# Standards for Assisted Reproductive Medicine Center

## Version (1.0)

**Issue date: 31/12/2025**

**Effective date: 28/02/2026**

Health Policies and Standards Department

Health Regulation Sector (2025)

## ACKNOWLEDGMENT

HRS developed this document in collaboration with Subject Matter Experts whose contributions have been invaluable. HRS would like to gratefully acknowledge these professionals, especially mentioning Dubai Fertility Center and thank them for their dedication toward improving quality and safety of healthcare services in the Emirate of Dubai.

**Health Regulation Sector**

**Dubai Health Authority**

# TABLE OF CONTENTS

## INTRODUCTION

The Health Regulation Sector (HRS) plays a key role in regulating the health sector. HRS is mandated by the Dubai Health Authority (DHA) Law No. (6) of the year (2018) with its amendments pertaining to DHA, to undertake several functions including but not limited to:

- Developing regulations, policy, standards, guidelines to improve quality and patient safety and promote the growth and development of the health sector.
- Licensure and inspection of health facilities as well as healthcare professionals and ensuring compliance to best practice.
- Managing patient complaints and assuring patient and physician rights are upheld
- Governing the use of narcotics, controlled and semi-controlled medications.
- Strengthening health tourism and assuring ongoing growth.
- Assuring management of health informatics, e-health and promoting innovation.

The Standard for Assisted Reproductive Medicine Center aims to fulfill the following overarching Dubai Health Sector Strategy 2026:

- Pioneering Human-centered health system to promote trust, safety, quality and care for patients and their families.
- Make Dubai a lighthouse for healthcare governance, integration and regulation.
- Strengthening the economic contribution of the health sector, including health tourism to support Dubai economy.

## EXECUTIVE SUMMARY

The purpose for the standard for Assisted Reproductive Medicine Centers is to regulate and ensure high-quality standard of care provided in Assisted Reproductive Medicine Centers. The standards have been developed in alignment with the enforced UAE federal legislations and local DHA regulations released, which include but not limited to:

- Ministerial Decree No. (79) of 2025 regarding types and classification private healthcare facilities and their scope of activity.
- Ministerial Decree No. (183) of the year 2024 regarding the adoption of the parentage declaration forms.
- Ministerial Decision (124) of 2024 amending some provisions of by Cabinet Decision no. (64) of 2020 concerning the executive regulations of Federal Law no. (7) of 2019 regarding Medical Assistance for Childbearing.
- Ministerial decision No. (117) of 2024 Concerning Medical and Technical Healthcare Professionals Required in Fertility Centers.
- Ministerial decision No. (115) of 2024 Concerning Quality Control Measures in Fertility Centers.
- Federal Law by Decree No. (17) of 2023 Amending Some Provisions of Federal Law No. (7) of 2019 regarding Medical Assistance in Reproduction.
- Federal Law by Decree No. (18) of 2023 Amending Some Provisions of Federal Law No. (4) of 2016 regarding Medical Liability.
- Federal Law by Decree No. (49) of 2023 Regulating the Use of the Human Genome.
- Ministerial decision No. (236) of 2022 Concerning Records of Operations in Assisted Reproduction Centers.

- Ministerial Decision No. (235) of 2022 Concerning Criteria for Evaluating Assisted Reproduction Centers.
- Ministerial Decision No. (233) of 2022 Concerning Required Medical Equipment and Devices in Assisted Reproduction Centers.
- Ministerial Decision No. (21) of 2022 Concerning the Approval of The Annual Report Template for Assisted Reproduction Centers.
- Ministerial Decision No. (101) of 2022 Concerning the Amendment of the Unified Healthcare Professional Qualification Requirements (PQR).
- Ministerial Decision No. (134) of 2021 Concerning the Identification of Medical Assisted Reproductive Technologies.
- Ministerial Decision No. (51) of 2021 Concerning the Health Data and Information Which May be Stored or Transferred Outside the Country.
- Ministerial Decision No. (14) of 2021 Concerning the Patient Rights and Duties Charter.
- Cabinet Decision No. (64) of 2020 Concerning the Executive Regulations of Federal Law No. (7) of 2019 Regarding Medical Assistance for Childbearing.
- Cabinet Decision No. (32) of 2020 Concerning Federal Law no. (2) of 2019 on Information and Communication Technology in the Health Field.
- Federal Law by Decree No. (7) of 2019 Concerning Assisted Reproduction.
- Federal Law by Decree No. (4) of 2016 on Medical Liability.
- DHA Pharmacy Guidelines.
- DHA Policy for Clinical Privileging.

- DHA Policy for Clinical Trials.
- DHA Policy for Clinical Laboratory Accreditation.
- DHA Policy for Collection and Cryopreservation of Oocytes.
- DHA Policy for Communicable Disease Notification.
- DHA Policy for Emergency Medication.
- DHA Policy for Health Data Quality.
- DHA Policy for Health Informational Assets Management.
- DHA Policy for Health Screening and Immunization of Healthcare Professionals.
- DHA Policy for Role and Responsibilities of Medical Director.
- DHA Policy for Patient Referral and Interfacility Transfer.
- DHA Standards for Clinical Laboratory Services.
- DHA Standards for Medical Advertisement Content on Social Media
- DHA Standards for Medical Equipment Management.
- DHA Standards for the Management of Mortality and Morbidity in Health Facilities.
- DHA Standards for Sentinel Events Notification and Management in Health Facilities.

The standard will reflect various important chapters of which are licensing requirements of the Assisted Reproductive Medicine Center, terms and condition for the medical assisted procedures, approved Assisted Reproductive Technology (ART) procedures, genetic testing and other crucial process provided within the standard for guided implementation. The standard for Assisted Reproductive Medicine Centers was developed in alignment with the best global applicable practices and an intention of enhancing the quality of healthcare provided and placing Dubai as a destination for in Assisted Reproductive Medicine treatment.

The standard for Assisted Reproductive Medicine Centers will replace the previously published Standards for Fertility Centers.

## DEFINITIONS

**Artificial Oocyte Activation:** Activating the oocyte artificially (using $Ca^{+2}$ ionophore or other methods) as to increase the calcium in the oocyte and therefore improves the chance of fertilization.

**Assisted Reproduction Technologies:** Medical/ART Laboratory procedures that aid in conception, encompassing methods like in vitro fertilization (IVF) and artificial insemination to assist couples in achieving pregnancy when traditional methods are unsuccessful.

**Assisted Reproductive Medicine Center:** A licensed standalone center or unit within a facility where assisted reproduction procedures are carried out.

**Assisted Zone Hatching (AZH):** A procedure used to facilitate embryo hatching from its protective shell (zona pellucida) by creating a small opening in its zona as to help embryo implantation in the uterus and as a prerequisite for embryo biopsy procedure.

**Concerned Parties:** The person from whom sperm or unfertilized eggs are extracted from.

**Conventional In Vitro Fertilization (IVF):** The process of in vitro fertilization by manually placing sperm and oocyte together in a laboratory dish in the ART laboratory.

**Embryo Biopsy:** An assisted reproductive technique which involves the removal of one cell or few cells from an embryo for the purposes of genetic testing.

**Embryo Culture Media Analysis:** Evaluation of certain biomarkers in the media in which embryos are cultured.

**Embryo Pre-implantation Genetic Testing:** Removal of one or few cells from an embryo as to assess its chromosomal consistency with regards to carrier mutation status, karyotyping, Human Leukocyte Antigen (HLA) matching etc.

**Embryo transfer:** The last step in the process of assisted reproduction in which embryos are placed into the uterus with the intent to establish a pregnancy.

**Frozen Embryo Transfer:** Process in which frozen/thawed embryos are placed into the uterus with the intent to establish a pregnancy.

**Frozen Oocytes Intracytoplasmic Sperm Injection:** A procedure in which a single sperm cell is injected directly into the cytoplasm of a frozen/thawed oocyte.

**Gamete and Embryo Freezing:** A procedure that involves use of cryopreservation materials in order to maintain gametes and embryos in their original state while in storage for later use.

**Gamete and Embryo Thawing:** A procedure that involves thawing materials in order to recover previously frozen gametes/embryos.

**Hyaluronan Based Media or Implantation Enhancing Medium:** An embryo transfer medium with increased amount of Hyaluronan which may promote embryo implantation.

**Intracytoplasmic Morphologically Selected Sperm (IMSI):** A technique used to examine and select sperm using high magnification digital imaging microscope for microinjection into the oocyte.

**Intra-cytoplasmic Sperm Injection (ICSI):** A procedure in which a single sperm cell is injected directly into the cytoplasm of oocyte.

**Intra-Uterine Insemination (IUI):** Fertility treatment that involves placing sperm inside a women's

**Micro-surgical Testicular Sperm Extraction (Micro-TESE):** A surgical procedure which involves the use of surgical microscope for extracting sperm directly from the testis.

**Oocyte In Vitro Maturation (IVM):** A procedure in which oocytes are collected and matured

outside the body under special conditions, using special media in the ART laboratory.

**Ovarian Tissue Cryo-preservation:** A technique used for ovarian tissue cryopreservation as to keep the tissues and organs in low temperature for future use.

**Ovulation Induction**: the stimulation of ovulation by use of medication.

**Percutaneous Epididymal Sperm Aspiration (PESA):** A surgical procedure which involves aspirating sperm from the epididymis using a surgical needle.

**Polar Body Biopsy**: An assisted reproductive technique which involves the removal of polar body from an oocyte as to assess its chromosomal status.

**Preconception, preimplantation, prenatal genetic services:** Genetic services related to fertility treatment like Preimplantation Genetic Testing, carrier mutation screening, karyotyping, HLA matching etc.

**Surgical Correction for Obstructive Azoospermia:** Microsurgical Reconstruction of the vas and/or epididymis or in cases of ejaculatory duct obstruction by transurethral resection of the ejaculatory duct.

**Testicular Sperm Aspiration (TESA):** A surgical procedure which involves aspirating tissue/sperm from the testes using a surgical needle.

**Testicular Sperm Extraction (TESE):** A surgical procedure in which a small portion of tissue is removed from the testicle and any viable sperm cells from that tissue are extracted for use in further procedures. uterus to facilitate fertilization in-vivo.

**Varicocele Repair:** A surgery performed to remove a varicocele to restore proper blood flow. A varicocele is an enlargement of the veins within the scrotum.

