distance of EL and procedure room(s) with processes of transit.
- Appropriate equipment and setup for transport and distant gamete retrieval and embryo transfer, including validation of transport incubator.

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Embryology |
|---|---|---|
| I.2.3. | Standard name: **Qualifications & staff structure:** Training and Competency monitoring. | ROP: No |

**Standard statement/Goal:**

**The performance of embryology procedures and manipulations should be controlled by training and credentials, and continuously monitored by appropriate competency benchmarks.**

**Intent:**

Precise handling and manipulation of gametes or embryos is an integral part of assisted reproduction. The performance of various embryology procedures should be done by adequately trained personnel. The laboratory should have a KPI monitoring and competency benchmark system is in place to confirm operator competency.

**Compliance Points:** ***(indicate evidence seen)***

- Policy and logs of staff training and credentials in embryology procedures.
- Policies on expected competency KPIs and benchmarks.
- Schedule of KPI calculations, reviews and discussions regarding competency and recommendations made.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Embryology |
|---|---|---|
| I.2.5. | Standard name: **Qualifications & Staff structure:** Staff structure and levels. | ROP: No |

**Standard statement/Goal:**

**Team structure should accommodate witnessing and supervision as needed during embryology and manipulation procedures.**

**Intent:**

Sufficient staff should be available according to embryology procedures provided. The team structure should provide supervision where training is done and supervised practice is indicated. Staff structure should also allow witnessing at critical steps.

**Compliance Points:** ***(indicate evidence seen)***

- Staff structure and levels providing supervision and witnessing as needed during embryology procedures.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Embryology |
|---|---|---|
| I.3.6. | Standard name: **Equipment & consumable management:** Equipment for embryology procedures. | ROP: No |

**Standard statement/Goal:**

**The Embryology laboratory should have the appropriate equipment that are in good working condition, and sufficient to perform the required processes and procedures.**

**Intent:**

The laboratory should contain appropriate equipment required for optimal embryo culture, handling as well as appropriate for the procedures that are offered. The amount of equipment should be according to the workload as well as the level of staff training.

**Compliance Points:** ***(indicate evidence seen)***

- The manufacturer user instruction manual should be available for all equipment items placed in the IVF laboratory.
- Guidelines and policies of equipment used (that should be listed) during procedures as well as troubleshooting guide should be available.
- Clinic policies to include the method of introduction and validation of new and serviced equipment.
- Monitoring logs of function and performance.
- Equipment quantities, including specific reference to incubator levels and workload.
- Equipment provisions made for training where applicable.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Embryology |
|---|---|---|
| I.3.7. | **Standard name:** Equipment & consumable management: Consumables for embryology procedures. | **ROP:** No |

**Standard statement/Goal:**

**Embryology procedures should be done using the appropriate consumables and media for embryo handling and culture.**

**Intent:**

Quality and types of consumables and media in conjunction with operator use thereof can affect embryo culture outcomes. The containers, media and oil used for embryo culture and manipulation should conform to additional safety and quality analyses (embryo tested) as fit for purpose to optimize embryo development. Consumables, media, and oils should be handled with aseptic technique and properly stored between use to maintain quality.

**Compliance Points: *(indicate evidence seen)***

- Policies and SOPs regarding the use, handling, monitoring and storage of opened items used by the EL.
- Policy and SOP regarding the traceability of batches, acceptance of new stock into the EL and management of compromised items.

**Compliance assessment: *[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Embryology |
|---|---|---|
| I.4.8. | Standard name: **Processes & Procedures:** Embryology standard procedures (SOPs) and manuals. | ROP: Yes |

**Standard statement/Goal:**

**The embryology laboratory must have current versions of the procedure manual of Standard Operating Procedure (SOP) documents available in the laboratory describing to all the procedures performed.**

**Intent:**

Consistency of the applying SOPs ensures reliable IVF outcomes despite differing staff and experience levels. SOPs enable staff to reliably reproduce procedures for optimal IVF outcomes. Embryology procedures must be guided by complete instructions of processes and procedures.

**Compliance Points:** ***(indicate evidence seen)***

- Outline/Index of procedure manual and SOPs of all embryology procedures.
- Original SOPs safely filed, with copies of updated versions of all SOPs present in the laboratory and at workstations where used.

