



Fertility Centre Standards and Regulations for Private Sector 2017

Introduction

These Standards and Regulations are based on the 2013 Report by the *Fertility Centres Supervision and Control Committee* under the Chairmanship of H.E. Undersecretary for Health affairs. The Standards and Regulations which were determined apply to both the Private and Government Sectors.

1. Purpose

These Standards and regulations are intended to ensure a consistent, research based, and safe framework for the provision of Assisted reproduction Centres operating in Oman.

2. Scope

All fertility services and centres in Oman

3. Definitions/Abbreviations

A Fertility or Assisted Reproduction Centre (ART)

This refers to the specialized physical facility and all of its personnel and equipment, where all fertility treatments in which both eggs and sperm are handled. In general, ART procedures involve surgically removing eggs from a woman's ovaries, combining them with sperm in the laboratory, and returning them to the woman's body.

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| 3.1. Fertility | The ability to produce offspring; power of reproduction. |
| 3.2. 'In vitro embryo' | An embryo that exists outside the body of a human being. |
| 3.3. 'License' | A license issued in respect of a controlled activity or premises. |
| 3.4. 'Minister' | The Minister of Health. |
| 3.5. 'Egg/ ovum' | A human ovum, whether mature or not. |
| 3.6. 'Sperm' | A human sperm, whether mature or not. |
| 3.7. 'A fertilized ova' | Is one that clearly displays two pronuclei and two polar bodies. |
| 3.8. MOH | Ministry of Health |
| 3.9. Committee | The Fertilization Centre's Oversight and Control Committee, by whatever local name it is known. |
| 3.10. Centre | The Fertilization Centre where assisted reproductive techniques are performed, including all clinical and biological procedures that are necessary to effect extracorporeal conception. |
| 3.11 DGPHE | The Directorate General of Private Health Establishments |
| 3.12 HFEA | The Human Fertilisation and Embryology Authority of the UK. |

General Rules and Regulations

1. The Licence holder and the person responsible for the operation of the Centre should have enough understanding of the scientific, medical, legal, social, ethical and other aspects of the centre's work to be able to supervise its activities properly to comply with all rules and regulations associated with ART.
2. All undertakings at the Centre should comply with the Sharia Law/Islamic rules and regulations as interpreted and implemented in the Sultanate of Oman.
3. The Centre shall obtain all relevant licences and permissions from the various governmental bodies necessary to conduct a healthcare related business in the Sultanate of Oman as well as fulfilling the requirements of these Standards as set out by the Ministry of Health.
4. If the Centre is within a healthcare establishment which provides other services a separate and specific license is required to provide ART services.
5. Prior to commencing its operations, the Centre shall undertake to develop all internal policies and procedures in relation to its services. A statement confirming the existence of these documents will be placed visibly on the notice board at the Centre. Copies of the policies and Procedures shall be provided to all the customers who request it, provided that it shall not include any data or information in violation of the Law and this Regulation and any other laws that regulate the operation of health facilities. The internal documentation cannot include any advertising material in connection with the Centre or any of its employees without an advertising license from the competent department at the Ministry of Health. The internal documentation shall not include any pictures or expressions that violate public decency and/or cultural constants.
6. It is prohibited to use donated sperm or eggs from a non-married couple.
7. All in vitro fertilization (IVF) programs and clinics should have an emergency plan to protect fresh and cryopreserved human tissue (embryos, oocytes, sperm) and to provide for continuation of patient care in the event of an emergency or natural disaster.
8. Pre-implantation genetic diagnosis shall be carried out for hereditary disease detection at the determined Centre upon the written consent of the spouses and by virtue of a reasoned report from the Centre where the Assisted Reproductive Techniques are performed, provided that the Centre shall take all the necessary measures to keep the fertilized ovum unharmed.
9. Detailed Medical Records must be maintained for each patient, showing full history, proposed plan of care, consent forms, and continuous updating of patient progress and outcomes.
10. The licence holder must provide DGHPHE with a detailed yearly report, which should include;

i-The number of patients who had IVF procedure including their diagnosis and number of previous IVF cycles

li-cancelation of cycles and reasons

lii- Pregnancy rate (Biochemical and clinical), singleton and multiple pregnancy rate

lv-Rate of ovarian hyper-stimulation syndrome and any other complications

This detailed report will be very important to monitor the IVF Centre, their performance and will be a guide for any needed advice to improve the quality of work

Licensing of the Centre

1. Prior to providing any activity involving ART a specific license must be obtained through the DGPHE. The licensing of the Centre is conditional upon fulfilling the technical conditions, specifications and the availability of medical personnel, equipment and devices as follows;

Site of the Centre

The Centre shall preferably be located on the ground floor. If it is located on an upper floor, the building should have an elevator that can accommodate a patient carrying stretcher or trolley

Contents of the Centre

The Centre shall contain at least the following:

1. A reception area;
2. Two (2) waiting rooms (one for men and one for women);
3. Two (2) toilets (one for men and one for women);
4. An examination room for each physician;

B- Treatment, operating and laboratory rooms:

1. At least two treatment rooms (with a maximum of two beds in each).
2. An operating room adjoined with a recovery room.
3. A laboratory containing:
 - a. A sample withdrawal room
 - b. A sperm treatment room/ Andrology Laboratory for sperm washing
 - c. A freezing room
 - d. An embryology laboratory
 - e. Fast hormone analysis room
 - f. A storeroom for surgery devices / solutions / laboratory equipment.

These rooms shall be well ventilated and temperature controlled.

The laboratory ventilation system should ensure that both humidity and temperature can be controlled to maximise embryo culture conditions. This includes ensuring adequate filtration to eliminate particles, Volatile Organic Compounds and Aldehydes using HEPA filters as well as activated charcoal and potassium permanganate as a minimum. The laboratory ventilation should provide positive air pressure in the embryology laboratory and allow for higher than average operating temperatures and humidity.

The operating room and the embryo laboratory room shall be situated close to each other and have audio or visual contact.

The embryology laboratory should have adequate space to ensure safe and comfortable working conditions and be of a design that is appropriate for the volume of procedures performed.