## ABBREVIATIONS

| | | |
|---|---|---|
| **ART** | : | Assisted Reproductive techniques |
| **AZH** | : | Assisted Zone Hatching |
| **DHA** | : | Dubai Health Authority |
| **HEPA** | : | High-Efficiency Particulate Air |
| **HFG** | : | Health Facility Guideline |
| **HLA** | : | Human Leukocyte Antigen |
| **HRS** | : | Health Regulation Sector |
| **ICSI** | : | Intra-cytoplasmic Sperm Injection |
| **IMSI** | : | Intracytoplasmic Morphologically Selected Sperm |
| **IUI** | : | Intra- Uterine Insemination |
| **IVF** | : | In Vitro fertilization |
| **IVM** | : | Oocyte In Vitro Maturation |
| **MOHAP** | : | Ministry of Health and Prevention |
| **OPU** | : | Ovum Pick-Up. |
| **PESA** | : | Percutaneous Epididymal Sperm Aspiration |
| **PGT** | : | Pre-implantation Genetic Testing |
| **TESA** | : | Testicular Sperm Aspiration |
| **TESE** | : | Testicular Sperm Extraction |
| **VOC** | : | Volatile Organic Compounds |

## 1. BACKGROUND

According to a report published by the WHO on infertility prevalence, which estimates about 17.5% of the adult population – roughly 1 in 6 worldwide- experience infertility, regardless of where they live and what resources they have, which portrays the urgent need to increase access to affordable and high-quality fertility care for those in need. Understanding the magnitude of infertility is critical for developing appropriate Standards, evidence-based interventions, monitoring the quality of fertility care, mitigating risk factors and consequences of infertility. The health regulation sector in Dubai plays a crucial role in developing these standards in alignment with UAE laws and legislations to ensure safety and providing best practice services in Assisted Reproductive Medicine Centers. Assisted Reproductive Medicine centers offer a range of evidence-based services to help couples achieve pregnancy. These services are typically supported by scientific research and clinical evidence, offering services in Assisted Reproductive Medicine Centers .

Healthcare professionals providing assisted reproductive techniques (ART) should consider the mental and physical strain the process may have on the couple and accommodate accordingly to ensure their health and safety throughout the journey.

ART has become the most used and effective treatment for infertility. Global applications and ongoing technological evolvement encourage research in this field as the outcomes of research studies will be used to enhance and improve success rates, enhance quality of care, reduce risks, update regulations and increase access to care, placing Dubai in a leading position for infertility treatment worldwide.

## 2. SCOPE

2.1. ART services in DHA licensed hospitals and standalone Assisted Reproductive Medicine centers.

## 3. PURPOSE

3.1. To assure provision of the highest levels of safety and quality ART services in Dubai Health Authority (DHA) licensed health facilities.

## 4. APPLICABILITY

4.1. DHA licensed healthcare professionals and health facilities providing assisted reproductive medicine services.

## 5. **STANDARD ONE**: REGISTRATIONS AND LICENSURE PROCEDURES

5.1. Assisted Reproductive Medicine Centers seeking to provide assisted reproductive medicine services must first obtain a license by submitting a form approved by the DHA with all the required documents attached to be licensed under the category of Assisted Reproductive Medicine Center.

5.2. Assisted Reproductive Medicine services should only be provided either by a standalone reproductive facility or within a dedicated ward/unit in a hospital.

5.2.1. In the case of standalone centers, the facility should be fully self-contained and functionally independent — not physically or administratively linked to other, unrelated medical services.

5.3. Register through the online facility licensing service (SHERYAN).

5.4. The Assisted Reproductive Medicine Center is prohibited from providing any medical services until it obtains a license.

5.5. To complete obtaining the license, the following shall be required:

5.5.1. Employ the authorized health and professional employees.

5.5.2. Appoint a director for the Assisted Reproductive Medicine Center.

5.5.3. Submit a statement of the registered medical devices and equipment.

5.5.4. Submit a certificate that the Assisted Reproductive Medicine Center has passed the requirements of public safety and security and environment.

5.5.5. Provide a copy of the policies and procedures approved by the facility to receive and to treat patients.

5.5.6. Submit a copy of medical waste disposal contract.

5.5.7. Submit a copy of valid commercial license issued by the concerned authority.

5.5.8. Provide location details along with the Makani number.

5.5.9. The Assisted Reproductive Medicine Center shall comply with the DHA Health facility Design Guidelines (HFG), employing requirements and layout/floor plan designed and approved by prequalified HF design consultants, with room and bed count specifications as per DHA HFG Part B- Health Facility Briefing & Design 210 – IVF Unit.

a. https://eservices.dha.gov.ae/CapacityPlan/HealthFacilityGuidelines/Guidelines/Index/DHAHFG

5.5.10. The assisted reproductive center must have the minimum functional units to be granted licensing.

a. These include at minimum:

i. Consultation Rooms,

ii. Ultrasound Room,

iii. OT,

iv. recovery area,

v. Embryology Laboratory/ Andrology Laboratory,

vi. Cryostorage area (for gamete/embryo storage).

5.5.11. Pass DHA inspection.

5.6. As per the DHA policy for patient referral and interfacility transfer, all Assisted Reproductive Medicine Centers must have a written agreement for patient referral and emergency transfer of critical cases to a nearby hospital setting. The transfer agreement shall detail the transfer plan/protocol of patients and meet the transfer timeframes for emergency patients with appropriate follow up plans for referred patients.

5.6.1. In the case of request for frozen specimen transfer by the patient, the Assisted Reproductive Medicine Center should guide patients to abide by the internal policies and procedures of the Assisted Reproductive Medicine Center. The Assisted Reproductive Medicine Center must fill the "Request of Frozen Specimen Transfer" form and submit to DHA. Refer to Service Description (dha.gov.ae).

5.7. The Assisted Reproductive Medicine Center shall have in place internal policies and procedures including but not limited to:

5.7.1. policy for sample collection, storage, and transportations.

5.7.2. Service Description and Scope of Services.

5.7.3. Laboratory and diagnostic services policy that includes turn-around

timeframes for reporting noncritical and critical results.

5.7.4. Infection control policy to include management, prevention and surveillance in relation to patient, employees, infection control and frozen specimen safety.

5.7.5. Reprocessing of reusable equipment, safe use of chemicals used for cleaning and disinfecting.

5.7.6. Medication management and pharmacy services as per DHA Guidelines for Pharmacy.

5.7.7. Narcotic Handling Policy which covers all the steps from ordering until discard to ensure that narcotics are not misused.

5.7.8. Laundry and housekeeping services.

5.7.9. Medical and hazardous waste management policy as per the Dubai Municipality (DM) Requirements.

5.7.10. There should be an allocated medical waste storage and collection area that is well ventilated, temperature controlled, monitored and secured from public and patient access.

5.7.11. The medical waste storage and collection area shall be adequately labelled with a hazard sign to prevent unexpected entry from patients or the public.

5.7.12. Policy for sample collection, storage, sample transportations and the fate of non-mature collected samples.

5.7.13. Contingency plan in the case of emergency as to where the gametes/ embryos will be transferred to in agreement with the receiving facility with

a clear exit strategy.

5.7.14. Patient assessment, acceptance, admission and referral criteria.

5.7.15. Patient belongings.

5.7.16. Patient education, communication and informed consent.

5.7.17. Patient health record, confidentiality and privacy as per DHA Policy for Health Information Assets Management.

5.7.18. Staffing plan, employee management and clinical privileging.

5.7.19. Violence against Staff/Zero Tolerance.

5.7.20. Clinical Audit including Quality, Performance Management and Learning System.

5.7.21. Incident reporting.

5.8. All Assisted Reproductive Medicine Centers shall have a business continuity plan to ensure the center's services are uninterrupted.

## 6. **STANDARD TWO**: ASSISTED REPRODUCTIVE MEDICINE CENTER REQUIREMENTS

6.1. The Assisted Reproductive Medicine center should be dedicated solely to reproductive services.

6.2. The Assisted Reproductive Medicine center must be accredited by a globally recognized accreditation body that is approved by DHA within a period of two years.

6.3. Assisted Reproductive Medicine Center director shall assure the submission of an annual report to DHA as per monitoring requirements (Refer to Standard Eleven).

6.4. The Assisted Reproductive Medicine Center shall ensure the treatment environment is accessible and supports patient needs, safety, privacy and confidentiality for all

patient groups.

6.5. Assisted Reproductive Medicine Centers shall abide by offering their services to all clients including people of determination.

6.6. The Assisted Reproductive Medicine Center must always have the appropriate equipment and qualified trained multidisciplinary healthcare professionals to perform the necessary diagnostics, patient assessments, management, surgery, resuscitations and stabilization as per this standard and regulations.

6.7. Availability of electronic medical records system as per DHA policy for Health Information Assets Management.

6.8. The ART lab should be accredited-by a recognized accreditation body that has specific ART lab standards as per DHA's clinical lab accreditation policy within a period of two years.

6.9. Areas such as labs, theatres, cryostorage rooms must not be shared with other clinical or diagnostic services.

6.10. Laboratories or outpatient clinics not licensed as Assisted Reproductive centers must not provide partial or full fertility treatments or related lab services.

6.11. HRS must be informed and approve changes to existing or new services or staffing levels.

6.12. Assisted Reproductive Medicine Centers should have a contingency plan in the case of emergency or center closure as to where the gametes/embryos will be transferred to in agreement with the receiving facility, which should be included in their internal policies and procedures with proper documentation. In addition, all ART laboratories

must have a clear exit strategy that includes a logical way to keep the storage tanks containing the cryopreserved specimens safe during transfer.

6.13. Collective transfer of stored gametes to another facility as per contingency should be as follows:

6.14. The Assisted Reproductive Medicine Center which is closing should ensure that in case of shutdown of the facility, proper process as per contingency plan is followed and DHA Process for Assisted Reproductive Medicine Center Closure (refer to appendix 6). The closing facility should provide an official letter to DHA with detailed information about the closure of the center, expected closure timeframe, followed by comprehensive patient details and quantity of gametes stored and to be exported, defined types of frozen samples (oocytes/semen/embryos/tissue) and sample parameters.

6.15. It is the responsibility of the closing Assisted Reproductive Medicine Center to notify its patients regarding the transfer of the frozen samples, and the requirement to submit mandatory documents and essential medical records including repeating of investigations at the importing facility, and clearance of all outstanding dues related to storage of gametes.

6.16. The Assisted Reproductive Medicine Center shall install and operate equipment required for the provision of proposed services in accordance with the manufacturer's specifications.

6.17. Monitoring medical, electrical and mechanical equipment, visual inspections for apparent defects and maintenance by the competent entity with valid testing certificates as per DHA Standards for Medical Equipment Management.

