Supreme Council of Health

Decree No. (62) for the year 2019

Licensing Conditions for the use of Artificial Fertilization and Assisted Reproductive Techniques

Head of the Supreme Council of Health:

National Health Regulatory Authority:

After reviewing Decree-Law No. (2) for the year 1987 regarding the practice of non-doctors and pharmacists allied health professions,

And Decree-Law No. (7) for the year 1989 concerning the practice of the profession of medicine and dentistry,

And Decree-Law No. (18) for the year 1997 concerning the organization of the profession of pharmacists and pharmaceutical centers, amended by Legislative Decree No. (20) of the year 2015,

Law No. (38) for the year 2009 establishing the National Health Regulatory Authority, as amended by Legislative Decree No. (32) for the year 2015,

And Decree-Law No. (21) for the year 2015 on private health facilities, as amended by Law No. (1) for the year 2019,

And Law No. (26) for the year 2017 concerning the use of artificial fertilization and assisted reproductive techniques,

And Decree No. (5) for the year 2013 concerning the establishment of the Supreme Council of Health

And Decree No. (1) for the year 1991 regarding the regulation of nursing profession,

And Decree No. 23 for the year 2017 on the standards and requirements for the licensing of health professionals,

And Decision No. (2) for the year 2019 on the classification of health care facilities, and the required health, technical, safety and preparation conditions to be met in these facilities,

Based on the presentation of the Chief Executive Officer of the National Health Regulatory Authority,

And the approval of the Head of the Supreme Council of Health

Decided the following:

Chapter I

Definitions

Article (1)

For the purposes of the application of this Decree, the words and phrases shall have the meanings assigned to each of them from Law No. (26) for the year 2017 concerning the use of artificial fertilization and assisted reproductive techniques, unless the context otherwise requires:

Kingdom: The Kingdom of Bahrain.

The Law: Law No. (26) for the year 2017 concerning the use of artificial fertilization and assisted reproductive techniques.

Health Facility: Any hospital, department or center equipped for the use of artificial fertilization and reproductive techniques, including obstetrics and gynecology clinics that treat infertility and stimulate and monitor ovulation.

Health Facilities Decision: Decision No. (2) for the year 2019 on the classification of health care facilities, and the required health, technical, safety and preparation conditions to be met in these facilities.

Chapter II

Assisted Reproductive Techniques and Artificial Fertilization

Article (2)

Licensing

No natural or juridical person may establish, operate or manage a health facility with the practice of artificial fertilization and assisted reproductive techniques, until a license has been obtained from the Authority.

Article (3)

Conditions of Practice

Taking into account the provisions of the Laws and Decrees and Decisions, of the conditions of practice of artificial fertilization and assisted reproductive techniques, those practicing artificial fertilization and assisted reproductive techniques must meet the following conditions:

First: Consultant Physician

1. Licensed by The Authority as a consultant in gynecology and obstetrics.
2. Attained a fellowship of at least a year from a certified training center specialized in the treatment of infertility.
3. Completed at least four years' experience in a certified training centre in the area of conception difficulty.
4. An accredited certificate from two bosses or supervisors, including information about their education level and professional and ethical conduct.
5. A Certificate proving that no criminal judgments have been passed against applicant prejudicing his integrity and honor unless he has been forgiven by competent authorities.

Second: Specialist Physician

1. Licensed by The Authority as a specialist in gynecology and obstetrics.
2. Attained a fellowship of at least a year from a certified training center specialized in the treatment of infertility.
3. Completed at least a years' experience in a certified training center in the area of conception difficulty.
4. Must not conduct any ovulation induction procedures in Health Facilities levels 1 and 2, unless under direct supervision from a consultant physician in gynecology and obstetrics and assisted reproductive techniques as licensed by the Authority.

Third: Fertilization Lab Technician

1. A bachelor's degree in a biological science or laboratory technology.
2. Completed practical work experience of at least two years in the area of fertilization labs.
3. Completed work experience in multiple lab applications through an accredited certificate from The Authority.
4. Licensed by The Authority as a fertilization lab technician.

Fourth: Nursing Staff

There must be at least two qualified nurses in the level 2 Health Facility, with experience in artificial fertilization.

Fifth: Medical Coordinator

The medical director can be a medical secretary or a licensed nurse by The Authority.

Chapter III

Classification and Conditions of Health Facilities

Article (4)

Classification

Health Facilities are classified into two levels:

Level 1:

Health Facilities specialized in evaluating and treating of cases of difficult conception with stimulating drugs and ovulation induction treatments, through normal contact or assisted reproductive techniques. However no artificial fertilization procedures are conducted within the Health Facility.

Level 2:

Health Facilities equipped and specialized in evaluating and treating of cases of difficult conception with stimulating drugs and ovulation induction treatments, through normal contact or assisted reproductive techniques. Artificial fertilization procedures are conducted within the Health Facility.