4. Storeroom.

5. Sterilization room.

6. Auxiliary rooms (clinical waste room / cleaner's room with two sinks/water closets / offices / break rooms for visitors and workers)

Medical Equipment and Devices that must be available in the Centre

See Table 1. These are in addition to the usual office equipment and other medical equipment necessary to run any healthcare service

Emergency Plan

All in vitro fertilization (IVF) programs and clinics should have a plan to protect fresh and cryopreserved human tissue (embryos, oocytes, sperm) and to provide for continuation of patient care in the event of an emergency or natural disaster.

The actions to be taken by an IVF program during an emergency or natural disaster should include providing for:

1. The safety and protection of program personnel and patients
2. The safety and preservation of fresh and cryopreserved human tissue
3. The protection and security of important IVF program materials, such as patient records, laboratory records, financial and operational documents, facility equipment, etc.

An IVF program should review and practice on a routine basis its Emergency Plan to ensure that personnel are capable of carrying out their assigned tasks during an emergency event.

Levels of Fertility clinics in the Sultanate of Oman

Fertility clinics will be divided into 4 levels dependent upon the type of fertility services provided.

Centres will be issued with a License certificate by DGPHE, showing the Level of service which the centre is authorised to provide.

A Centre cannot move from one level to the upper level without revisit and recertification from DGPHE

Level one: Treatment with fertility medications including oral and gonadotropins only

- The doctor should be appropriately qualified and licenced in Obstetrics and Gynaecology at Consultant level with experience in fertility treatment of not less than 2 years.
- Experience in the use of Ultrasound (vaginal and /or abdominal). if this experience is not available, the clinic should recruit an experienced sonographer who has enough experience in Gynaecological services of not less than 2 years.
- Any doctors assisting in the Centre should have at least a diploma in Obstetrics and Gynaecology

Level Two: Treatment with fertility medications including intra uterine insemination

- As above

Plus

- Technicians (bachelor degree or equivalent) in medical laboratories, with experience of not less than 3 years in fertility laboratory (This part can be excluded if the clinic has enough experienced staff in preparation of seminal fluid to be used in IUI accepted by the DGPHE)

Level Three: Assisted Reproductive Technology Centre (In vitro fertilization and Intra cytoplasmic sperm injection)

The full staffing as outlined in the Staffing Section above should be available

Level Four: Pre-implantation Genetic Diagnosis (PGD) and Pre-implantation Genetic Screening (PGS) Laboratory

Centres wishing to operate at this level must adhere to the following requirements and advice;

Indications for PGD

The following are the common conditions for which PGD is generally recommended internationally:

A. Familial single gene disorders including:

- Cystic fibrosis
- Thalassaemia major

- Sickle cell disease
 - Spinal muscular atrophy
 - Huntington's disease
- B. Familial sex-linked disorders including:**
- Fragile-X syndrome
 - Haemophilia
 - Duchenne's muscular dystrophy
- C. Familial chromosomal disorders including:**
- Reciprocal translocations
 - Robertsonian translocations
- D. Non-familial chromosomal disorders including:**
- Down syndrome
 - Turner's syndrome
- E. Couples with history of recurrent pregnancy loss due to genetic disorders.**
- F. Couples with a child who has a genetic disease and are at high risk for having another similarly affected child.**

A PGD CENTER

The PGD center licensed by the MoH should meet the following criteria:

- The centre must abide by the regulations set out by the Human Fertilization and Embryology Authority (HFEA) or equivalent, which includes the provision of PGD, including adherence to the HFEA regulations for PGD testing.
- The laboratory where the test is being carried out must have Clinical Pathology Accreditation (CPA) or equivalent.
- The staff should be specifically licensed to undertake these procedures.
- The Centre experience/success rate should be evaluated and should meet those reported internationally (30-50% success rate). This data should be supplied to DGPHE annually, or more often if required, in the Annual report referred to above.

PATIENT SELECTION CRITERIA

Mandatory Criteria for the Couple:

- The couple should be at risk of having a child with a serious genetic condition.
- The couple should have been recommended for PGD by a qualified Geneticist, specialized Obstetric and Gynaecologist Consultant, Metabolic Consultant or Clinical Haematologist.
- The risk of conceiving a pregnancy affected by a serious genetic condition should be 10% or more.
- The couple should have received genetic counselling from a clinical geneticist or a registered genetic counsellor.
- The female partner should be under 40 years of age at the time of treatment.
- The female partner should have a BMI of more than 19 and less than 30.
- There should be no living unaffected child from the current relationship.
- The disorder, for which PGD is considered, has been identified in the family and there is evidence that the future individual may be seriously impaired as a result of the disorder.

Exclusion criteria:

- Non-medical gender selection e.g. for the purpose of family balancing. This is illegal in Oman.
- Human Leucocyte Antigen (HLA) typing to produce a donor sibling for a child requiring an allogeneic stem cell transplant.
- Using PGD to address infertility or to prevent miscarriages of unknown aetiology.
- Pre-implantation Genetic Screening (PGS). Here, genetic testing is used to screen embryos for various abnormalities in chromosomes typically the number of chromosomes (chromosomal aneuploidies).
- Couples with 2 or more normal offspring or asymptomatic carrier.

INFORMATION AND COUNSELING

- Providers must ensure that those seeking PGD are given all of the information relevant for informed decision-making, and this must include reference to the following:
 - The processes and procedures associated with IVF and PGD.
 - The risks associated with the procedures.
 - The success rate of the procedure, both in general, and at this specific Centre
 - The alternatives to PGD.
- Providers must ensure that those seeking PGD are given all of the following information prior to giving consent:
 - Genetic and clinical information about the specific disorder/infertility.
 - The likely impact of the disorder/infertility on those affected and their families.
 - Information about treatment, counselling, and the extent of community and social support available.