6.18. Assure medical equipment and devices are in place for emergency scenarios.

## 7. **STANDARD THREE:** HEALTHCARE PROFESSIONALS REQUIREMENT

7.1. All Assisted Reproductive Medicine Centers shall have the required healthcare professionals in accordance with Ministerial decision No. (117) of 2024 Concerning Medical and Technical Healthcare Professionals Required in Fertility centers Ministerial Decision (51) for 2025 concerning the amendment of certain provisions of the Unified Healthcare Professional Qualification Requirements (PQR).

7.2. Required healthcare professionals include:

7.3. The Medical Director: DHA licensed consultant in consultant in reproductive medicine and infertility or in obstetrics and gynecology with a subspecialty license in reproductive medicine and Infertility with minimum of 10 years of experience in fertility treatment.

7.4. Minimum of one full time DHA licensed Specialist or Reproductive Medicine and Infertility or in Reproductive Endocrinology and Infertility with minimum of 3 years of experience in fertility treatment.

7.5. Minimum of one DHA licensed consultant or specialist urologist with subspecialty in Andrology and a minimum of two years of experience in male reproductive health. This service may be delivered by a full-time qualified physician within the health facility or by a part-time licensed professional from another health facility.

7.6. Minimum of one full time DHA licensed consultant or specialist Anesthesiologist.

7.7. Laboratory director: A full-time licensed embryologist with a minimum master's degree in biology or Embryology and at least 6 years of experience in this field.

7.7.1. Minimum of two full time DHA licensed embryologist working under the supervision of the laboratory director.

7.7.2. The number of embryologists should reflect the number of cycles performed per year. As an approximate guide, clinics that perform up to 150 retrievals and/or cryopreservation cycles per year should always have a minimum of two qualified embryologists and additional embryologists should be allocated for any added cycles and to be maintained as per update to the guidelines.

7.7.3. The initial number will increase depending not only on the number of cycles, but also on the complexity of the procedures, techniques and tasks undertaken within the ART Lab.

7.8. DHA licensed Medical Laboratory Technologist DHA licensed Medical Laboratory Technologist with 6 months Andrology certification or at least 2 years of experience in andrology laboratory services which can be delivered by a full-time Medical Laboratory Technologist within the health facility or by a part-time licensed professional from another health facility.

7.9. Minimum of one full time DHA licensed Anesthesia technologist or technician that corresponds to the minimum number of consultant or specialist Anesthesiologist in the Assisted Reproductive Medicine Center.

7.10. Minimum of two full time DHA licensed Radiographer/Sonographer /Radiography technologist or technician, with not less than 2 years of experience in the field.

7.11. Minimum of five, DHA licensed registered nurses which of whom include those

experienced in operation rooms.

7.11.1. It's recommended that the number of nurses should be proportionate to the number of cases.

7.12. Full-time or part-time DHA licensed healthcare professionals and services:

7.12.1. DHA licensed Genetic counsellor.

7.12.2. DHA licensed Clinical or Health Psychologist.

7.12.3. Central Sterile Services technician.

7.13. A formal service-level agreement (SLA) and traceability mechanism must be mandated for any permitted outsourcing.

7.14. Additional Required Support Employees:

7.14.1. Administrative and Financial manager.

7.14.2. Biomedical engineer

7.14.3. Customer Service.

7.14.4. Medical Record Clerk.

7.14.5. Storage Supervisor.

7.14.6. Security Personnel.

7.14.7. Cleaner.

7.14.8. Quality Officer.

7.15. Only DHA licensed fertility specialists shall be permitted to perform assisted medical reproductive procedures that include but not limited ovulation induction and intra-uterine insemination.

7.16. Healthcare Professionals shall perform medical assisted reproduction procedures in

accordance with UAE legislations.

7.17. The Assisted Reproductive Medicine Center employees are responsible for maintaining confidentiality of information and treatments provided in the facilities and in accordance with the relevant UAE laws and decrees.

7.18. ART laboratory employees shall comply and refer to the DHA standards of Clinical Laboratory services when applicable.

## 8. **STANDARD FOUR:** ASSISTED REPRODUCTIVE CENTER MEDICAL DIRECTOR RESPONSIBILITIES

8.1. The medical director is responsible for submitting required documentation to DHA for the assisted reproductive center.

8.2. The Medical Director shall:

8.2.1. Ensure Assisted Reproductive Medicine center's compliance to quality and safety control measures as per Ministerial Decision No (115) of 2024 Concerning Quality Control Measures in Fertility Centers for compliance with the quality and safety measures.

8.2.2. The privilege shall be aligned with the physician's DHA license title, education, training, experience, and competencies, in accordance with the PQR and the DHA Clinical Privileging Policy.

8.2.3. Ensure the Assisted Reproductive Medicine Center has in place a quality management system which guarantees the highest form of care delivered and includes but not limited to the following:

8.2.4. Oversee and monitor the quality of work at the Assisted Reproductive Medicine Center, as specified in this standard and UAE legislations.

8.2.5. Develop and raise the efficiency of all ART healthcare professionals working at the Assisted Reproductive Medicine Center through continuous educational programs, specifically ART technologist (Embryologist), medical laboratory technologist (Andrologist/ ART Lab scientists), nurses, clinicians and anesthesiologist according to training programs approved by DHA.

8.2.6. Maintain and ensure the privacy of health records of all procedures related to medically assisted reproduction.

8.2.7. Set in place a risk assessment and management system.

8.2.8. Set and overlook the implementation of internal policies and standard operating procedures before starting any treatment, if it includes the standards and mechanisms of internal control, and monitoring Key Performance Indicators in accordance with the provisions of related law and its executive decree and any law or regulation issued in this regard.

8.2.9. Meet with Assisted Reproductive Medicine Center's management team on regular basis to discuss KPI results, targets and action plans to improve the services.

8.2.10. Assure the accreditation of the Assisted Reproductive Medicine Center and ART laboratory is carried out by an accreditor specialized in ART Accreditation.

## 9. **STANDARD FIVE:** MEDICAL EQUIPMENT AND DEVICES

9.1. All Medical equipment and devices must be monitored and controlled as per

Ministerial decision No. (115) of 2024 Concerning Quality Control Measures in Fertility.

9.2. The laboratory must include all essential items required for ART services.

9.3. Materials used in laboratory construction, painting, flooring and furniture should be appropriate for clean room standards, minimizing Volatile Organic Compounds (VOC) release and embryo toxicity.

9.4. The Assisted Reproductive Medicine Center must contain the following minimum medical equipment and devices that are approved by MOHAP, which includes the following:

9.4.1. Refer to minimum equipment in ART laboratory and andrology unit **Appendix 1.**

9.4.2. Refer to minimum machinery with preferred backup in case of emergency **Appendix 2.**

9.4.3. Refer to minimum operating room equipment **Appendix 3**.

9.4.4. Refer to minimum additional equipment must be available in OT room **Appendix 4**.

9.4.5. UPS Generator.

9.5. The number of Laminar Flow Hoods and Micromanipulation Workstations must be proportionate to both the expected ART workload and the complexity of procedures performed

9.6. Incubator numbers should be calculated according to incubator capacity and facility cycle numbers as culture conditions fluctuate by frequent opening of doors and can

negatively impact gamete/embryo development and viability.

9.7. Gametes and embryos should be conveniently distributed across incubators to minimize door openings.

9.8. Equipment must be adequate for optimal laboratory work, easy to disinfect and kept clean to avoid contamination.

9.9. All equipment must be validated as fit for its purpose and performance verified by calibrated instruments.

9.10. Equipment should preferably be CE-marked.

9.11. Gas cylinders should be located outside the laboratory, there should be an automatic change over system and sufficient cylinders stocked for immediate replacement. High purity gas and inline HEPA and VOC filters are highly recommended.

9.12. The Assisted Reproductive Medicine Center shall maintain a copy of operator and safety manuals of all medical equipment and inventory list with equipment location. All Medical Equipment should be registered and documented properly in the inventory which will be updated every time a new equipment arrives prior to use. To follow the Standards for Medical Equipment Management.

9.13. Equipment validation, calibration, maintenance and repair must be documented and records retained.

9.14. Employ a biomedical engineer or maintain a service contract with a certified maintenance company to ensure safety, reliability, validity and efficiency of medical devices and mechanical equipment.

9.15. Accepted ranges of use for all measured parameters should be determined and

recorded. If measures are out of range, correction should be made and their effectiveness verified.

9.16. For every item of equipment, the instruction manual and the simplified instructions should be available.

9.17. Malfunctioning equipment and those under maintenance should be labelled out of use to avoid its usage and stored in a proper allocated area.

9.18. Critical equipment such as incubators, fridges, freezers and liquid nitrogen cryo-storage units should be continuously monitored and equipped with alarm systems.

9.19. An automatic emergency backup power system must be in place for all critical equipment. e.g.: includes incubator, fridge, and freezers.

9.20. Cryopreservation storage units should be continuously monitored and equipped with alarm systems, detecting any out of range temperature and/or levels of liquid nitrogen (LN2).

9.20.1. Personal low oxygen alarms are recommended as an additional security measure.

**10. STANDARD SIX:** MEDICAL ASSISTED REPRODUCTION PROCEDURES TERMS AND CONDITIONS/ PRE-REQUISISTES

10.1. The Assisted Reproductive Medicine Center shall ensure that medical assisted reproduction is the most appropriate medical intervention after confirming that pregnancy through natural contact cannot happen naturally or due to medical indication, after ensuring adequate time for allowing natural pregnancy was given.

10.2. A written consent from the spouses or concerned parties must be obtained in-person

at the Assisted Reproductive Medicine Center before every and any procedure including cryopreservation. Refer to DHA Guideline for Patient Consent and Federal Decree No. (17) of 2023 Amending Some Provisions regarding Medical Assistance in Reproduction.

10.3. Any cryopreservation procedures must comply and refer to the DHA Policy for Collection and Cryopreservation of Gametes/Embryos/Reproductive Tissues.

10.4. The cryopreservation consent forms are required before every procedure and they include all stipulations specified in Ministerial Decision (124) of 2024 amending some provisions of by Cabinet Decision no. (64) of 2020 concerning the executive regulations of Federal Law no. (7) of 2019 regarding Medical Assistance for Childbearing while keeping in accordance with the Cabinet Decision no. (64) of 2020 concerning the executive regulations of Federal Law no. (7) of 2019 regarding Medical Assistance for Childbearing.

10.5. The Assisted Reproductive Medicine Center must obtain all the mandatory documents from spouses and concerned parties before admitting the patient to start treatment as per the Federal Law No. (7) of 2019 and Decree No. (17) of 2023 Amending Some Provisions of regarding Medical Assistance in Reproduction.