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Embryology |
|---|---|---|
| I.4.9. | Standard name: **Processes & Procedures:** Quality management system for embryology procedures. | ROP: No |

**Standard statement/Goal:**

**Laboratory processes should be managed to optimize outcomes and performance indicators monitored to support quality assurance processes. Outcomes of ART cycles should be monitored by key performance indicators (KPIs) to continuously evaluate efficacies.**

**Intent:**

A quality management system should be in place to provide a statistical monitoring system that can provide an early detection in culture condition shifts in embryology procedures and to monitor and optimize cycle outcomes. Key performance indicators (KPIs) should be calculated, compared to accepted benchmarks, and reviewed in regular intervals for adjustments.

**Compliance Points: *(indicate evidence seen)***

- Presentation of laboratory database for capturing and analysis for KPI calculations with comparisons to own defined and published competency and/or benchmark values.
- Schedule of KPIs reviews and discussions.
- Guideline of trouble-shooting and corrective actions when KPIs fall below expected values.

**Compliance assessment: *[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Embryology |
|---|---|---|
| I.4.10. | Standard name: **Processes & Procedures:** Traceability & Identification of embryology samples. | ROP: Yes |

**Standard statement/Goal:**

**There must be specific and clear labelling and identification SOPs and protocols to ensure accurate patient and sample traceability during ART processes to control critical steps and avoid possible misidentification.**

**Intent:**

It is a requirement for an ART laboratory to ensure accurate clear identification of a patient samples at the time of handling to easily and accurately trace, retrieve and process the correct patient sample(s). Two unique identifiers are required for all samples to ensure positive identification during the IVF process. Identification and direct verification via a witness of patient details and labelled container must be done at critical steps during ART processes.

**Compliance Points: *(indicate evidence seen)***

- SOPs and policy addressing the witnessing chain in combination with identified critical steps.
- SOPs and policy indicating process of patient identification and unique identifiers generation.

**Compliance assessment: *[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Embryology |
|---|---|---|
| I.5.11. | Standard name: **Information, communication & Feedback:** Documentation and reporting of embryology procedures. | ROP: No |

**Standard statement/Goal:**

**To accurately document the relevant outcomes for communication to both other healthcare professionals and patients. All processes and/or procedures should be well documented in addition to outcomes and all relevant information.**

**Intent:**

Embryology processes should be properly recorded, with outcomes and relevant information communicated to the treating physician and appropriate departments to ensure quality reproductive care. It should promote information sharing, patient feedback and patient communication.

**Compliance Points:** ***(indicate evidence seen)***

- Presentation of laboratory procedures for documentation, recording, filing, and reporting of all procedures performed, outcomes, sample types involved (show blank or anonymized examples) including the different types of manipulation.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Embryology |
|---|---|---|
| I.5.12. | Standard name: **Information, communication & Feedback:** Patient information and consents for ART. | ROP: Yes |

**Standard statement/Goal:**

**To receive informed consent for embryology procedures in advance of treatments and following appropriate information and explanations to the patient(s).**

**Intent:**

Informed consent must be given by the patient in advance of performing embryology procedures. Information and the contents of the consent regarding the planned procedures must be relayed and be available to patients in order to give proper informed consent for appropriate processing of their samples. Consents must be filed and kept for future reference.

**Compliance Points:** ***(indicate evidence seen)***

- Consent documentation for all embryology procedures.
- Policies on information discussions with patients about embryology procedures.
- Policy on consent from patients with additional requirements.

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Embryology |
|---|---|---|
| I.6.13. | Standard name: **Risk & Emergency Management**: Contingency plans for embryology equipment and records. | ROP: No |

**Standard statement/Goal:**

**To establish clear and concise procedures and practices for reporting of equipment failure or malfunction and troubleshooting.**

**Intent:**

The EL consist of critical and non-critical equipment used for ART. It is imperative that should an equipment item fail or malfunction; there should exist procedural plans for reporting of the malfunction or failure and troubleshooting.