REFERENCES

- Ref Clinical Commissioning Policy: Pre-implantation Genetic Diagnosis (PGD), April 2013.
- Guidelines on Pre implantation Genetic Diagnosis. Prepared by the National Ethics Committee on Assisted Human Reproduction, March 2005
- Robertson, JA: Extending pre implantation genetic diagnosis: medical and non-medical uses. *J Med Ethics* 29, 213-6 (2003).
- Verpoest W, Haentjens P, De Rycke M, Staessen C, Sermon K, Bonduelle M et al. Cumulative Reproductive Outcome after pre implantation genetic diagnosis: a report on 1498 couples. *Hum. Reprod*,2009;24(11):2951-2959.
- Karnon J, Zeuner D et al. Lifetime treatment costs of beta-thalassaemia major. *Clin Lab Haematol*. 1999 Dec;21(6):377-85.
- Teresa L. Kauf, Thomas D. Coates. et al. The cost of health care for children and adults with sickle cell disease. *American Journal of Hematology*, Volume 84, Issue 6, 2009.

STAFFING OF THE CENTRE

Every person applying for a license to operate a fertilization centre in Oman shall ensure the availability of medical, technical and administrative staff licensed to work in the centre. The license shall be subject to the availability of suitably qualified and experienced staff as set out below:

a- **Medical Director of the Centre:**

1. He/she shall be a Consultant Gynaecologist and Obstetrician;
2. He/she shall have the highest professional degree in the field of Gynaecology and Obstetrics with reproductive endocrinology and infertility certification from an accredited training program recognized by MOH;
3. He shall have at least (5) years of experience in the same field after obtaining the highest professional degree (entry qualification different from exit qualification, of which at least (2) years of experience at fertilization centres accredited by the Ministry with a certificate of fellowship from a recognized medical society (Royal college OBGYN UK, FRCS Canada etc.);
4. He shall pass the personal interviews and technical evaluation by fertilization specialists licensing committee in MOH or employed in his/her specialty by MOH or other recognized government health institutions.

b- A **Specialist Gynaecologist - Obstetrician**, working under the supervision of the Medical Director of the Centre, provided that:

1. He/she shall have a minimum qualification of Clinical Master's Degree or its equivalent in gynaecology and obstetrics.
2. He/she shall have (3) years of experience after obtaining the Clinical Master's Degree, at fertilization centres accredited by the Ministry.
3. He shall pass the personal interviews and technical evaluation by fertilization specialists licensing committee in MOH.

c- An **Andrology and Infertility Specialist Surgeon** (optional), provided that:

1. He shall have a minimum qualification of Clinical Master's Degree or its equivalent in one of the following medical specializations: andrology medicine and surgery or urology surgery.
2. He shall have clinical and surgical experience of at least (3) years in one of the areas mentioned in paragraph (1) above after obtaining the Clinical Master's Degree.
3. He shall pass the personal interviews and technical evaluation by male infertility specialists.

In the event that this specialization is not available at the Centre, collaboration with a centre or a hospital where this specialization is available shall take place.

d- **A Specialist in Anaesthesia**, provided that:

1. He shall have a Master's Degree or its equivalent in the field of anaesthesia and should be an M.D.
2. He shall have at least (3) years of experience after obtaining the Master's Degree.
3. He shall pass the personal interviews and technical evaluation by anaesthesia specialists.

e- **A Genetics Specialist** (optional) more details of qualifications. Clinical genetics for counselling, molecular geneticist for PGD tests.

f- **A Laboratory Director**, who shall have one of the following degrees or their equivalent in medical science, biology or embryology:

1. A Doctorate or its equivalent in addition to at least (4) years of hands on experience, after obtaining the Doctorate, at fertilization centres accredited by the Ministry;
2. A Clinical Master's Degree or its equivalent in addition to at least (6) years of hands on experience, after obtaining the Clinical Master's Degree, at fertilization centres accredited by the Ministry;
3. He shall pass the personal interviews and technical evaluation by fertilization specialists.

g- An **Embryology Technician** working under the supervision of the laboratory director, provided that:

1. He/she shall have a Bachelor's Degree in Biology or Medical Science.
2. He/she shall have at least (1) year of experience, after obtaining the Bachelor's Degree, at fertilization centres accredited by the Ministry.
3. He shall pass the personal interviews and technical evaluation by fertilization specialists.

h- An **Anaesthesia Technician / Nurse**, provided that:

1. He shall have a Diploma in Anaesthesia with at least (3) years of studies.
2. He shall have at least (5) years of experience after obtaining the Diploma in Anaesthesia.
3. He shall pass the personal interviews before obtaining a license.

- i- **A Radiologist** (optional). Mandatory if hysterosalpingogram is to be done in the centre.
- j- At least (4) **Registered Nurses**, including an operating room nurse.
- k- **Administrative staff** consisting of:
 1. An Administrative and Financial Director.
 2. A Social Worker (optional)
 3. A Receptionist
 4. A Medical Records Clerk (optional)
 5. A building Security Guard
 6. Cleaner

The centre shall employ a sufficient number of qualified laboratory personnel to provide embryology services as needed in a timely manner with a mechanism in place to provide backup for the laboratory personnel. Staffing level should be appropriate for the size and volume of the IVF program. At a minimum, there should be two qualified embryologists.

The following table provides the minimum staff sizes for the volume of cycles (retrievals and cryopreservation cycles).

Laboratory cycles and embryologists

Number of laboratory cycles Minimum number of embryologists

1–150	2
151–300	3
301–600	4
>600	1 additional embryologist per additional 200 cycles

m. Counsellor. The Centre should make an effort to employ a counsellor, to assist patients in considering the following points prior to embarking on ART

- A couple shall not be provided with any ART services unless they are given a suitable Opportunity to receive proper counselling about the implications of being provided with these treatments
- A woman shall not be provided with any nonmedical fertility services involving the use of sperm other than her husband sperm

- The treatment services involve the use of the gametes of any person and that person's consent is required for the use in question.
- The counselling should include the full implications of the proposed treatment and relevant information including the importance of the presence of Hepatitis and HIV infections in either partner, scenarios in case of ovarian hyper stimulation syndrome, feasibility of cancelling the IVF cycle or embryos freezing.
- They should also be emotionally and psychologically prepared for all possible outcomes

Strategy to minimize multiple births

1 -The person responsible should ensure that the Centre's annual multiple birth rate does not exceed the figure specified by Directions.