10.6. In the case of non-married individuals, the following stipulations apply:

10.7. The Assisted Reproductive Medicine Center must obtain necessary forms, documents and approvals in the presence of both non-married individuals before beginning the service as per Ministerial Decree No. (183) of the year 2024 regarding the adoption of the parentage declaration forms. **Refer to appendix 7.**

10.8. The declaration forms must be signed and sealed by the embassy/consulate of which both the non-married individuals are from.

10.9. The declaration forms must be signed and sealed by the Ministry of Foreign affairs.

10.10. The Assisted Reproductive Medicine Center must submit the necessary forms for the parties non-married individual to DHA for approval through assistedreproduction@dha.gov.ae

10.11. The required documents that must be submitted from the Assisted Reproductive Medicine Center to DHA include:

10.11.1. Completed Parentage Declaration Form as found on Ministerial Decree No. (183) of the year 2024 regarding the adoption of the parentage declaration forms refer to **appendix 7**.

10.11.2. Official Request from The Facility.

10.11.3. Signed Freezing Consent Form.

10.11.4. Signed Informed Consent for Fertility Treatment.

10.11.5. Recent Medical Reports for Both Patients.

10.11.6. Emirates ID Copies for Both Individuals.

10.11.7. Proof of Religion.

10.12. Comprehensive Clinical Assessment by the concerned physician should be conducted before starting the treatment to ensure patients have no contraindications or risk factors and is fit for the procedure and medical journey.

10.13. The assisted reproductive techniques are specified and decided by the Ministry of Health and Prevention and listed in Standard Seven.

10.14. All healthcare professionals must work with extreme caution and abide by the internal policies and protocols when dealing with gametes during ART procedures.

10.15. The Assisted Reproductive Medicine Center must abide by the law and regulation placed when conducting any assisted reproductive procedures, especially when dealing with the following:

10.15.1. Number of fertilized oocytes that were implanted.

10.15.2. Cryopreservation of fertilized and unfertilized oocytes and sperm for future use.

10.15.3. Agreement of both spouses on preserving the frozen fertilized oocytes, agreement of the concerned partied on preserving the frozen unfertilized oocytes and sperms, agreement of concerned parties on preserving fertilized oocytes and sperms.

10.16. Provision of medical assisted reproduction procedures is limited to physicians licensed in this field.

10.17. Centers must hold the highest controls when handling fertilized or unfertilized oocytes and frozen sperms and provide the upmost caution and precaution to preserve them and prevent their use in unauthorized ways, such as exploitation, replacement, or mixing.

## 11. **STANDARD SEVEN**: APPROVED MEDICAL ASSISTED PROCEDURES

11.1. Assisted Reproductive Medicine Centers are required to comply with Ministerial Decision (124) of 2024 amending some provisions of by Cabinet Decision no. (64) of 2020 concerning the executive regulations of Federal Law no. (7) of 2019 regarding

Medical Assistance for Childbearing while keeping in accordance with the Cabinet Decision no. (64) of 2020 concerning the executive regulations of Federal Law no. (7) of 2019 regarding Medical Assistance for Childbearing.

11.2. It is permissible to fertilize oocytes that are sufficient for multiple implantations, according to the conditions and controls determined by the with Ministerial Decision (124) of 2024 amending some provisions of by Cabinet Decision no. (64) of 2020 concerning the executive regulations of Federal Law no. (7) of 2019 regarding Medical Assistance for Childbearing while keeping in accordance with the Cabinet Decision no. (64) of 2020 concerning the executive regulations of Federal Law no. (7) of 2019 regarding Medical Assistance for Childbearing as defined in the below controls :

11.2.1. A clear policy and procedure identifying the steps taken to preserve gametes and embryos.

11.2.2. A detailed mechanism that will ensure the correct and approved steps taken to ensure traceability of the gametes and ensure the time and place of collection.

11.2.3. A mechanism set in place to verify success of cryopreservation and keep track of success rates within a lab report that details the number of preserved gametes/ embryos mentioning the duration of time the gametes/ embryos will be preserved for.

11.2.4. A clear mechanism for the disposal of the gametes through allowing them to perish in the case of the death of the spouse/concerned party, or ending

of the relationship between the spouses/concerned parties.

11.2.5. A clear process for the separation of gametes/embryos of the viral positive parents from other gametes/embryos originating from viral negative parents.

11.3. The number of oocytes (egg retrieval procedures) for the purpose of fertilization should not exceed six times per year per patient.

11.3.1. Patient health risks such as poor responder patients and physician assessment must be taken into consideration.

11.4. Embryo transfer should not exceed two embryos at one time.

11.5. High risks patients and/ or patients with chronic disease that are associated with an increased risk of complications to the mother or fetus require a medical report from a specialized treating physician indicating the safety of fertility treatment before commencing the fertility treatment.

11.6. The Assisted Reproductive Medicine Center shall ensure the highest medical, administrative, safety and other accuracy measures when fertilizing several oocytes for multiple implantations to prevent fertilized and unfertilized oocytes and sperms from mixing with other samples or using them in ways beyond the permissible procedures.

11.7. Assisted Reproductive Medicine Centers are required to comply with main and associated procedures as per Ministerial Decision no. (134) of 2021 concerning the identification of medical assisted reproductive technologies. Refer to **appendix 5.**

11.8. Any procedures other than the approved procedures as per Ministerial Decision No.

(134) of 2021 including ART research procedures shall subjected to DHA approval. (Refer to Standard Ten: Research and Medical Trials)

11.9. Preservation and disposal:

11.9.1. Fertilized eggs may be preserved, for a period of five years subject to extension for the same period upon on a written request by the spouses.

11.9.2. Unfertilized eggs or frozen sperms may be kept for a period of five years, subject to extension for same period upon a written request by the concerned parties.

11.9.3. The Assisted Reproductive Medicine Center shall have in place evidence of contacting the concerned parties or the spouses in the case of cryo-storage expire with frequent reminders decided by the Assisted Reproductive Medicine Center as per internal policies and procedures.

11.9.4. Fertilized eggs that were not implanted into the wife should be disposed (left without medical care until they naturally perish, unless concerned parties request otherwise) with clear documentation in the medical file in the following cases:

a. The death of one of the spouses.

b. Ending of the marital relationship.

c. Spouses request.

d. Expiry of the preservation period without a request for extension (after five years) with evidence of contacting the concerned parties.

e. Where there is no need for the rest of the fertilized eggs, or in cases

where a legal or a medical reason prevents their implantation.

11.9.5. Fertilized/unfertilized eggs and frozen sperms of concerned parties should be allowed to perish in the following cases:

a. The request of the concerned parties.

b. Death of the concerned party.

c. Ending of the concerned party's relationship.

d. Expiry of the preservation period without a request for extension as per agreement and signed consent with evidence of contacting the concerned party.

11.10. It is prohibited to take samples of unfertilized or fertilized eggs or frozen sperms that were prepared inside the country and send them outside, or to bring these samples into the country if they were prepared outside, except in accordance with the controls and procedures determined by Cabinet Decision in accordance to Ministerial Decision (124) of 2024 amending some provisions of by Cabinet Decision no. (64) of 2020 concerning the executive regulations of Federal Law no. (7) of 2019 regarding Medical Assistance for Childbearing.

11.11. Fertilized or unfertilized eggs or frozen sperms that were kept for the purpose of medical assisted reproduction may not be transferred from one Assisted Reproductive Medicine center to another except upon the consent of the spouses or concerned parties, and upon the approval of DHA.

11.12. In the case of request for transfer, patients must abide by the internal policies and procedures of the Assisted Reproductive Medicine Center. Facilities must fill the "Request of Frozen Specimen Transfer" form and submit to DHA. Refer to Service

Description (dha.gov.ae).

## 12. **STANDARD EIGHT**: PATIENT SAFETY

12.1. To ensure patient safety, the Assisted Reproductive Medicine Center shall ensure the availability of electronic medical records for patients is documented as per the DHA Policy for Health Data Quality with the following but not limited to:

12.1.1. Patient Emirates I.D or Passport

12.1.2. Medical history and family history

12.1.3. Evidence of consultation, physical examination and confirmatory Laboratory diagnostics.

12.1.4. No emerging issues since the last pre-op assessment.

12.1.5. Informed consent for the procedure.

12.2. The Assisted Reproductive Medicine Center shall ensure providing the following to guarantee patient safety in the center:

12.2.1. Adequate employee qualifications, experience and levels for the procedure.

12.2.2. Emergency training and preparedness of employees.

12.2.3. Up to date medical records.

12.2.4. Confirmation of functioning equipment and a backup plan.

12.2.5. Fully functional and maintained medical devices.

12.2.6. Control of concentrated electrolyte solutions.

12.2.7. Assuring medication availability, accuracy and safe dosing as per DHA pharmacy guidelines.

12.2.8. Infection control program,

12.2.9. Single use of injection devices and insert of the IV line.

12.2.10. Mandatory Emergency Medication.

a. Class C Emergency medication as per DHA Policy for Emergency Medication.

12.2.11. Stopping the procedure in the event if the patient health deteriorates.

12.2.12. Patient recovery plan.

12.2.13. Falls management plan.

12.2.14. International patient safety goals.

12.2.15. Communication of employees before and during patient hand over.

12.2.16. Patient post-op instructions, discharge and follow up.

## 13. **STANDARD NINE:** INFECTION CONTROL

13.1. There shall be written policies and procedures in the Assisted Reproductive Medicine Center regarding infection control program to include management, prevention and surveillance.

13.2. Policy for infectious diseases screening notification and protocols healthcare professionals should abide by for patients who test positive for specific diseases such as HIV, Hepatitis B and C as per DHA Policy for Communicable Diseases Notification.