**Compliance Points:** ***(indicate evidence seen)***

- SOPs, instruction manuals on troubleshooting including the contact list of technician support.
- Placement of parts and training of troubleshooting and reporting protocols.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

## J. CRYOPRESERVATION & CRYOBANKING

*Table IV.4. Framework for standards: Cryopreservation.*

| LABORATORY SERVICES | J: CRYOPRESERVATION & CRYOBANKING |
|---|---|
| **1. FACILITY, PLANNING & DESIGN** | 1. Dewar storage locations.<br>2. Cryopreservation workspace. |
| **2. QUALIFICATIONS & STAFF STRUCTURE** | 3. Training and Credentials.<br>4. Team structure, witnessing and supervision. |
| **3. EQUIPMENT & CONSUMABLE MANAGEMENT** | 5. Cryopreservation and Cryobanking equipment.<br>6. Storage dewars.<br>7. Cryopreservation consumables and mediums. |
| **4. PROCESSES &**<br>**5. PROCEDURES** | 8. Cryopreservation protocols (SOPs) for all sample types. ***ROP***<br>9. Quality management for cryopreservation.<br>10. Traceability and identification of cryopreservation samples. ***ROP***<br>11. Transportation of cryopreserved samples. |
| **6. INFORMATION, COMMUNICATION & FEEDBACK** | 12. Documentation and reporting of cryopreservation procedures.<br>13. Patient information and consents for cryopreservation, storage, and termination. ***ROP***<br>14. Consents and documentation for transportation procedures. |
| **7. RISK MANAGEMENT & EMERGENCY PLANS** | 15. Incidents and adverse events during cryopreservation procedures.<br>16. Accessibility and liquid nitrogen safety. ***ROP***<br>17. Disaster plan for Cryobank integrity and records. |

| DEPARTMENT Laboratory Services | | Sub-Department Cryopreservation & Cryobanking |
|---|---|---|
| J.1.1. | Standard name: **Facility, planning & design:** Dewar storage locations. | ROP: No |

**Standard statement/Goal:**

**Storage dewars and liquid nitrogen reservoirs should be in well ventilated spaces and accessible to trained staff.**

**Intent:**

Nitrogen is an asphyxiant which displaces breathable oxygen. The design of the allocated space(s) where storage dewars and reservoirs are kept should ensure sufficient ventilation and only accessible to properly trained staff. Accessibility should also ensure safe movement between cryopreservation works space and storage.

**Compliance Points:** ***(indicate evidence seen)***

- Storage area(s) design with indication of ventilation, LN contact materials, and movement between workspaces and storage area(s) for access.
- Equipment related to storage dewars or LN reservoir use and their location and instructions.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Cryopreservation & Cryobanking |
|---|---|---|
| J.1.2. | Standard name: **Facility, planning & design:** Cryopreservation workspace. | ROP: No |

**Standard statement/Goal:**

**Cryopreservation procedures should be performed in appropriate workspaces compatible with use of liquid nitrogen.**

**Intent:**

Cryopreservation of gametes or embryos is essential for fertility preservation and to postpone use of the material. Therefore, the material should be handled in an environment that does not compromise the gamete or embryo survival or quality. The design of the space should ensure minimizing risk to the samples and staff and allow proper execution in accordance with laboratory protocols and policies. Space where liquid nitrogen (LN) is used, should be fit for purpose.

**Compliance Points:** ***(indicate evidence seen)***

- Lab design with indication of workspaces and movement between administrative area, dewar storage area and LN reservoir.
- Indication of provision of LN fit for purpose materials where LN is used and spills on surface can occur.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Cryopreservation & Cryobanking |
|---|---|---|
| J.2.3. | Standard name: **Qualifications & staff structure:** Training and Credentials. | ROP: No |

**Standard statement/Goal:**

**Cryopreservation should be performed by personnel with appropriate training and credentials via benchmarks.**

**Intent:**

Cryopreservation of gametes or embryos is an integral part of assisted reproduction. The performance of various cryopreservation procedures should be done by adequately trained personnel. The laboratory should have a KPI monitoring and competency benchmark system is in place to confirm survival rates of cryopreserved material per operator.

**Compliance Points:** ***(indicate evidence seen)***

- Evidence of staff training/competency in specific cryopreservation protocols.
- Policies on training expectations for performing cryopreservation methods by staff in the laboratory.
- Policies on KPIs and benchmarks for monitoring cryopreservation procedures that also includes operator competency.
- Schedule of KPI reviews and discussions regarding competency and recommendations made.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Cryopreservation & Cryobanking |
|---|---|---|
| J.2.4. | Standard name: **Qualifications & staff structure:** Staff structure and levels. | ROP: No |

**Standard statement/Goal:**

**Team structure should accommodate witnessing and supervision as needed during cryopreservation and banking procedures.**

**Intent:**

Sufficient staff should be available according to cryopreservation procedures provided. The team structure should provide supervision where training is done and witnessing at critical steps.