2 -When implementing the centre's strategy to minimize multiple births, the person responsible should consider:

- a) The higher rate of multiple births from blastocyst transfers, and
- b) The finding that the live birth rate does not increase with the transfer of three embryos but the risk of an adverse perinatal outcome does increase.

3- Where appropriate, the centre should have documented standard operating procedures for embryo transfer. Reduce the annual rate of multiple births resulting from treatments at the centre.

The strategy must set out:

1) How the centre aims to reduce the annual multiple birth rate (more than two) following treatment at that centre, and to ensure the rate does not exceed the maximum rate specified by the Authority as set out in Directions

2) The circumstances in which the person responsible would consider it appropriate to recommend single embryo transfer (SET) to a patient (in setting out such circumstances, the centre should give proper consideration to relevant professional guidance), and

3) Evidence that the risks of a multiple pregnancy were fully discussed with the patient before the procedure including the:

- a) The higher risk of miscarriage and complications during pregnancy
- b) The higher rate of premature birth and the problems arising from low birth weight, the higher rate of still birth, and the higher rate of perinatal mortality
- c) The higher rate of disability and other health problems, plus the potential need for extended stays in hospital before and after birth, and
- d) The possible practical, financial and emotional impact on the family and any children.

4) The centre should give the woman the opportunity to discuss the number of embryos to be transferred just before embryo transfer.

5) If a woman is to undergo embryo transfer, the centre should:

- a) Obtain her consent to the proposed number of embryos to be transferred and the reasons for this (including her acceptance of the risk of multiple births), and
- b) Record her consent in her medical records.

Below is the recommended guideline on the numbers of embryos to transfer –adopted from ASRM guideline 2013

TABLE 1

Recommended limits on the numbers of embryos to transfer.

Prognosis	Age (y)			
	< 35	35–37	38–40	41–42
Cleavage-stage embryos ^a				
Favorable ^b	1–2	2	3	5
All others	2	3	4	5
Blastocysts ^a				
Favorable ^b	1	2	2	3
All others	2	2	3	3

^a See text for more complete explanations. Justification for transferring one additional embryo more than the recommended limit should be clearly documented in the patient's medical record.
^b Favorable = first cycle of IVF, good embryo quality, excess embryos available for cryopreservation, or previous successful IVF cycle.

Practice Committee. Pharmacogenetic approach to male infertility. *Fertil Steril* 2013.

Important notes

1- Worldwide the pregnancy rates from elective single embryo transfer are similar to the pregnancy rates from double embryo transfer.

2- It is advised now, a maximum of two embryos can be transferred to women under the age of 35, and a maximum of three embryos can be transferred in women aged 40 and over.

3- Our aim as a whole is to reduce the multiple pregnancy rates in 3 years in any centre from average of less than (24%) in year one, to (20%) in year two and hopping by year three to have the rate below 10-15%. This will help us in future to consider single embryo transfers (level of blastocyst) in certain group of patients, Hopping by this the quality of IVF centres and management will improves.

PERSCRIBING MEDICATIONS

The prescribing of ovulation induction medication will be restricted to Senior Consultant, Consultant, Senior Specialist or Specialist Gynaecologist – Obstetricians who have a license from MOH to practice in a fertility centre or are employed in their specialty of Reproductive Endocrinology and Infertility by MOH or other recognized government health institutions.

The list of medications may include but not limited to the following while noting that some of these may be used by specialties other than gynaecology and may have different commercial names:

1. Clomiphene Citrate
2. Tamoxifen (is also used by oncologists)
3. Letrozole (is also used by oncologists)
4. Urinary or Recombinant Follicle Stimulating Hormone: Follitropin alpha, beta and corifollitropin.
5. Gonadotropin-releasing hormone (GnRH) antagonist
6. Human Menopausal Gonadotropin
7. Human Chorionic Gonadotropin (hCG): Urinary or recombinant.
8. Lutinizng Hormone: Urinary or recombinant.

MEDICAL ETHICS

The medical and technical staff working at the Centre shall be trustworthy according to the following standards and any other standards established by the Committee:

1. They shall not have been convicted and sentenced so as to restrict their freedom due to a crime of misconduct or breach of trust, unless they have been rehabilitated.
2. They shall not have been dismissed from their positions through a court judgment or dismissed from service through a disciplinary judgment.
3. They shall not have been convicted for violating the controls and conditions of Assisted Reproductive Techniques.
4. They shall not have been subject to a court judgment or a disciplinary punishment for violating the established professional standards and principles or as a result of medical negligence.
5. They shall be known among physicians for their integrity, honesty and honour.
6. They should apply the law of health practices of Oman.

HEALTH INFORMATION AND CONSENT

The Centre shall notify the husband and wife of the following information and obtain a written acknowledgment of such notification:

- i. A detailed explanation of the different Assisted Reproductive Techniques and their potential negative effects and complications in addition to the total financial cost and the conception success rate expected for similar cases in the same Centre.
- ii. An explanation of the aspects related to the information and determined under the Law.
- iii. The feasibility of preserving unfertilized ova and sperm and the preservation procedures and conditions.
- iv. How to dispose of surplus fertilized ova.
- v. The prohibited practices at the Centre such as using the fertilized and unfertilized ova or sperm for commercial purposes, introducing genetic modifications to the features of foetuses, taking the unfertilized or fertilized ova and sperm specimens that have been prepared inside the Country abroad and bringing such specimens into the Country if they have been prepared abroad or dealing with embryo banks without permission of the supervising and control committee.

For the purpose of research certain centres should apply for permission from MOH as well as obtaining consent from their clients.

- vi. The husband and wife are prohibited from authorizing the Centre to donate their embryos, ova or sperms to other spouses.
- vii. The maximum number of embryo transfer limits authorized according to the supervising and control committee of the Centre.

All the information acquired from the customers of the Centre shall be confidential and may not be disclosed to other than the husband and wife concerned, and to the competent judicial authority as may be required.