13.3. Policy and procedures to ensure employee safety and prevent cross-contamination should be established to prevent the transmission of pathogens across the Assisted Reproductive Medicine center:

13.4. The infection control program shall support safe practice and ensure a safe environment for patients, health workers and Assisted Reproductive Medicine Center visitors. The infection control system shall address factors related to the spread

of infections among professional/patient and prevention which includes:

a. The clinical procedures for safe patient care and minimizing risks by /cleaning/disinfection/sterilization.

b. Use of standard precautions which are the infection prevention and control practices that must be used at all times for all patients in all situations and additional precautions in certain cases.

c. The essential measures for infection control such as hand hygiene, the personal protective equipment, the safe use and disposal of sharps, the use of aseptic “non-touch” technique for all invasive procedures, reprocessing of reusable instruments and equipment, routine environmental cleaning, waste management, respiratory hygiene and cough etiquette, appropriate handling of linen.

d. Healthcare professional vaccination and immunizations as per DHA’s policy for health screening and Immunization of healthcare professional.

e. Frequent monitoring auditing of demonstrated or suspected spread of infection and of working practices within the Assisted Reproductive Medicine Center.

f. Environmental cleaning, single use items and reprocessing of sterile instruments.

g. Recommended cleaning, disinfectant and sterilization in the healthcare for procedure and non-procedure areas as per municipality’s approved list and prepared as per manufacturer’s instructions and the handling

is by trained employees.

h. Sterilization may be outsourced and is subject to DHA approval.

   i. In case sterilization is not outsourced then there should be a sterilizing area, which can be located near the procedure room with an adequate high-speed autoclave machine. Cleaning and sterilizing medical tools should be done in a sterilizing area next to the cleaning room for the tools to be cleaned, sterilized and then received from the cleaning room, preferably through a window passage.

i. An active infection prevention surveillance program and ongoing educational competency evaluation of employees regarding activities pre- procedure, intra-procedure and post procedure phases that are necessary for employee and patient safety.

j. Prevent pathogen transmission resulting from improper use or reuse of syringes, multiple dose drug vials and IV equipment which shall be adhered to the following:

   i. Preparing medications for multiple patients shall be done in an area away from direct patient care or procedure rooms.

   ii. All medications shall be appropriately labelled, including those used for sedation, unless the medication is for immediate use (prepared and administered directly without leaving the provider's

hand).

iii. Medications either marked on the container or noted in the package as "single patient use" shall be used for a single patient only, and any remaining drug should be discarded.

iv. New fluid administration sets units shall be used for each patient.

v. A single dose vial is preferred over multiple-dose vials, particularly when medications are administered to multiple patients.

13.5. Treatment of viral-positive patients should only be performed in ART laboratories with dedicated areas and equipment.

13.6. Whenever biological material is imported into the ART laboratory from another clinic, full screening results should be obtained in advance.

## 14. **STANDARD TEN:** RESEARCH AND MEDICAL TRIALS

14.1. All research and medical trials conducted in the Assisted Reproductive Medicine Center should be as per Federal Law by Decree No. (4) of 2016 on Medical Liability and DHA policy for Clinical Trials.

14.2. All research concerning medical assisted reproductive procedures and other subjects relating to assisted reproduction require approval from DHA and Dubai Ethical Committee as per Clinicals Trials Policy.

14.2.1. Proposals should be submitted to Medical Research (dha.gov.ae)

14.3. Obtain a written consent of each of the spouses and concerned parties.

14.4. The consent to the spouses or the concerned parties should include the following information:

14.4.1. Clarify to the spouses that refusal from agreeing to the research will not negatively impact their treatment at the Assisted Reproductive Medicine Center.

14.4.2. Clarify the purpose and impact of the scientific research.

14.4.3. The expected period it will take to complete the research.

14.5. Fulfil the clinical trial and research requirements as per local laws and regulations.

14.6. The spouses or the concerned parties have the right to reject or revoke from participating in the research at any stage of the clinical trial. This decision should not affect the treatment plan of the concerned parties at the Assisted Reproductive Medicine Center.

14.7. The principal researcher and the Assisted Reproductive Medicine Center must declare that there is no conflict of interest between the Assisted Reproductive Medicine Center and the concerned parties financial or otherwise.

14.8. The Assisted Reproductive Medicine Center is allowed to conduct research for the following purposes:

14.8.1. Increase the knowledge regarding certain cases or diseases.

14.8.2. Developing medications for certain cases or diseases.

14.8.3. Improving or developing fertility treatments.

14.8.4. Increase knowledge regarding causes of miscarriage.

14.8.5. Develop methods for detecting chromosomal abnormalities, genetic or mitochondrial disorders in the embryo prior to implantation into the uterus.

14.8.6. Increase knowledge on embryo development.

14.8.7. Increase knowledge on the procedures of freezing gametes or

embryos.

14.8.8. Develop methods for detecting chromosomal abnormalities or genetic or epigenetic disorders in gametes/ embryos.

14.9. The Assisted Reproductive Medicine Center is prohibited from conducting research or experiments on the following:

14.9.1. Reproductive cloning.

14.9.2. Selective genetic features.

14.9.3. Commercial purposes.

14.9.4. Alteration to human genome

14.10. When using gametes or embryos in research, the following should be taken into consideration:

14.10.1. Refraining from using them for other than the specific purpose of the search.

14.10.2. The consent of the spouses or the concerned parties to conduct the research should not be a result of any financial or other compensation, nor the result of physical or moral persuasion, nor that the consent is based on fraud or deception.

14.11. Any other conditions and controls decided by DHA.

## 15. **STANDARD ELEVEN**: MONITORING AND EVALUATION

15.1. The Assisted Reproductive Medicine Centers shall comply with the following performance measures as per Ministerial Decision no. (235) of 2022 concerning Criteria for Evaluating Assisted Reproduction Centers:

15.1.1. Availability of the minimum required medical and paramedical employees

available in the Assisted Reproductive Medicine Center.

15.1.2. The availability of required policies and procedures in relation to processes, patients, employees, infection control and frozen specimen safety.

15.1.3. Availability of documentation on all frozen specimen (gametes/embryos).

15.1.4. Availability of documentation of full details of the patient's cycle from the point of egg collection to the conclusion of the treatment inclusive the fate of each of the oocytes collected as well as the remaining of the semen sample collected.

15.1.5. Availability of electronic medical records system.

15.1.6. Availability of training and continuous medical education programs.

15.1.7. The availability of minimum equipment required, machinery and all medical necessities in the Assisted Reproductive Medicine Center with its size and number of cases conducted using the respective equipment as well as routine maintenance as per manufacturer specification.

15.1.8. Compliance to the UAE legislations in conducting medical research/experiments on gametes/embryos. (if applicable).

15.1.9. Compliance with the legislation and regulations about transferring frozen oocytes, embryos, seminal fluid inside or outside the country.

15.2. The following performance measures shall be reported to DHA (MonitoringKPIs@dha.gov.ae) annually as per UAE legislations:

15.3. Positive Pregnancy rate/Embryo Transfer/ age group stratification (<35, 35-37, 38-40, 41-42, >42).

15.4. Number of Cycles performed (IVF, ICSI, split IVF/ICSI procedures).

15.4.1. Total number and Percentage of Clinical Pregnancy from total number of embryos transferred.

15.4.2. Total number and Percentage of Live births from total number of embryos transferred.

15.4.3. Total number and Multiple Pregnancy Rate (Twins or Triplets) from total number of embryos transferred.

15.4.4. Number of FER (Frozen Embryo Replacement) Procedures.

15.4.5. Number of FE-ICSI (Frozen eggs Intracytoplasmic Sperm Insemination) Procedures.

15.4.6. Number of IUI (Intrauterine Insemination) Procedures.

15.4.7. Total number of cases with Positive fetal hearts as confirmed by ultrasound 2-4 weeks after positive pregnancy test following ART procedure.

15.4.8. Total number of cases with embryo transfer performed.

15.4.9. Total number and percentage of incomplete ART cycle from total number of ART cycles.

15.4.10. Total number of frozen samples:

a. Frozen Oocytes.

b. Frozen Embryos.

c. Frozen semen sample.

15.4.11. Percentage and number of complications resulted from ART from all cases.

15.4.12. Total number of research studies conducted or participated in.

15.4.13. Patient satisfaction rate.

15.4.14. Total number of cases with preimplantation genetic diagnosis and total number of normal or mosaic embryos.

## 16. **STANDARD TWELVE**: MEDICAL RECORDS

16.1. Assisted Reproductive Medicine Centers should keep the medical records of the medical assisted reproduction procedures and patient information as per the following conditions.

16.2. Patients' identification in the medical records (Electronic or Physical), as per Ministerial decision No. (236) of 2022 Concerning Records of Operations in Assisted Reproduction Centers shall include, but not limited to the following:

16.2.1. Assisted Reproductive Medicine Center name and logo.

16.2.2. Name of the spouses or concerned parties with pictures and copy of Emirates IDs or passports for both spouses or concerned parties.

16.2.3. Nationality of spouses/concerned parties.

16.2.4. Date of birth.

16.2.5. Medical record number.

16.2.6. Dates of visit.

16.2.7. Name of treating physician.

16.2.8. Address, phone number and email address of spouses/ concerned parties.

16.2.9. Date of first registration of patient.

16.2.10. Confirmation of receiving a copy of the passport or Emirates ID, recent pictures of each of the spouses or concerned parties and a copy of attested

marriage certificate (for spouses).

16.3. Patient Medical record shall include all the patient identification information in addition but not limited to the following:

16.3.1. Current health status of the spouses (or concerned parties).

16.3.2. Medical history.

16.3.3. Presence of chronic and/or genetic diseases.

16.3.4. Clinical and physical examination results.

16.3.5. Medical test results.

16.3.6. Management plan and selected assisted reproduction technique.

16.3.7. Sperm characteristics and status/fate of every sperm sample unused.

16.3.8. Number of eggs retrieved from the patient.

16.3.9. Number of fertilized eggs.

16.3.10. Each embryo characteristics (number of cells and types).

16.3.11. Fate/ status and use of each embryo (transfer, freezing, disposal, use for research).

16.3.12. Treating physician's notes following each visit.

16.3.13. Results of ultrasound following each visit.

16.3.14. Medication information (number and type of medications) for each treatment cycle.

16.3.15. Record of the name and signature of the embryologist and treating physician handling the procedures.

16.3.16. Traceability records of media and consumables are recorded in the ART

Laboratory Records of the patient.

16.3.17. Coordination between the laboratory team and the treating physicians' team for updates on the fate of the embryos and recording the results in the medical files.

16.3.18. Copy of all required consents and approvals for each treatment cycle.

16.4. ART Laboratory records, shall include all the information in the identification card, in addition to, but not limited to the following:

16.4.1. Place, date and time of specimen/sample collection.

16.4.2. Record of identification code and specimen/sample reference.

16.4.3. Evidence records of manual or electronic witnessing that has taken place during all critical steps in the ART Laboratory journey of the gametes (collection, processing, mixing of gametes, transferring from container to container, cryopreserving, thawing and transferring back to the patient). In case of pre-implantation genetic testing and biopsy these steps should be witnessed as well.