**Compliance Points:** ***(indicate evidence seen)***

- Staff structure providing supervision and witnessing as needed during cryopreservation.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Cryopreservation & Cryobanking |
|---|---|---|
| J.3.5. | Standard name: Equipment & consumable management: Cryopreservation and Cryobanking equipment. | ROP: No |

**Standard statement/Goal:**

**Cryopreservation should be performed with fit for purpose and dedicated equipment that is maintained in good working condition.**

**Intent:**

The equipment used during offered cryopreservation procedures should be in good working condition and fit for cryopreservation procedures.

**Supporting Information:**

- SOPs on cryopreservation methods employed by the laboratory, with description of equipment required.
- Equipment manuals for proper use and fit for cryopreservation.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Cryopreservation & Cryobanking |
|---|---|---|
| J.3.6. | Standard name: Equipment & consumable management: Storage dewars. | ROP: No |

**Standard statement/Goal:**

**Storage dewars in use should be sufficient, operational, and monitored.**

**Intent:**

ART cryopreserved material is stored in dewars using either LN or nitrogen vapor. These storage dewars and the LN reservoir should be in good working condition, to maintain the temperatures needed for cryopreservation storage and regularly checked for stability and operation.

**Compliance Points: *(indicate evidence seen)***

- Quality control SOPs with logbook of LN2 levels etc. as evidence of assessments).
- Protocol on the management of storage dewars, including inspections and validations.

**Compliance assessment: *[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Cryopreservation & Cryobanking |
|---|---|---|
| J.3.7. | Standard name: Equipment & consumable management: Cryopreservation consumables and mediums. | ROP: No |

**Standard statement/Goal:**

**Cryopreservation should be performed using appropriate devices and media.**

**Intent:**

Cryopreservation of gametes or embryos should be performed using appropriate devices and media specifically manufactured for such purposes, and which have not been compromised.

**Compliance Points: *(indicate evidence seen)***

- Reference to and descriptions of consumables required in laboratory SOPs/guidelines.
- Product inserts, manufacturers' instructions and validations of contact products.
- Integrity checks of cryopreservation mediums and consumables.

**Compliance assessment: *[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Cryopreservation & Cryobanking |
|---|---|---|
| J.4.8. | Standard name: **Processes & Procedures:** Cryopreservation protocols (SOPs) for all sample types. | ROP: Yes |

**Standard statement/Goal:**

**ART laboratories must provide embryo cryopreservation for surplus embryos. Clear written instructions and protocols must be available and up to date for the cryopreservation services/procedures it provides to ensure consistency and reliable results.**

**Intent:**

IVF laboratories: It is required to be able to provide cryopreservation and storage of embryos (any stage from zygote to blastocyst) after IVF/ICSI procedures. All other sample types are optional.

Different cryopreservation approaches, i.e., slow freezing, rapid freezing, and vitrification, can be used appropriate to type of sample. Consistency of the applied methods ensures reliable cryopreservation results between staff members preforming the procedures.

**Compliance Points:** ***(indicate evidence seen)***

- Clinic policies regarding cryopreservation services provided.
- SOPs including but not limited to the cryopreservation process of every type of sample cryopreserved that has been revised as up to date not older than 12months.
- SOP in place for handling and thawing of samples cryopreserved according to previous cryopreservation methods and/or in/on discontinued devices.

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Cryopreservation & Cryobanking |
|---|---|---|
| J.4.9. | Standard name: **Processes & Procedures:** Quality management for cryopreservation. | ROP: No |

**Standard statement/Goal:**

**Cryopreservation processes should be managed to optimize outcomes and performance indicators monitored to support quality assurance processes. Outcomes of cryopreservation cycles should be monitored by key performance indicators (KPIs) to continuously evaluate method efficacies.**

**Intent:**

A quality management system should be in place to ensure technician proficiency and cryopreservation method efficacy to optimize cycle outcomes. Cryopreservation key performance indicators (KPIs) should be calculated and reviewed in regular intervals.