Article (5)

General Conditions for Health Facilities

Taking into account the provisions of Appendix (1) attached to the Health Facilities Decision, every Health Facility must have:

1. An area to provide analysis for cases of sterility and conception difficulty, with consideration to not combine the those cases with other medical cases.
2. All necessary devices, especially ultrasound (U/S) machine to follow up monitoring and development of ovulation.

Article (6)

Special Conditions for Level 1 Health Facilities

A Level 1 Health Facility must:

1. Be a specialized clinic under a center or hospital, or independent, or a gynecology and obstetrics specialized center.
2. provide an administrative staff.
3. Provide a medical staff including at least one consultant physician.

Article (7)

Special Conditions for Level 2 Health Facilities

A Level 2 Health Facility must:

1. Be an independent fertilization hospital, or an integral fertilization center in a hospital.
2. To provide a technical staff with at least two lab technicians available at once to coincide with rounds of treatment offered.
3. Provide one embryo lab technician for every 150 cases of ova suction, and supporting staff.
4. **Reception:** Have a reception and waiting area available for patients with conception difficulty cases to be greeted and wait, with considerations to privacy.
5. **Clinics insides a Healthcare Facility:** Be equipped with all necessary devices, especially an (U/S) machine to monitor ovulation, and it is possible for the clinics to be outside the fertilization unit but must be within the area of the hospital.
6. **Semen Collection Room:** A room for receiving the couple with considerations to privacy, outfitted with a bed and a bathroom to provide the semen, with a way to communicate between the room and lab.

7. **Artificial Insemination Room:** A room with privacy, where the sperm extracted from the husband's semen is inseminated into the wife's uterus during the process of natural or artificial ovulation.
8. **Operating Room:** A room specialized only for artificial insemination and fertilization operations. Including the conditions outlined in Appendix (11) attached to the Health Facilities Decision, the room must:

a. Be directly connected to the embryo lab by a window or door or both.
b. Be specialized to extract ova and conduct any operations pertaining to artificial insemination and fertilization only.
c. Be equipped with all operation room equipment.
d. Provide a (U/S) machine and any attachments needed to collect the ova.
e. Provide a machine for extracting the ova.
f. Provide the complete equipment and surgical tools necessary to conduct a full operation in emergency situations in case of complications.
g. Provide the necessary surgical equipment and drugs for resuscitation in case of complications during surgery.

9. **Embryo Transfer Room:** A separate room connected with the embryo lab by a window or door or both, which must be:

a. Equipped with the necessary equipment for an examination room.
b. Equipped with a (U/S) machine, if necessary.

10. **Resuscitation Room:** A room designed to care for patient's care and their recovery from general or topical anesthesia, with equipment outlined in Appendix (11) attached to the Health Facilities Decision.
11. **Day Case Room:** A room to receive patients before and after surgery, and with the number of beds depending on the capacity of the hospital.
12. **Fertilization Labs:** categorized based on the specialty and needs of each lab, on the following basis:

a. Embryo lab.
b. Andrology lab.
c. Cryopreservation lab.

Each lab must be equipped with smoke and fire detectors, anti-hacking computer software, and an IT network to record results based on each lab's specialty.

13. **Medical Device Storage:** Must be separate from the assisted reproductive techniques labs.
14. A room to store patient files and medical records if using paper files.

Article (8)

Duties of the Health Facilities

General Duties of the Health Facilities

Taking into account article (6) of the Law, the Health Facility is committed to use artificial fertilization and assisted reproductive techniques in the following ways:

1. For a Level 1 Health Facility to contract with a Level 2 or higher Health Facility, to conduct artificial insemination and fertilization procedures in the Level 2 or higher Health Facility's premises.
2. There is a clear system in place provide a replacement for treating physician if he/she is unavailable for any reason.
3. A coordinator is available in the Level 1 Health Facility to follow up on patients' treatment plans, and to communicate and coordinate with the coordinator from the Level 2 Health Facility, and the fertilization centers.
4. Before the transfer to the Level 2 Health Facility, commit to collate a list containing test results for (B&C), AIDs, and STIs for both the husband and wife, an observation form for monitoring ovulation stimulation stage, and the required lab tests, especially the test results for the semen analysis in the Level 2 Health Facility lab, before the artificial insemination and fertilization procedure is undertaken, with the written consent of the husband and wife to start the treatment, and the Health Facility's acknowledgement that all the treatment steps were explained, with proof in writing or evidence to those concerned.
5. The physician conducting the ovulation induction qualifications and expertise that would prevent them developing ovarian hyperstimulation syndrome (OHSS) or multiple pregnancies.