The Centre shall acquire appropriate consent and inquire about the husband and wife's medical history, the diseases and illnesses they may have and the cases of hereditary diseases in the family, with a

view to evaluating the applicability of Assisted Reproductive Techniques treatment in their case, based on the medical conditions and genetic factors. The husband and wife shall then sign their consent.

The husband and wife's written consent shall be obtained in the following cases according to the forms attached hereto:

- i. Performing of Assisted Reproductive Techniques, as per attached form (1).
- ii. Embryo transfer into the uterus or the fallopian tube, as per attached form (2).
- iii. Sperm injection into the uterus, as per attached form (3).

Compliance with all requirements will be recorded within each individual patient medical record.

STORING OF UNFERTILIZED OVA, SPERM & EMBRYOS

For the purpose of storing unfertilized ova, sperm and embryos, according to the approved controls and forms, the following requirements shall be fulfilled:

1. A table of the steps to be followed in storage.
2. A schedule to verify the place and time of storage and a special program determining the procedures followed to determine the donor of the unfertilized ova, sperm or embryo and the steps to be followed in case a specimen cannot be found.
3. A program verifying the success of storage process and the success rates of these procedures, including the approved laboratory forms and the number of years required to keep the unfertilized ova, sperm and embryos in storage.
4. The approach to be adopted by the supervising and control committee in case of demise of one of the spouses or the occurrence of a legal separation.
5. Separating the unfertilized ova, sperm and embryos extracted from a couple or an individual who is infected with a contagious disease from the rest of the unfertilized ova, sperm and embryos in storage.
6. Obtaining the husband's consent (if married) to preserve the unfertilized ova by freezing, as per attached form (4).
7. Obtaining the husband's consent to preserve the sperm by freezing, as per attached form (5).
8. Obtaining the couple's consent to preserve the frozen embryos, as per attached form (6).

LABORATORY MANAGEMENT

The laboratories in the Centre shall carry out their duties in accordance with the Assisted Reproductive Techniques applicable protocols. They shall undertake to regulate the process of maintaining the sperms, unfertilized and fertilized ova and embryos, and exercise the highest degrees of care and precaution so that these may not be used, exploited or replaced hence leading to a mix-up in the lineage.

The Laboratory must have written Standard Operating Protocols (SOP) for all techniques and processes carried out in the laboratory. Furthermore the laboratory must have an established system using a minimum of two identifiers for each patient to ensure traceability of gametes and embryos during the IVF cycle. All sample containers must be identified using these two identifiers as a minimum. The clinic must also have a written SOP to describe all steps taken to ensure the correct identification of patients and their gametes and embryos throughout all processes of treatment.

Including:

1. The use of a form for recording the ova maturity level and evaluating the quality of the embryo and how the unfertilized or fertilized ova are handled.
2. To use a form for determining the quality and quantity of sperm intended to be used to complete the fertilization process.
3. To record in the medical file of each client at the Centre complete information regarding the treatment cycle, namely:
 - a. The number of ova extracted from the ovary.
 - b. The characteristics of the sperm.
 - c. The fate of all the extracted ova.
 - d. The number of fertilized ova.
 - e. The characteristics of each embryo.
 - f. The number and characteristics of embryo cells.
 - g. The fate of each embryo.
4. To have the name and signature of the laboratory technician, director and attending physician recorded in the file of every patient undergoing treatment.

5. To have the source of the culture medium and that of the protein solution required for the fertilization process recorded and signed by the laboratory technician and director.
6. There shall be coordination between the technical staff and the attending medical staff to determine the fate of the transferred embryos and appropriately record these results in the relevant records.
7. The laboratory supervisors shall, upon receiving a sperm sample, record the following information and attach same to the sample:
 - a. The time of receiving the sample.
 - b. The method of obtaining the sample.
 - c. The type of sample container.
 - d. The time of last intercourse.
 - e. Any problems encountered in providing the sample.
 - f. Severe temperature changes.
 - g. Whether the container does not hold the entire sample.
 - h. Any problems in sample liquidity.
8. To ensure awareness of the characteristics and properties of the gas used in the incubators and to verify that the incubators fulfil the required medical specifications.
9. To verify the gas concentration percentages and the temperature of the internal environment of the incubators and record these percentages every day.
10. To ensure awareness of the procedures to be taken in case a certain gas concentration degree cannot be attained in the incubators.
11. To provide a backup generator to be used in case of sudden electrical shutdown.
12. To install an alarm system in the incubators in case of a sudden failure and to explain how to respond to these alarms.

They shall especially observe the following:

1. The laboratory must use universal precautions and sterile techniques to eliminate the risk of introducing biological contaminants into the culture system.
2. The laboratory must keep a record of every batch of culture media used along with copies of all certificates of conformity if purchased media. If media is made in-house: quality control documentation including Mouse embryo assay results must be available for every batch.
3. A laboratory record must be completed and included in the medical file for every case. The laboratory record must include complete semen analysis details, the number of ova retrieved, the number of fertilised ova, the fate of unfertilised ova, a quality indication for each embryo including cell number and grade, and the fate of each embryo. The embryologist who carried out each step of the process must be indicated and he/she must sign off on the technique. The batch number of culture media needs to be recorded for each case. The laboratory director and treating physician must also sign the record to indicate that the record is complete and correct.
4. There must be a registry for all aspects related to quality control in the laboratory which should be completed on a daily basis.
5. In case there are surplus embryos, the Centre shall give the options to the couple of freezing excess embryos or leaving the embryos without medical care until they perish naturally. Consent needs to be taken for either option.

The Centre shall guarantee the quality especially in relation to the control systems inside the laboratory, by following international quality standards, at least the following:

- a. The laboratory contact materials touching the embryos and the gametes, whether disposable or reusable, shall be of good quality.
- b. The culture media shall undergo the required calibration measures, whether in relation to the cells or the tissues of the contact materials, to ensure that they are free from bacteria and toxic pollutants, any imbalance in the acidity level and any other risks that might harm the gametes and human embryos.
- c. The Centre shall design the quality control and verification programs as it deems appropriate and as per the internationally applicable principles in embryology, fertility and Assisted Reproductive Techniques.
- d. The Centre shall provide all the necessary information related to each culture medium.
- e. Every piece of equipment, such as the Laminar flow Hood, shall be provided with a cultivation system.
- f. The devices, such as scales and thermometers, shall be calibrated.