**Compliance Points:** ***(indicate evidence seen)***

- Presentation of laboratory database for capturing and analysis for KPI calculations with comparisons to own defined and published competency and/or benchmark values.
- Schedule of KPIs reviews and discussions.
- Guideline of trouble-shooting and other recommendations when KPIs fall below expected values.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Cryopreservation & Cryobanking |
|---|---|---|
| J.4.10. | Standard name: Processes & Procedures: Traceability & Identification of cryopreservation samples. | ROP: Yes |

**Standard statement/Goal:**

**Labelling reference and placement of cryopreserved samples must allow accurate traceability of patient samples with unique identifiers throughout the cryopreservation and storage processes to allow precise and clear identification of samples for retrieval.**

**Intent:**

It is a requirement for a cryobank to ensure accurate clear identification of a specific patient sample at the time of cryopreservation to easily trace and correctly retrieve the required patient sample in the cryostorage system.

The cryobank storage system must be organized to ensure easy access, clear identification and accurate positioning for sample entry and retrieval.

Identification and direct verification via a witness of patient details and labelled devices must be done at critical steps during cryopreservation processes.

**Compliance Points:** ***(indicate evidence seen)***

- SOPs or sections dedicated thereto in Cryopreservation SOPs for: witnessing at critical steps, generation of unique identifiers, storage allocation and cryobank system.

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Cryopreservation & Cryobanking |
|---|---|---|
| J.4.11. | Standard name: **Processes & Procedures:** Transportation of cryopreserved samples. | ROP: No |

**Standard statement/Goal:**

**Transportation processes of cryopreserved material should ensure to maintain their safety and integrity between cryobanks.**

**Intent:**

Cryopreserved samples, especially vitrified oocytes and embryos are highly temperature sensitive. Slight temperature shifts can cause whole sample loss or quality deterioration. During processes necessary for transporting, i.e., packing and unpacking of samples from shipping containers, are at risk of being exposed to temperature fluctuations.

Appropriate procedures, couriers, and shipping containers for sending and receiving cryopreserved samples should be in place to maintain required temperature for entire transit time, minimize temperature fluctuations and minimize the risk of loss. The risk of cross-contamination between cryobanks should also be minimized in transport processes.

**Compliance Points:** ***(indicate evidence seen)***

- SOPs for packing and unpacking cryopreserved samples into and from shipping containers, and acceptance and storage into cryobank including reference to securing methods.
- List of specialist couriers and shipping containers used to recommend to patients in need of transport to and from the laboratory.

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Cryopreservation & Cryobanking |
|---|---|---|
| J.5.12. | Standard name: **Information, communication & Feedback:** Documentation and reporting of cryopreservation procedures. | ROP: No |

**Standard statement/Goal:**

**Information regarding cryopreservation processes is well documented and relevant outcome communicated to treating health care professionals.**

**Intent:**

Cryopreservation of patient samples should be well documented and outcomes and relevant information communicated to the treating physician to ensure quality reproductive care.

**Compliance Points:** ***(indicate evidence seen)***

- Presentation of laboratory procedures for documentation, recording, filing, and reporting of cryopreservation of all sample types (show blank or anonymized examples).

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Cryopreservation & Cryobanking |
|---|---|---|
| **J.5.13.** | **Standard name: Information, communication & Feedback:** Patient information and consents for cryopreservation and storage. | **ROP: Yes** |

**Standard statement/Goal:**

**Patients receive sufficient information regarding cryopreservation and informed consent is given for all freezing, storage and storage termination procedures.**

**Intent:**

Information about all procedures involved with cryopreservation, i.e., freezing, storage, thawing and termination of storage must be discussed and/or be available to patients in order to give proper informed consent for appropriate processing of their samples.

**Compliance Points:** ***(indicate evidence seen)***

- Presentation of information and informed consent form used for all cryopreservation procedures of all sample types (show blank or anonymized examples).
- Policy regarding the processes of termination or abandonment of stored samples.
- Policy on when and how discussions and communication about cryopreservation with patients take place.

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Cryopreservation & Cryobanking |
|---|---|---|
| J.5.14. | Standard name: Information, communication & Feedback: Consents and documentation for transportation procedures. | ROP: No |

**Standard statement/Goal:**

**Information and informed consent should be given regarding transportation procedures, and include the potential risks and liability.**

**Intent:**

Patient requiring transport of their specimens should be well informed of the potential risks and liabilities, and recommended shippers or mode of transport and available couriers.