16.4.4. Sperm characteristics or report of sperm examination and diagnosis.

16.4.5. Results of specimen/sample tests.

16.4.6. Number of eggs retrieved from the patient.

16.4.7. Fate/ status of all the retrieved eggs.

16.4.8. Number of fertilized eggs.

16.4.9. Records/Traceability of all ART consumables that come into contact with the gametes/embryos.

16.4.10. Each embryo characteristics (number of cells and grades).

16.4.11. Fate/status of each embryo (transfer, freezing, disposal, use for research).

16.4.12. Incubator details and location of specimen/samples in all the incubators. Records of media and plasticware as part of ART consumables.

16.4.13. Documentation of procedures outcomes for all the Assisted Reproductive Medicine Center procedures.

16.4.14. All ART laboratory records above shall be signed by the laboratory operator.

16.5. Laboratory records when receiving the seminal fluid shall include:

16.5.1. Time of receiving semen fluid sample.

16.5.2. Method used to procure the sample.

16.5.3. Days of abstinence.

16.5.4. Room/incubator temperature.

16.5.5. If sample not received as per standards i.e. uncapped, not labelled, leaking etc. to be rejected and patient to be requested to produce a second sample.

16.5.6. Presence of any viscosity and/ or gelatinous material in the semen sample.

16.6. Patient file /record shall include all the information recorded in the ART laboratory.

16.7. Store record should include all the information about Assisted Reproductive Medicine Center assets including but not limited to furniture, machines, equipment, solutions, medications and dates of productions and expiry.

16.8. Employees' record should include names of all employees working in the Assisted Reproductive Medicine Center, each separately, with their identification, roles, responsibilities, reporting manager and all related human resource information

including their performance evaluation and employee's immunizations as per DHA policy for Health Screening and Immunization of Healthcare professionals.

17. **STANDARD THIRTEEN:** SOCIAL MEDIA AND ADVERTISING COMPLIANCE.

17.1. All DHA licensed Assisted Reproductive Medicine Centers or healthcare facilities providing fertility services must comply and refer to Cabinet Resolution No. (7) of 2007 Concerning the Health Advertisement Regulations.

17.2. All DHA licensed Assisted Reproductive Medicine Centers or healthcare facilities providing fertility services must comply and refer to DHA's Standards for Medical Advertisement Content on social media.

17.3. Healthcare professionals who are engaged in social media advertisements (SMAs) should be competent through education, training and experience to provide the service advertised and act in a manner of professional capacity, integrity and authenticity as advertised.

17.4. Assisted Reproductive Medicine Centers using healthcare professionals in advertisements should only use DHA-licensed titles.

17.5. No absolute or superlative claims should be used during the advertisement (e.g., "best," "only," "100% success," "guaranteed pregnancy," "unprecedented results").

17.6. Maintain an archive of posts/edits for audit; include social media in your organizational risk assessment and access controls refer to DHA's Standards for Medical Advertisement Content on social media.

17.7. Assure protection of patient health information on social media platforms.

17.8. Assisted Reproductive Medicine Centers must not push people through advertisements toward self-diagnosis or inappropriate self-treatment for serious conditions.

17.9. Assisted Reproductive Medicine Centers wishing to advertise through influencers must

ensure the individual creating promotional posts/reels/stories about the center must hold a valid Advertiser Permit. Refer to UAE Media Council's Advertisers Guide.

17.10. The Medical Director of the DHA licensed health facility shall ensure the following:

17.10.1. All SMAs shall be aligned with UAE federal and local laws and local regulations.

17.10.2. The content provided on the SMAs shall be factually accurate, reliable and substantiated and contains all risks and benefits; advantages and disadvantages of services provided.

17.10.3. The content and language used in the SMAs shall be professional and culturally sensitive and acceptable.

17.10.4. The Medical Directors of the health facilities are accountable for the content and style of SMAs on any account that promotes the health facility.

## 18. **STANDARD FOURTEEN**: PROHIBITED ACTIONS

18.1. Assisted Reproductive Medicine Centers are prohibited and should refrain from conducting the following actions:

18.1.1. In the case of married couples, fertilization of a sperm taken from the husband and an egg taken from a woman who is not his wife.

18.1.2. In the case of married couples, fertilization of an egg taken from the wife and a sperm taken from a man who is not her husband.

18.1.3. Performing in vitro fertilization of a sperm taken from the husband or concerned party and an egg taken from the wife or concerned party, then implanting the fertilized egg in the uterus of another woman.

18.1.4. Performing in vitro fertilization of a sperm taken from a man and an egg

taken from a woman, then implanting the fertilized egg in the uterus of another woman.

18.1.5. Using fresh or frozen gametes/embryos for commercial purposes, or making non-therapeutic genetic modifications to them, or using them for others.

18.1.6. Using fresh or frozen gametes/embryos for other not approved purposes/procedures even if there was a consent from the spouses.

18.2. Any other case determined by a decision of the Cabinet.

**19. STANDARD FIFTEEN**: LABORATORY REQUIREMENTS AND SAFETY CONTROLS

19.1. The Assisted Reproductive Medicine Center must comply and refer to Ministerial decision No. (115) of 2024 Concerning Quality Control Measures in Fertility for quality and safety control measures in ART laboratories.

19.2. The laboratory director shall ensure the Assisted Reproductive Medicine Center's quality management system is implemented and monitored in ART laboratories of which include but not limited to:

19.2.1. Defining job descriptions, responsibilities and ensuring all personnel are qualified and competent.

19.2.2. Having validated, written instructions for each process (SOP), including management of adverse events.

19.2.3. Ensuring full traceability of cells and tissues, materials, equipment and personnel involved in specific laboratory activities, with records maintained accordingly.

19.2.4. Documentation system should be in place when dealing with non-compliance, emergencies, errors, adverse events and complaints. Corrective and preventive actions, implementation dates and assessments of their effectiveness should be documented.

19.2.5. Confirming that all media/reagents/disposables are tested for quality and have appropriate quality certificates as well as are from any form of bacterial infection to produce valid and reliable results.

19.2.6. Ensuring proper and periodic equipment maintenance, service and calibration- verifying conformance to specifications.

19.2.7. Quality Control records should be maintained and reviewed, including documentation of results and any corrective action taken.

19.2.8. Reviewing performance (KPIs) to ensure continuous and systematic QMS improvement. In addition to laboratory and clinical performance, operator performance should be checked regularly to ensure competence, compliance and consistency.

19.2.9. Participation in Internal Quality Control (IQC) and External Quality Assurance (EQA) programs.

19.3. Every ART laboratory should have an up-to-date disaster preparedness or emergency plan.

19.3.1. Andrology and embryology laboratories need to have an exit strategy that includes a sensible way to salvage the storage tanks with the cryopreserved specimens.

19.4. The ART laboratory must have adequate functionalities to minimize any damaging effects upon reproductive cells an ensure good laboratory practice.

19.4.1. All ART involve handling of biological material and pose a potential hazard -9 of transmitting diseases to personnel and other patients' biological material (cross-contamination). Procedures to ensure personnel safety and prevent cross-contamination should be established, taking national and international safety regulations into consideration.

19.5. The ART Laboratory should be adjacent to the operating room where clinical procedures are performed.

19.6. Operating rooms must maintain positive pressure while keeping in consideration monitoring the air changes per hour based on ISO 100 instructions and standards.

19.7. Materials used in laboratory construction, painting, flooring and furniture should be appropriate for clean room standards, minimizing Volatile Organic Compounds (VOC) release and embryo toxicity.

19.7.1. Air supply vents should be located in the ceiling and return ducts should draw from close-to-floor level. Attention must be paid to the possibility of drafts from incoming air vents affecting the operation of some pieces of equipment.

a. To optimize environmental conditions, laboratory air should be subjected to high-efficiency particulate air (HEPA) and VOC control (Grade A environment with a background of at least GMP Grade D)

b. Positive pressure is recommended to minimize air contamination-

apart from cryopreservation room where negative pressure is required to protect from liquid nitrogen (LN2) leakage.

19.8. Laboratory access should be restricted to authorized personnel.

19.9. Laboratory design should ensure optimal workflow over small distanced while handling gametes/embryos during the whole treatment phase.

19.10. Rooms for changing clothes should be separate from the laboratory.

19.11. Hand washing facilities should be placed outside and within the laboratory.

19.12. Office spaces for administrative work should be available separately outside the laboratory while in proximity of the ART laboratory.

19.13. Area for cleaning and sterilization of materials should be separate from the laboratory.

19.14. All body fluids (blood, follicular fluid, semen, etc.) should be treated as potentially contaminated.

19.15. Mandatory Protective measures for laboratory employees to ensure aseptic conditions for tissue, gametes and embryos include:

19.15.1. Strict adherence to employees' hygiene regulations and aseptic techniques.

19.15.2. Use of protective laboratory clothing, preferably with low particle shedding.

19.15.3. Use of hairnets and nontoxic, non-powdered gloves and masks where appropriate.

19.15.4. Use of appropriate Biological Class II flow hood cabinet in order to protect sample and operator.

19.15.5. Use of mechanical pipetting devices.

19.15.6. Disposal of single-use consumables immediately into proper waste containers.

19.15.7. Potentially infectious materials must be disposed of in a manner that protects laboratory workers and other employees from exposure. Viral-positive waste segregated into a separate bin, labelled and disposed of according to biosafety policies).

19.15.8. Needles, glassware and other sharp objects should be handles with extreme caution and discarded into sharps containers.

19.15.9. Disinfectants with proven compatibility and efficacy for an ART laboratory should be used.

19.15.10. Food, gum, drinks and tobacco are strictly forbidden within the ART Laboratory.

19.15.11. Use of cosmetics and perfumes should be avoided within the ART Laboratory.

19.15.12. Employees should be appropriately attired to diminish possible sources of contamination.

19.16. Precautions that are encountered in ART laboratories related to samples/specimen that carry the risk of disease transmission include semen, blood and follicular fluid. Blood samples from patients with gametes/embryos destined to be cryopreserved should be tested for infectious diseases before cryopreservation.

19.17. Sanitation should occur when there is a spill and at the end of every shift.

19.18. Facilities should be available to cryopreserve and store biological material.

19.19. During storage and handling of cryopreserved material, high care should be taken to maintain adequate and safe conditions, temperatures should never rise above -130 C.

19.20. The protocols should be present and clear for employees to avoid any form of exploitation, mixing or replacement of gametes with incorrect ones and they include:

19.20.1. Presence of approved infection control processes, sanitation and sterilization processes for equipment and Assisted Reproductive Medicine Center, and separation of viral positive gametes/embryos from others in the ART laboratory.

19.20.2. Evaluate and record number of mature oocytes and have a clear policy and procedure on the fate of the non-mature oocyte collected.