- g. The quality control procedures shall be carried out regularly by conducting daily tests to check the degree of temperature in the coolers, freezers, and incubators and the degree of humidity in the incubators. There shall be an external verification of the control of gas atmosphere inside the incubators, the liquid nitrogen level in the gamete storage vessels and the condition of the gas and liquid nitrogen feeds.
- h. There shall be a program to provide regular preventive maintenance to ensure complete cleanliness and prevent pollution in the incubators and flow hoods.
- i. Every batch of culture media must have a certificate of conformity that must be registered in the laboratory. Furthermore every case must have the batch of media used recorded in the patient file.
- j. All equipment must be regularly calibrated both internally and on an annual basis by an external third party.
- k. There needs to be a written policy of maintenance and cleaning along with a register to prove that the maintenance and cleaning is up to date.

Medical and Other Records

The Centre shall keep all required records in relation to the Assisted Reproductive Techniques procedures as follows:

a- Medical Record

ID card, and containing the following data:

1. Name and logo of the Centre.
2. Names and photos of husband and wife.
3. Nationality of each of the spouses and passport number.
4. Medical file number.
5. Visit dates.
6. Name of attending physician.
7. Address and telephone numbers.

b- Reception record, containing the following information on each of the spouses:

1. Date of first registration.
2. Name.
3. Nationality.
4. Date of birth.
5. Address, place of residence and telephone numbers.
6. Number of passport, ID card.
7. Indication of receipt of a copy of the passport or the ID card, a copy of an authenticated marriage contract and a recent personal photo for each of the spouses, to be attached to the medical file.

c- The laboratory record:

It shall include all the data mentioned in the reception record in addition to the following data:

1. The place, date and time of samples collection from the Centre's customer.
2. The code and number of the samples.
3. The name and signature of the samples recipient.
4. The sperm characteristics.
5. The result of the sample tests.
6. The number of ova extracted from the ovary.
7. The fate of all the extracted ova.
8. The number of fertilized ova.
9. The source of the culture medium and the source of the protein solution.

10. The characteristics of each embryo and cell number and quality.
11. Information on the use of the incubators.
12. The fate of each embryo (transfer or disposal).

Provided that the aforementioned information shall be signed by the respective information recorder and approved by the Laboratory Director. The name of the embryologist at each step of the process must be recorded (i.e. semen washing, egg retrieval, fertilisation or ICSI, fertilisation check, etc....)

d- The Centre Technical Director's record:

It shall include all the data mentioned in the laboratory record.

e- The medical file:

It shall include all the data mentioned in the reception record in addition to the following data:

The health condition of the spouses, the medical history and hereditary diseases, if any, the clinical tests and medical exams, the technique intended to be used and its results. The details related to the following information shall be mentioned in the medical file:

1. The sperm characteristics.
2. The number of ova extracted from the ovary.
3. The fate of all extracted ova.
4. The number of fertilized ova.
5. The characteristics of each embryo and cell number and quality.
6. The fate of every embryo (transfer or disposal).
7. The notes of the attending physician following every visit.

The name of the laboratory technician and the attending physician shall be mentioned in the medical file, and all the documents and consent forms under this regulation shall be enclosed.

f- The storeroom record:

It shall include the Centre's inventory data, such as the equipment, machines, devices, solutions and medications as well as the production and expiration dates and the data of the furniture storeroom.

g- The Centre's staff record:

It shall include the names of the employees at the Centre and a file for each one of them including their data, responsibilities, reporting relationship with their superiors and all other employment affairs including the annual performance evaluation of each employee.

INSPECTION STANDARDS & MONITORING

The following indicators are regarded as standards for evaluating the Centre's performance:

1. The extent to which the medical, technical and administrative staff are available.
2. The quality level of sterilization and disinfection.
3. The extent to which the measures for the storage of the unfertilized ova and sperms are safe.
4. The method of handling and disposing of surplus fertilized ova or the fertilized ova which are unfit for implantation.
5. The success rate of the Assisted Reproductive Techniques procedures in comparison with the number of cases handled by the Centre.
6. Customer satisfaction with the Centre by conducting surveys as per the form developed by the Committee.
7. The offence rate within the Centre during the year.
8. The extent to which the Centre is committed to keeping and organizing the records stipulated under the law.
9. The level of maintaining files and documents.
10. The extent to which the Centre is committed to developing its employees' skills and competences through continuing medical education and professional development.
11. The extent to which the required medical equipment, devices and other requirements and the regular maintenance are available.
12. The extent to which the Centre is committed to developing the internal by-law.
13. The extent to which the Centre is committed to implementing the internal by-law.
14. The extent to which the Centre is committed to submitting the periodic reports.
15. The extent to which the Centre is committed to implementing the instructions and guidelines issued by the Ministry. The Committee may approve other indicators for the evaluation of the Centre's performance.

CANCELLATION OF LICENSE

The Minister may cancel the license of the Centre in the following cases:

1. Passing of a criminal judgment of conviction against the Centre in an occurrence related to its practice of Assisted Reproductive Techniques activity.
2. Recommendation of cancellation by the Committee in case a disciplinary punishment is imposed on the Centre by the competent Health Body.
3. If it is established that the Centre did not achieve success in its Assisted Reproductive Techniques procedures within a year, as per the standards of the Committee.
4. Repeated offences by the Centre against the controls and standards stipulated under the Law and this Regulation, according to the gravity of the offence.

SUSPENSION OF LICENSE

- The Minister may order the provisional suspension of the Centre's operation until the responsibility for any offence against the Law and this Regulation is determined.
- The Minister may also order the provisional suspension for a maximum period of (60) day for the following reasons:
 - If the license expires and is not renewed.
 - If the Centre violates any of the controls and standards stipulated under the Law and these standards and regulation.
 - If the Centre violates any of the prohibitions under these requirements.
 - If the Centre commits any of the offences listed in the private health facilities law and any other requirements or standards of DGPHE.
- In case of the provisional suspension of the Centre, the clients whose Assisted Reproductive Techniques procedures have not been completed shall be referred to any other Centre, provided that the referring Centre shall meet all the costs incurred due to referral.
- The Minister may cancel or suspend the Centre's operation upon the recommendation of the Violation Committee if the Committee has serious reasons to believe that the continuing operation of the Centre will pose threat to public health or the health of clients.