Transport of patient specimens should only take place with informed consent.

Sending and receiving clinics should communicate regarding the transport process and ensure necessary documentation/information relating to the transported specimens without compromising patient confidentiality.

**Compliance Points: *(indicate evidence seen)***

- Presentation of laboratory consents for transporting cryopreserved gametes and embryos.
- Presentation of patient information regarding recommendations and potential risks of transporting cryopreserved material.

**Compliance assessment: *[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Cryopreservation & Cryobanking |
|---|---|---|
| J.6.15. | Standard name: Risk Management & Emergency Plans: Incidents and adverse events during cryopreservation procedures. | ROP: No |

**Standard statement/Goal:**

**Special protocols and protective gear with precautionary measures and corrective actions should be in place for the management of adverse events and incidents that might occur during cryopreservation.**

**Intent:**

Protective gear and special protocols should be in place to either reduce chances of adverse event or incidents and provide a corrective action for staff to follow in case of occurrence of such an adverse event. This provides staff safety and enables continued learning based on experience and improved safety measures.

**Compliance Points: *(indicate evidence seen)***

- Location and types of protective gear provided, instructions on use and accessibility at LN sites.
- Presentation of laboratory procedures for identified possible cryopreservation adverse events and historical incidents with preventative and/or corrective actions.

**Compliance assessment: *[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Cryopreservation & Cryobanking |
|---|---|---|
| J.6.16. | Standard name: Risk Management & Emergency Plans: Accessibility and liquid nitrogen safety. | ROP: Yes |

**Standard statement/Goal:**

**Safety of personnel during cryopreservation and cryopreservation storage and workspaces.**

**Intent:**

Large volumes of liquid nitrogen can displace breathable oxygen rapidly when transitioning to vapor phase, which can cause life-threatening asphyxiation. The design of the cryopreservation areas must have controlled access of only trained personnel and appropriate safety measures and to prevent health risks.

**Compliance Points:** ***(indicate evidence seen)***

- Warning system for nitrogen leakage and/or build-up in storage area(s).
- Emergency plan when a nitrogen leak has been identified.

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Laboratory Services | | Sub-Department Cryopreservation & Cryobanking |
|---|---|---|
| J.6.17. | Standard name: **Risk Management & Emergency Plans**: Disaster plan for Cryobank integrity and records. | **ROP:** No |

**Standard statement/Goal:**

**An emergency plan should be in place specifically to ensure reasonable efforts are made to maintain the necessary cryo-environment and retrieval of records of the cryobank during disaster situations.**

**Intent:**

Local highly probable natural and other disasters should be identified, and an emergency plan put in place to minimize loss of cryopreserved biological material while ensuring safety of staff during these situations.

**Compliance Points:** ***(indicate evidence seen)***

- Presentation of emergency plan section relating to cryobank.
- Demonstration of emergency plan execution by different staff of the identified minimum disaster scenarios (e.g., evacuation plan).

**Compliance assessment:** ***[select one]***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

# V. PSYCHOLOGY AND COUNSELLING SERVICES

## Assessors

**On-site Counsellor(s) or Nursing staff and Fertility Specialist(s).**

**Assessor 1 Name: _____**

**Assessor 2 Name: _____**

**Assessor 3 Name: _____**

**Assessor 4 Name: _____**

## K. FERTILITY COUNSELLING

**The relevant standards of this section will apply to the organization according to the location or affiliation of the counsellor (on-site or off-site counselling services). Counselling information provided by organization regarding services will be relevant in all instances.**

**Indicate Counselling set-up:**

☐ **On-site Counsellor(s) with information provided**

☐ **Information provided with external (off-site) counselling**

*Table V.1. Framework for standards: Counselling services.*

| COUNSELLING SERVICES | K: FERTILITYCOUNSELLING |
|---|---|
| **1. FACILITY, PLANNING & DESIGN** | 1. Counselling room(s). ***ROP*** |
| **2. QUALIFICATIONS & STAFF STRUCTURE** | 2. Counselling qualifications. ***ROP*** |
| **3. EQUIPMENT & CONSUMABLE MANAGEMENT** | 3. Assessment tools. |
| **4. PROCESSES & PROCEDURES** | 4. General ART patients.<br>5. Donors and recipients. ***ROP***<br>6. Surrogacy. ***ROP***<br>7. Fertility preservation and oncofertility. |
| **5. INFORMATION, COMMUNICATION & FEEDBACK** | 8. Documentation and reporting. |
| **6. RISK MANAGEMENT & EMERGENCY PLANS** | 9. Emergency numbers and network for referral.<br>10. Patient file security and back-up. |