19.20.3. Evaluate and document semen fluid parameters.

19.21. Cryopreservation documentation on biological materials include the following:

19.21.1. Labelling of devices.

19.21.2. Cryopreservation method.

19.21.3. Date and time of cryopreservation.

19.21.4. ART Laboratory Operator.

19.21.5. Embryo quality and stage of development.

19.21.6. Number of oocytes or embryos per device.

19.21.7. Number of devices stored per patient.

19.21.8. Location of stored samples.

19.22. Different cryopreservation approaches can be used according to the biological material, which include slow freezing and vitrification. The different types of slow

freezing and vitrification are as follows:

19.22.1. Sperm: slow freezing is the method of choice, but rapid cooling is a possible alternative.

19.22.2. Oocytes: vitrification has been reported to be highly successful and is recommended.

19.22.3. Tissues: slow freezing is the method of choice, but vitrification of ovarian tissue is an option.

19.23. Every ART laboratory should have in place an effective system to uniquely identify, trace and locate reproductive cells.

19.23.1. Before starting any procedure, the Laboratory must be given each patient's unique identification code which clearly identifies and refers to the patient's documentation. Each treatment cycle must be assigned a unique code.

19.23.2. Consent forms, clinical data and blood tests should be made available to the laboratory employees.

19.23.3. Rules concerning the correct identification and processing of reproductive cells must be established in the laboratory by a system of codes and checks including:

a. Direct verification of patient identity and correspondence with their assigned unique identification code is required at every critical step. Patients should be directly asked to give their own identifying information (full name and date of birth) before artificial insemination/embryo transfer.

b. All devices containing biological material must be clearly and permanently labelled with the unique patient identification code and date of treatment.

c. Biological material from different patient must not be processed in the same working area at the same time.

d. Incubators and cryo- storage systems should be organized to ensure easy access and identification of the biological materials inside.

e. Products and material used with biological materials must be traceable.

19.24. Identity check before the oocyte retrieval is mandatory.

19.25. Timing of oocyte retrieval, number of collected oocytes and the operator should be documented.

19.26. Semen samples should be collected in non-spermicidal sterile, plastic containers with clear labelling and identification confirmed by the patient.

19.27. Records should be kept of the type of container used, the time and place of collection as well as the time between collection and analysis/preparation.

19.28. The following data on sperm preparation should be documented:

19.28.1. Sample origin (ejaculate, epididymal/testicular, fresh/frozen).

19.28.2. Preparation method.

19.28.3. Pre- and post-preparation sperm parameters and any dilution carried out.

19.29. All ART laboratories should have an emergency plan in place with specific procedures in case of failure of infrastructure and facilities.

19.30. The plan should describe actions related to the following:

19.30.1. Safety of personnel and patients.

19.30.2. Protection of all fresh and cryopreserved human material.

19.30.3. Limitation of damage to equipment and medical records.

19.31. Information to be provided to Laboratory personnel working with chemicals include:

19.31.1. The signs and symptoms associated with exposures to hazardous chemicals used in the laboratory.

19.31.2. The location and availability of known reference materials on the hazards, safe handling, storage and disposal of hazardous chemicals found in the laboratory including, but not limited to, the Material Safety Data Sheets received from the chemical supplier.

19.31.3. The circumstances under which a particular laboratory operation, procedure or activity requires prior approval from the employer or the employer's designee before being implemented.

19.32. Laboratory training should include in addition to all other trainings methods and observations that may be used to detect presence or release of hazardous chemicals like:

19.32.1. Continuous monitoring devices.

19.32.2. Visual appearance, color and odor of hazardous chemicals when released.

19.32.3. Measures required of Laboratory workers to take to protect themselves from chemical hazards.

19.32.4. Training Laboratory employee on use and handling of gases, specifically Liquid Nitrogen Gas.

## 20. **STANDARD SIXTEEN:** GENETIC SCREENING AND TESTING

20.1. Genetic Screening of Gametes and Embryos may be performed at Assisted Reproductive Medicine Centers based on the approval of a licensed Specialist Physician and after the consent of the person from whom the sperm and the unfertilized eggs are extracted from, provided that the screening is being conducted for the purpose of identifying and preventing hereditary diseases. To prevent transferring chromosomally abnormal embryos or for gender selection (only for family balance or genetic diseases avoidance).

20.2. It is permissible to conduct genetic testing using Pre-implantation Genetic Testing (PGT) processes before implanting the embryo in the mother's uterus based on the following conditions:

20.2.1. Defining the need to conduct the genetic testing before implanting the embryo in the mother's uterus from the Assisted Reproductive Medicine Center's genetic counsellor or an affiliated genetic Laboratory to the Assisted Reproductive Medicine Center.

20.2.2. Provision of multi-disciplinary team from the Assisted Reproductive Medicine Center to conduct the genetic which includes:

a. Reproductive Medicine and Infertility Specialist or Reproductive Endocrinology and Infertility Specialist.

b. Embryologist.

c. Genetic counsellor.

20.2.3. Approval and signed consent forms from married couple and non-married

concerned parties who wish to conduct the genetic testing.

20.2.4. Assisted Reproductive Medicine Centers should provide the couple with information detailing the genetic testing process with specific emphasis on the following points:

a. Presence of a medical genetic concern in the family or from either spouse that requires further testing to the embryo.

b. The process that will take place and its side effects.

c. The genetic test does not guarantee pregnancy success as well as does not prevent miscarriage from happening in the case of pregnancy.

d. The financial cost and the mental health strain that could occur in the case of unsuccessful pregnancy even though genetic testing was conducted pre-implantation.

e. The average rate of false diagnosis in the genetic testing.

20.3. Conducting genetic testing to the embryos for the purpose of Human Leukocyte Antigen (HLA) matching the Assisted Reproductive Medicine Center must acquire a medical report from the physician treating the patient asking for the necessity of this test.

## REFERENCES

1. American Society for Reproductive Medicine, 2022. Comprehensive Guidance For Human Embryology, Andrology, And Endocrinology Laboratories: Management And Operations: A Committee Opinion. [Online]Available at: https://www.asrm.org/practice-guidance/practice-committee-documents/comprehensive-guidance-for-human-embryology-andrology-and-endocrinology-laboratories-management-and-operations-a-committee-opinion-2022/ [Accessed 2023].
2. Cabinet Decision no. (64) of 2020 concerning the executive regulations of Federal Law no. (7) of 2019 regarding Medical Assistance for Childbearing.
3. DHA, (2024). Policies and Regulations. [online] Available at: https://www.dha.gov.ae/en/licensing-regulations-policies
4. DHA Pharmacy Guidelines
5. DHA Policy for Clinical Privileging.
6. DHA Policy for Clinical Trials
7. DHA Policy for Clinical Laboratory Accreditation.
8. DHA Policy for Collection and Cryopreservation of Oocytes.
9. DHA Policy for Communicable Disease Notification.
10. DHA Policy for Emergency Medication.
11. DHA Policy for Health Data Quality,
12. DHA Policy for Health Informational Assets Management.
13. DHA Policy for Health Screening and Immunization of Healthcare Professionals.

14. DHA Policy for Role and Responsibilities of Medical Director.
15. DHA Policy for Patient Referral and Interfacility Transfer.
16. DHA Policy for Sentinel Event Notification and Management.
17. DHA Standards of Clinical Laboratory Services.
18. DHA Standards for Medical Advertisement Content on Social Media
19. DHA Standards of Medical Equipment Management.
20. European Society of Human Reproduction and Embryology, 2015. *Revised guidelines for good practice in IVF laboratories (2015).* [Online]
Available at: https://www.eshre.eu/Guidelines-and-Legal/Guidelines/Revised-guidelines-for-good-practice-in-IVF-laboratories-(2015) [Accessed July 2023].
21. Federal Law by Decree No. (4) of 2016 on Medical Liability
22. Federal Law no. (7) of 2019 concerning Assisted Reproduction.
23. Federal Law by Decree No. (17) of 2023 Amending Some Provisions of Federal Law No. (7) of 2019 regarding Medical Assistance in Reproduction.
24. Federal Law by Decree No. (49) of 2023 Regulating the Use of the Human Genome.
25. Ministerial Decree No. (79) of 2025 regarding types and classification private healthcare facilities and their scope of activity.
26. Ministerial Decision (124) of 2024 amending some provisions of by Cabinet Decision no. (64) of 2020 concerning the executive regulations of Federal Law no. (7) of 2019 regarding Medical Assistance for Childbearing.
27. Ministerial Decree No. 183 of the year 2024 regarding the adoption of the parentage declaration forms

28. Ministerial decision No. (117) of 2024 Concerning Medical and Technical Healthcare Professionals Required in Fertility Centers.
29. Ministerial decision No. (115) of 2024 Concerning Quality Control Measures in Fertility Centers.
30. Ministerial Decision No. (31) of 2024 Concerning Crash Cart Management.
31. Ministerial Decision No. (21) of 2022 Concerning the Approval of the Annual Report Template for Assisted Reproduction Centers.
32. Ministerial Decision no. (235) of 2022 concerning criteria for evaluation Assisted Reproduction Centers.
33. Ministerial Decision no. (134) of 2021 concerning the identification of medical assisted reproductive technologies.
34. Ministerial Decision no. (233) of 2022 concerning Required Medical Equipment and Devices in assisted Reproduction Centers.
35. Ministerial Decision no. (236) of 2022 concerning Records of Operations in Assisted reproduction Centers.
36. Ministerial Decree No. (430) of the year 2007 regarding the health advertising regulations
37. UAE Media Council for Advertiser.
38. Unified Healthcare Professional Qualification Requirements (PQR).