Spouses' Consent to Assisted Reproductive Techniques Procedure

We, (the married couple)

Mr. Nationality:

ID/Passport No. and

Mrs. Nationality:

ID/Passport No.

Residing at the following address:

Declare that we have applied to Centre, through the medical and technical staff, to have the procedure of Assisted Reproductive Techniques (internal – external) performed, and that we have been informed and understand that the method used may include the following:

- a. Preparing the wife by giving her hormone medication as prescribed by specialists.
- b. Extracting ova from the ovaries through the vagina.
- c. Fertilizing the ova with the husband's sperm.
- d. Maintaining the embryos resulting from the fertilization process for the period determined by the medical and technical staff with a view to preparing the embryos for implantation into the uterus or the Fallopian tubes.
- e. Selecting the most suitable embryos by the medical and technical staff.
- f. Transferring the selected embryos into the wife.

We agree to these procedures and to the wife's treatment with medication and anaesthesia whenever necessary.

We also agree to any other measures within the procedure that the medical staff deem necessary during treatment.

We understand and accept that there is no assurance of a pregnancy resulting from these procedures because the success rate is relative even if the ova have been treated and transferred

into the uterus. Furthermore, we understand and accept that the medical staff cannot guarantee that the pregnancy will result in the birth of a living and normal baby.

We agree that the decisions regarding the suitability of the embryos to be transferred into the uterus shall be based on the opinion of the Centre's medical staff.

We do not approve to the transfer of the embryos to any woman other than the wife.

We understand the following:

- That as in natural pregnancy, foetal deformity is possible.
- That as in natural pregnancy, abortion is possible.
- That there is no guarantee that the ova shall develop during the determined induction cycle and that the extraction process may be cancelled in case of no response.
- That there is a slight possibility for excessive ovarian stimulation and the risks of exposure as the medical and technical staff has explained to us.
- That the ova are not always in good condition upon extraction.

Signature of the husband Date.....

Signature of the wife Date.....

Form (2)

Spouses' Consent to the Transfer of Embryos into the Uterus or the Fallopian Tube

We, (the married couple)

Mr. Nationality:

....

ID/Passport No. and

Mrs. Nationality:

....

ID/Passport No.

Residing at the following address:

..

Declare that we have applied to Centre, through the medical and technical staff, to have the procedure of Assisted Reproductive Techniques (internal –external) performed, and that we have been notified and understand that the method used may include the following:

- a. Preparing the wife by giving her hormone medication as prescribed by the specialists.
- b. Extracting ova from the ovaries through the vagina.
- c. Fertilizing the ova by the husband's sperm.
- d. Maintaining the embryos resulting from the fertilization process for the period determined by the medical and technical staff with a view to preparing the embryos for implantation into the wife's uterus or the Fallopian tubes.
- e. Selecting the most suitable embryos by the medical and technical staff.
- f. Transferring the selected embryos into the wife.

We agree to these procedures and to the wife's treatment with medication and anaesthesia whenever necessary during the treatment.

We understand and accept that there is no assurance that a pregnancy will result from these procedures because the success rate is relative even if the ova have been treated and transferred

into the uterus. Furthermore, we understand and accept that the medical staff cannot guarantee that the pregnancy will result in the birth of a living and normal baby.

We agree to the transfer of the embryos to the Fallopian tubes via endoscopy and under general anaesthesia. We have been informed of the complications resulting from endoscopy, such as bleeding, intestinal perforation and other.

We approve that the medical staff at the Centre carry out the necessary procedures in case of occurrence of any complications .We understand that the pregnancy may result in twins or triplets (depending on the number of transferred ova and embryos).

We also understand that multiple-birth pregnancies may lead to complications that might develop during the pregnancy at a higher percentage than in single pregnancies.

We understand that as in natural pregnancy, risks and complications of ectopic pregnancy are a possibility. We accept the decisions issued by the Centre's medical and technical staff regarding the suitability of the embryos to be transferred into the uterus or the Fallopian tube.

Signature of the husband Date.....

Signature of the wife Date.....

Form (3)

Spouses' Consent to the Transfer of Sperm into the Uterus

We, (the married couple)

Mr. Nationality:

....

ID/Passport No. and

Mrs. Nationality:

....

ID/Passport No.

Residing at the following address:

..

Declare that we have applied to Centre, for assisted reproduction through the Centre's medical and technical staff, and to assist me, I the abovementioned wife to become pregnant by my above mentioned husband.

The Centre has informed us of the things set out hereunder of which we approve:

- That there is no guarantee whatsoever of a pregnancy resulting from these procedures and that there is no guarantee that the pregnancy will result in the birth of a living and normal baby.
- That as in natural pregnancy, foetal deformity is possible.
- That as in natural pregnancy, miscarriage is slightly possible.
- That there is a slight possibility for excessive stimulation and that the effects of such occurrence have been explained to us.

- That there is no guarantee that the ova shall develop during the induction cycle and that the induction process may sometimes be cancelled.
- That in case we failed to follow-up with the centre, we will be totally responsible; and that we have been given sufficient time to understand the contents of this form and discuss same with the medical and technical staff.

Signature of the husband Date.....

Signature of the wife Date.....

Form (4)

Couple's Consent to the Preservation of Unfertilized Ova by Freezing

We, (the married couple)

Mr. Nationality:

....

ID/Passport No. and

Mrs. Nationality:

....

ID/Passport No.

Residing at the following address:

..

Approve to the preservation and storage of our unfertilized ova at Centre, at the discretion of the Centre's medical and technical staff, and such for a period of five years, where the approval shall be subject to renewal every year.