| DEPARTMENT Counselling Services | | Sub-Department Fertility Counselling |
|---|---|---|
| K.1.1. | Standard name: **Facility, planning & design:** Counselling room(s). | ROP: Yes |

**Standard statement/Goal:**

**If the ART clinic provides a counselling service, then the clinic provides this service in a safe, private, comfortable, and dedicated counselling space.**

**Intent:**

For the on-site psychologist, the counselling space must be suitable for this purpose and provide privacy and confidentiality.

**Compliance Points:** ***(indicate evidence seen)***

- Plan of facility showing counselling room(s).
- Includes anyone giving test results, post-ART follow-up of a sensitive nature.

**Compliance assessment:** ***[select one]***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Counselling Services | | Sub-Department Fertility Counselling |
|---|---|---|
| K.2.2. | Standard name: **Qualifications & Staff structure:** Counselling qualifications. | ROP: Yes |

**Standard statement/Goal:**

**Counselling must be provided by appropriately qualified and registered practitioner.**

**Intent:**

To deliver a professional counselling and assessment service, and be held accountable for that service.

**Compliance Points:** ***(indicate evidence seen)***

- Current registration with either HPCSA or SACSSP as applicable.
- BHF registration number.
- The agreement or letter of arrangement or memorandum of understanding between the organization and the on-site counsellor.
- Information on psychologists/counsellors/social workers with the applicable qualifications/ registrations.

**Compliance assessment:** ***(select one)***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Counselling Services | | Sub-Department Fertility Counselling |
|---|---|---|
| K.3.3. | Standard name: Equipment & Consumable Management: Assessment tools. | ROP: No |

**Standard statement/Goal:**

**Counsellors making use of assessment tools to provide better patient prognosis and counselling, dependent on the stage of treatment. These can include information, brochures and articles relevant to providing a standard or foundation from which to work from.**

**Intent:**

There should be evidence of some psychometric testing conducted on patients to ensure a measure of ascertaining patient's state of mind, and whether referral is necessary to other mental health professionals.

**Compliance Points: *(indicate evidence seen)***

- Baseline psychometric testing tools in use.
- Patients are informed about counselling options, upon entry to clinic, during treatment and finishing treatment.

**Compliance assessment: *(select one)***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Counselling Services | | Sub-Department Fertility Counselling |
|---|---|---|
| K.4.4. | Standard name: **Processes & Procedures**: General ART patients. | ROP: No |

**Standard statement/Goal:**

**The organization provides access to counselling for patients undergoing ART. The purpose is to explore, understand, and resolve issues related to infertility and fertility treatment and to clarify ways of dealing with the fertility related aspects more effectively.**

**Intent:**

It is important to consider the needs of the patient and the couple undergoing fertility treatment, as well as any other person who might be affected by the ART treatment process including the decisions that have to be made.

**Compliance Points: *(indicate evidence seen)***

- Information on fertility counselling and supportive resources available.
- Access of counsellors visible on website/ brochures/ pamphlets.
- A means to monitor the satisfaction of, and access to, counselling services via a patient satisfaction questionnaire.
- Evidence with regards to assessing patients at-risk.

**Compliance assessment: *(select one)***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Counselling Services | | Sub-Department Fertility Counselling |
|---|---|---|
| K.4.5. | Standard name: **Processes & Procedures:** Donors and recipients. | ROP: Yes |

**Standard statement/Goal:**

**Counselling services concerning the use of donor gametes are available to recipients, and donors are psychologically screened.**

**Intent:**

Counselling services concerning the use of donor gametes are available to patients donating or receiving donor gametes or embryos. There must be informed knowledge of the psychological implications and decisions to use donor gametes, either anonymous or known to the recipients and partners, and donors psychologically screened to obtain their readiness to donate and to ensure they are aware of the risks therein.