## APPENDIX

APPENDIX 1: MINIMUM EQUIPMENT IN ART LABORATORY AND ANDROLOGY UNIT

| Machine | Quantity | Backup |
|---|---|---|
| TRI-GAS/CO2 incubator | 2 | no |
| BIOLOGICAL CLASS II HOOD | 3 (2 in embryology Laboratory and 1 in Andrology Laboratory) | 1 |
| Stereomicroscope | 3 (the number should match the biological class II hood ratio 1:1) | 1 |
| Air filtration tower | 1 | |
| Phase contrast microscope | 1 | |
| Tube heater | 1 | |
| Thermometer | 1 | |
| ANTIVIBRATION TABLE | 1 | |

| | | |
|---|---|---|
| portable incubator | 1 | |
| Continuous Monitoring System (24hrs) | 1 | |
| O2 Sensor | 2 | |
| Laboratory Oven | 2 | |
| Gas Automatic Manifold | 2 | |
| Laser System (if Assisted Reproductive Medicine Center offers embryo genetic testing) | 1 | 1 |

## APPENDIX 2: MINIMUM MACHINERY WITH PREFERRED BACKUP IN CASE OF EMERGENCY

| Machine | Quantity | Backup |
|---|---|---|
| Inverted Microscope | 1 | 1 |
| Micromanipulator | 1 | 1 |
| Centrifuge | 1 | 1 |
| Freezing Tanks | 2 | 1 |
| Electrical pipettes | 2 | 1 |
| Variable pipettes | 2 | 1 |
| O2/CO2 GAS ANALYZER (the machine name must be the same name as stated) | 1 | 1 |
| Pharmaceutical fridge | 2 | |
| Camera and monitor | 1 of each | |
| Computer | 1 | |
| UPS BACKUP | 1 | |
| Backup warm plate | 1 | 1 |
| Digital weighing media | 1 | |

## APPENDIX 3: MINIMUM OPERATING ROOM EQUIPMENT

| Machine | Quantity | Backup |
|---|---|---|
| IVF Vacuum pump | 1 | 1 |
| Suction Unit | 1 | |
| Laparoscopy Unit (optional for hysteroscopy) | 1 | |
| Tele-cam | 1 | |
| Endoflater (optional for hysteroscopy) | 1 | |
| Light source XEN (optional for hysteroscopy) | 1 | |
| Monitor | 1 | |
| Anesthesia machine | 1 | |
| OR table | 1 | |
| cardiac monitor O2 monitor | 2 | |
| Crash cart & defibrillator along with Intubation Kit (laryngoscope with different sized blades, ETT Tubes different sizes, LMA different sizes) | 1 | |

| | | |
|---|---|---|
| and AMBU Bag with different sizes Ambu masks. | | |
| ultrasound | 1 | |
| OR lamp | 1 | 1 portable standby |
| Examination table | 1 | |
| Hormone immunoassay (optional) | 1 | |

## APPENDIX 4: MINIMUM ADDITIONAL EQUIPMENT IN MUST BE AVAILABLE IN OT ROOM

| Machine | Quantity | Backup |
|---|---|---|
| Water bath or bottle holder heater for flush | 1 | - |
| Block heater for tubes | 2 | |
| Surgical light | 1 | |
| Anesthesia pen tents | 1 | |
| Anesthesia cart | 1 | |
| Patient shifting trolley | 1 | |
| nursing trolley | 1 | |
| Surgical chair | 1 | |
| Instrumental trolley | 1 | |
| IV pole | 1 | |
| Wormer | 1 | |

## APPENDIX 5: LIST OF APPROVED MAIN AND ASSOCIATED ART PROCEDURES.

1. Main ART procedures:
    a. Ovulation induction and ovarian stimulation.
    b. Fertilization Conventional In Vitro (IVF).
    c. Intra-cytoplasmic Selected Sperm Injection (ICSI).
    d. Intra-Uterine Insemination (IUI).
2. ART Associated Procedures:
    e. Artificial Oocyte Activation.
    f. Embryo Biopsy.
    g. Embryo culture media analysis.
    h. Embryo transfer (ET).
    i. Frozen Embryo Transfer (FET).
    j. Frozen Oocytes Intracytoplasmic Sperm Injection.
    k. Gamete and embryo freezing.
    l. Gamete and embryo thawing.
    m. Intracytoplasmic Morphologically Selected Sperm Injection (IMSI).
    n. Microsurgical Testicular Sperm Extraction (Micro-TESE).
    o. Oocyte In Vitro Maturation (IVM).
    p. Ovarian and Testicular Tissue Cryo-preservation.
    q. Percutaneous Epididymal Sperm Aspiration (PESA).
    r. Polar Body Biopsy.
    s. Preconception, preimplantation and prenatal genetic services.

t. Surgical Correction for Obstructive Azoospermia.

u. Testicular Sperm Aspiration (TESA).

v. Testicular Sperm Extraction (TESE).

w. Oocyte Retrieval (Ultrasound guided).

x. Use of Hyaluronan based media.

y. Varicocele repair.

z. Zone assisted hatching.

APPENDIX 6: DHA PROCESS FOR ASSISTED REPRODUCTIVE MEDICINE CENTER CLOSURE.

| Steps | Subject | Requirements | Responsibility |
|---|---|---|---|
| 1. Prior to Closure | Patient Notification | - Provide a written notice to patients at least 90 days before closure date as per DHA Policy for Health Informational Assets Management. The notice should include the closure date, reasons for closure and contact information for inquiries. The Facility should utilize multiple channels for notifying the patients including email, SMS, and phone calls to ensure receipt as well as a record of all provided communication.<br>- Inform patients of their options regarding discharge of their samples in case of expiration, as well as receive their approval and written consent of transfer | Exporting Facility |

| | | | |
|---|---|---|---|
| | | - Ensure all actions taken during the closure process are documented and reported to relevant authorities. | |
| 2. Transfer Request from the Exporting Facility. | Frozen Specimen Transfer | The Exporting Facility must have a formal agreement with another equipped Assisted Reproductive Medicine Center that outlines the terms of safe storage, transfer responsibilities, liabilities, and handling of the samples.<br><br>The exporting Facility must submit to DHA the following in order to transfer the frozen specimens to another facility through ( DHAhealthadvertising@dha.gov.ae):<br><br>- Letter from closing facility with details of closing date and reasons for closure.<br>- Letter of approval from receiving facility with claiming responsibility to ensure the safety, care and integrity of patient specimens. | Exporting and Receiving Facility. |

| | | | |
|---|---|---|---|
| | | - A sheet that includes the following information for the transfer of frozen specimens:<br>- Spouses names.<br>- Freezing and Refreezing date.<br>- Expiration Date.<br>- Contact Details.<br>- Emirates ID.<br>- Sample Type.<br>- Sample Quantity.<br>- Consent to Freeze/Storage.<br>- Consent to Transfer.<br>- Name of Receiving Facility.<br>- Communication Details.<br>- Type of Communication.<br><br>The exporting facility shall ensure that the following details have been communicated to the laboratory of the Receiving Facility along with the information mentioned above: | |

| | | | |
|---|---|---|---|
| | | - Electronic Medical record details and File number.<br>- OPU Date.<br>- Screened Tanks.<br>- Viral Markers.<br>- Vitrification Sheet.<br>- Medical Report.<br>- Virology Screening Result.<br>- Marriage Certificate (if applicable).<br><br>If no instructions are provided by the patient, the exporting facility is responsible on ensuring that all specimens are stored in the agreed upon receiving facility. | |
| 3. Facility Closure | | The Closing Facility must follow SHERYAN process for Facility closure. | Exporting Facility |

## APPENDIX 7: PARENTAGE DECLARATION FORMS

**مرفق القرار الوزاري رقم ( 183 ) لسنة 2024**

**نموذج رقم (1)**

**إقرار الزوج/ الأب بالنسب (بنوة)**

**إنه في يوم ..... الموافق / / 202**

**حضر أمامنا نحن ..... وبصفتي ..... بمقر .....**

**(يذكر اسم الجهة المختصة بالدولة التي ينتمي إليها الشخص المقر والتي سيحمل المولود جنسيتها**

**واسم الموظف المسؤول بهذه الجهة وصفته)**

**السيد/ (يذكر الاسم كاملاً): .....**

**الجنسية:..... رقم جواز السفر / رقم الهوية الإماراتية:.....**

**تاريخ الإصدار:.....تاريخ الميلاد:.....**

**محل الإقامة: .....**

**وأقر بما يأتي:**

1. بأنني مسؤول عن كل تصرفاتي وان إقراري هذا قد تم بمحض إرادتي واختياري دون إكراه مادي أو معنوي من أي طرف.
2. وبأن الطفل الذي سيولد نتيجة لاستخدام تقنيات المساعدة الطبية على الإنجاب هو ابني وأؤكد نسبه لي.

3. وبأنه لا يوجد انكار من الأم صاحبة البويضة التي سيتم تلقيحها بنسب المولود لي أنا المقر والموقع أدناه ويعتبر توقيعها على هذا الإقرار اعترافاً منها بصحة ما جاء به ولا يجوز لها المنازعة أو إنكار نسب المولود لي واكتسابه جنسيتي ومسؤوليتي عنه.

| | |
|---|---|
| المقر بما فيه: الزوج (الأب) | إشهاد: الزوجة (الأم) |
| الاسم: ..... | الاسم: ..... |
| التوقيع: ..... | التوقيع: ..... |

اسم الموظف الموثق: .....

الوظيفة: .....

أصادق على هذا الإقرار باعتباره وثيقة إثبات نسب — ختم البعثة الدبلوماسية

التوقيع: ..... — للدولة التي ينتمي اليها الزوج (الأب)

تصديق وزارة الخارجية
لدولة الامارات العربية المتحدة

## نموذج رقم (2)

### إقرار الزوجة / الأم بالنسب (بنوة)

إنه في يوم ..... الموافق / / 202

حضرت أمامنا نحن ..... وبصفتي .....بمقر .....

(يذكر اسم الجهة المختصة بالدولة التي ينتمي إليها الشخص المقر والتي سيحمل المولود جنسيتها واسم الموظف المسؤول بهذه الجهة وصفته)

السيدة/ (يذكر الاسم كاملاً):.....

الجنسية:.....رقم جواز السفر/ رقم الهوية الإماراتية:.....

تاريخ الإصدار:.....تاريخ الميلاد:.....

محل الإقامة:.....

وأقرت بما يأتي:

1- بأنني مسؤولة عن كل تصرفاتي وإن إقراري هذا قد تم بمحض إرادتي واختياري دون إكراه مادي أو معنوي من أي طرف.

2- وبأن الطفل الذي سيولد نتيجة لاستخدام تقنيات المساعدة الطبية على الإنجاب هو ابني وأؤكد نسبه لي

3- وبأنه لا يوجد انكار من الأب صاحب الحيوان المنوي بنسب المولود لي ويعتبر توقيعه على هذا الإقرار اعترافا منه بصحة ما جاء به ولا يجوز له المنازعة أو إنكار نسب المولود لي واكتسابه جنسيتي ومسؤوليتي عنه.

المقر بما فيه: الزوجة(الأم)

الاسم: .....

التوقيع: .....

إشهاد: الزوج(الأب)

الاسم: .....

التوقيع: .....

اسم الموظف الموثق: .....

الوظيفة: .....

أصادق على هذا الإقرار باعتباره وثيقة إثبات نسب

التوقيع: .....

ختم البعثة الدبلوماسية

للدولة التي تنتمي اليها الزوجة (الأم)

تصديق وزارة الخارجية

لدولة الامارات العربية المتحدة