We are aware that it is not permitted to transfer or transport any of the unfertilized ova preserved under the custody of the medical and scientific staff without the written consent of the husband, the wife, and the medical staff. Such consent shall be given within 28 days prior to the transfer or transportation.

We are also aware that the transportation of unfertilized ova outside the Country is prohibited.

We agree that, upon the expiration of the storage period agreed upon, the Centre or medical staff may dispose of the unfertilized ova through approved methods.

Signature of the husband Date.....

Signature of the wife Date.....

Form (5)

Consent to the Preservation of Sperm by Freezing

I, Mr. Nationality:
.....

ID/Passport No.

Residing at the following address: Declare
that:

I have read the information regarding sperm freezing that has been provided to me, and that I request that the medical staff at the Assisted Fertilization and Conception Unit at Centre preserve my sperm by freezing for five years.

I am aware that the staff of the Assisted Fertilization and Conception Unit are not responsible for any diminished or damaged quality of the sperm after melting.

I request that the Centre dispose of all my preserved sperm after my death.

I am aware that I am responsible for notifying the Centre each year of my desire to continue to freeze my sperm, and that in case I do not notify the Centre thereof, the Centre shall write to the Ministry to obtain its consent to the disposal of the frozen sperm if the Centre cannot contact me, and I hereby exempt the Centre and the Ministry from any responsibility in this regard.

Signature of the sperm provider. Date.

Form (6)

Consent to the Preservation of Embryos by Freezing

I, Mr. Nationality:
.....

ID/Passport No.

Residing at the following address: Declare
that:

I have read the information regarding embryo freezing that has been provided to me, and that I request that the medical staff at the Assisted Fertilization and Conception Unit at Centre preserve my embryos by freezing for five years.

I am aware that the staff of the Assisted Fertilization and Conception Unit is not responsible for any diminished or damaged quality of the embryos after thawing.

I request that the Centre dispose of all my preserved embryos after my death.

I am aware that I am responsible for notifying the Centre each year of my desire to continue to freeze my embryos, and that in case I do not notify the Centre thereof, the Centre shall write to the Ministry to obtain its consent to the disposal of the frozen embryos if the Centre cannot contact me, and I hereby exempt the Centre and the Ministry from any responsibility in this regard.

Signature of the husband Date.....

Signature of the wife Date.....

Form (7)

Consent to the Pre-implantation Genetic Diagnosis (PGD)

I, Mr. Nationality:
.....

ID/Passport No.

Residing at the following address: Declare
that:

I have read the information regarding Pre-implantation Genetic Diagnosis that has been provided to me, and that I agree that the medical staff at the Assisted Fertilization and Conception Unit at Centre perform the necessary procedures for Pre-implantation Genetic Diagnosis.

I am aware that the staff of the Assisted Fertilization and Conception Unit is not responsible for any diminished or damaged quality of the embryos after PGD.

Signature of the husband Date.....

Signature of the wife Date.....

Supporting Documentation/ References:

1. Federal Law No. (11) of 2008, Licensing of Fertilization Centres in the State of UAE
2. Cabinet Decision No. (36) of 2009, Issuing the implementation Regulation of Federal Law (11) of 2008, Licensing of Fertilization Centres in the State of UAE
3. Royal Decree 76/M, 21/11/1424 and Cabinet Decision No. 260, 23/9/1424 and Ministerial Decree 12/1/2870, Saudi Fertilization Centres Regulations 6/1/1426.
4. Revised minimum standards for practices offering assisted reproductive technologies. American Society of Reproductive Medicine. Fertility and Sterility_Vol. 90, Suppl 3, November 2008.
5. Revised guidelines for human embryology and andrology laboratories. American Society of Reproductive Medicine. Fertility and Sterility_ Vol. 90, Suppl 3, November 2008
6. ESHRE Revised guidelines for good practice in IVF laboratories. Human Reproduction Vol.23, No.6 pp. 1253–1262, 2008
7. Competency profiles for assisted reproductive technology laboratory professionals in Canada. Committee on Professional Standards of the CFAS ART Lab Special Interest Group, October 29, 2007.
8. Guidelines for qualifications and responsibilities for each assisted reproductive technology laboratory professional position in Canada. Committee on professional standards of the CFAS ART lab special interest group, February 27, 2009.
9. Essential elements of informed consent for elective oocyte cryopreservation: a practice committee opinion. American Society of Reproductive Medicine. Fertility and Sterility Vol 90, Suppl 3, Nov 2008
10. Recommendations for development of an emergency plan for in vitro fertilization programs: a committee opinion Practice Committees of the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology. American Society for Reproductive Medicine and Society for Assisted Reproductive Technology, Birmingham, Alabama. Fertil Steril_ 2012;98:e3–e5. 2012

11. Committee Report on Fertility Centres Standards and Regulations for Private and Government Sectors, MoH Sultanate of Oman, 2013

**Table1- Example of Minimum Equipment and Quantity in IVF Laboratory
and Andrology Unit**

Machine	Quantity
CO2 Incubator	2
Laminar Hood/ IVF chamber	1
Inverted Microscope	1
Stereomicroscope	1
Microscope	1
Micromanipulator	1
Centrifuge	1
Freezing system	1
Freezing tanks	1
Electrical pipette	2
Variable pipettes	2
Mackler cell	1
Fyrite analyzer	1
Fridge / freezer	2
Camera + monitor	1
Computer	1
UPS back-up	1
Warm plate	1
Digital weighting Media	1
Generator	1

All critical equipment is either backed up (i.e. two available) or there is a written system in place to ensure continuity of care in the case that equipment fails.

Table 2- Minimum Equipment and Quantity in Operating Room

Name	Quantity
IVF vacuum pump	1
Suction unit 1	1
Laparoscopy/hysteroscopy unit (optional)	1
Telecam (optional)	1
Endoflator (optional)	1
Light source Xen (optional)	1
Monitor (optional)	1
Anaesthesia Machine	1
OR Table	1
O2 Monitor	2
Defibrillator	1
Ultrasound	1
OR lamp	1
Examination table	1
ECG monitor	1
Hormoneimmunoassay (optional)	1