**Compliance Points: *(indicate evidence seen)***

- Patient information including psychological services and parental rights in known donation.
- Information on donor agencies.
- Information on legal services for known gamete donation agreement.
- Policy on psychological screening for donors and known donation recipients (generic sample report of known donor assessments).
- Supporting information of counselling done and/ or offered (to be available to the surveyor anonymized to protect patient confidentiality.

**Compliance assessment: (*select one*)**

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Counselling Services | | Sub-Department Fertility Counselling |
|---|---|---|
| K.4.6. | Standard name: **Processes & Procedures:** Surrogacy. | ROP: Yes |

**Standard statement/Goal:**

**Information and referral to experienced and appropriately qualified professionals for surrogacy applications before ART treatment commences.**

**Intent:**

Patients requiring surrogacy treatment and willing surrogate mothers to be counselled and properly informed regarding the processes involved. Information to include referral to professionals that are known to the organization as experienced and appropriately qualified for High Court application of Surrogacy Agreements.

**Compliance Points: *(indicate evidence seen)***

- Policy on information, explanation and counselling services for patients and potential surrogate mothers.
- Information on legal services for surrogacy.
- Supporting information of counselling done and/ or offered (to be available to the surveyor anonymized to protect patient confidentiality.)

**Compliance assessment: *(select one)***

☐ **Fully compliant** ☐ **Largely compliant** ☐ **Partially compliant** ☐ **Non-compliant**

**Comments / Notes**

| DEPARTMENT Counselling Services | | Sub-Department Fertility Counselling |
|---|---|---|
| K.4.7. | Standard name: **Processes & Procedures:** Fertility preservation and oncofertility. | ROP: No |

**Standard statement/Goal:**

**Counselling services are provided for patients considering or requiring fertility preservation and such services are available on short notice for oncofertility patients.**

**Intent:**

There should be a process for counselling patients as to the process of fertility preservation, as well as the benefits and risks. Counselling services should be readily available to oncofertility patients on a limited time schedule due to urgent medical treatments.

**Compliance Points: *(indicate evidence seen)***

- Policy regarding informing patients of counselling before, during and after fertility preservation procedures including specific processes for oncofertility.
- Provides a checklist indicating women seeking fertility preservation have been offered counselling prior to embarking on fertility preservation.

**Compliance assessment: (*select one*)**

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Counselling Services | | Sub-Department Fertility Counselling |
|---|---|---|
| K.5.8. | Standard name: **Information, communication & Feedback:** Documentation and reporting. | ROP: No |

**Standard statement/Goal:**

**Comprehensive written reports on counselling services provided to clinics to be submitted in a timely manner especially for third party ART.**

**Intent:**

There should be a process of timeous reporting regarding counselling for patients and specifically for donor gametes and surrogacy treatments.

**Compliance Points: *(indicate evidence seen)***

- Policy on assessment reports and supporting information of counselling and reporting.
- A de-identified sample report.

**Compliance assessment: (*select one*)**

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Counselling Services | | Sub-Department Fertility Counselling |
|---|---|---|
| K.6.9. | Standard name: Risk Management & Emergency Plans: Emergency numbers and network for referral. | ROP: No |

**Standard statement/Goal:**

**The organization should provide emotional support to patients in the event of the unavailability of a counsellor.**

**Intent:**

There should be contact details of one or more additional therapists, available on the website or patient brochures, in the event of an after-hours emergency or unavailability of the on-site counselor.

**Compliance Points: *(indicate evidence seen)***

- Policy for psychological referral.
- A checklist of patients referred and an emergency number, support groups or local emergency room contact details.

**Compliance assessment: *(select one)***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**

| DEPARTMENT Counselling Services | | Sub-Department Fertility Counselling |
|---|---|---|
| K.6.10. | Standard name: **Risk Management & Emergency Plans**: Patient file security and back-up. | ROP: No |

**Standard statement/Goal**

**Counsellors should maintain patient records and reports securely and confidentially, including backups in case of loss of data or premises.**

**Intent:**

There should be evidence of files kept redundantly in the event of disaster.

**Compliance Points: *(indicate evidence seen)***

- Policy of data and report management including back-up system.

**Compliance assessment: *(select one)***

☐ Fully compliant ☐ Largely compliant ☐ Partially compliant ☐ Non-compliant

**Comments / Notes**