6. Provide the patient with all information regarding ovulation stimulation symptoms and 24 hour contact numbers for the Health Facility, with a clear system to deal with complications if the patient needs a hospital.
7. Inform The Authority in the case of complications, especially in ovulation stimulation multiple pregnancy, or ectopic pregnancy cases, or any other extreme complication.
8. Provide a guide or pamphlet to help patients understand fertilization techniques and procedures, with pictures and the Health Facility's statistics and rates of success, including complications and issues the patient might face, and the names and responsibilities of the employees of the Health Facility, so that the patient knows who to reach.
9. The couple sign written consent form including all information of the treatment cycle, with the physician signature.
10. Complete sexually transmitted infection disease (STI) testing and any tests conducted for the couple before treatment and regularly every 6 months, and if there are any positive results, it must to be reported based on the policies and standards of The Authority.
11. The Health Facility treating those with positive results outlined in item (10) of this Article, should have clear procedures to prevent infection transmission to patients and employees. The Health Facility storing embryos, gametes, or any tissue from those infected, should have clear procedures to prevent infection transmission.
12. The Health Facility is prohibited from possessing drugs to induce ovulation for the purpose of sale, unless the Health Facility has a private pharmacy, with clear procedures to store and handel the drugs safely, and commit to the standards and conditions of pharmacies.
13. Except for pharmaceutical tablets, it is prohibited to dispense any drugs to induce ovulations without a medical prescription which is written, signed, and stamped by a physician who is licensed by The Authority in the specialty of fertilization.
14. Provide counseling services when appropriate.

Chapter IV

Fertilization Labs

And Day Hospitals

Article (9)

Conditions for Fertilization Laboratories

Fertilization labs should include the embryo lab, the cryopreservation lab, and the andrology lab, and must be equipped with computers, an IT network to record results based on each lab's specialty, and support the equipment with a safety system to protect against fire, in addition all fertilization laboratories must:

First: Embryo Lab:

1. Should be away from patient review area, and with security to prevent unauthorized access.
2. Should be connected directly to the operating room for ova suctions and embryo transfers, by a window or door or both.
3. Should be away from areas where it can be affected by tests and material conducted by other specialties, especially the genetic testing lab and cryopreservation lab.
4. The walls, floors, and surfaces of the lab are of materials that are easy to clean and wash, free from substances that assist in the growth of bacteria and viruses, and not to use non-authorized organic and chemical cleanser are not to be used for cleaning the embryo lab.
5. Equipped with methods to regulate heat, humidity, light, and a machine to regulate positive pressure with (HEPA Filter).
6. Should be Equipped with additional methods to filter and sterilize the air from dust, gases, smells, and trapped micro particles.
7. Appropriate amount of medical tools and supplies for daily use to be placed in drawers. It is prohibited to have a storage in the lab.

8. Equipped with all necessary devices to produce embryos until they are transferred, with the required minimum standards and quality assurance met, especially the following devices:

a. II Laminar Flow Cabinet class, with Stereo Microscope and thermal surface and supported with CO2 gas or other gas necessary to preserve cultures.
b. Inverted Microscope with light filters and the necessary attachments to conduct Micromanipulation System.
c. To provide at least two small size incubators to grow and incubate embryos, and a nursery to store cultures and another to prepare sperm, with each incubator having a gauge for gases used and temperature, and an alarm system in case of deviation of gas and heat in the internal support systems, with consideration that the number of incubators correlate with capacity of the Health Facility.
d. Two centrifuges.
e. Devices that preserve the temperature of cultures, test tubes, catheters, and other tools at 37 degrees Celsius.
f. Central centrifuge device

Second: Cryopreservation Lab:

Taking into account the conditions for an embryo lab, the cryopreservation lab must have negative pressure equipment as compared to the embryo lab and operating room, in addition to the following:

1. Methods to cryopreserve embryos and gametes in all the necessary lab attachments to achieve the highest performance.
2. Aseptic air station supported by a thermal surface.
3. Special storages to preserve all cryopreserved embryos and gametes, with a gauge to measure cooling temperature directly connected to a backup generator.
4. A special storage of cryopreserve samples from patients with STIs.
5. A device to regulate negative pressure or to extract fumes from liquid nitrogen used in small storages.

Third: Andrology Lab:

Taking into account the conditions for an embryo lab, the andrology lab must have positive pressure equipment less than the embryo lab and higher than the cryopreservation lab, and in addition to the following:

1. A microscope with the lens (x20, x40, x100) which is required to analyze semen and sperm.
2. A nursery to prepare the sperm.
3. A centrifuge.

Article (10)

Labs Guide

Human embryo labs must have a guide to describe scientific fertilization methods, and all employees of the lab must abide by the guide, and especially:

1. The basic scientific principles and rules for all lab methods, which are reviewed periodically and annually by the scientific manager or the lab manager.
2. The medical concepts for each lab method and its clinical importance.
3. The requirements for each biological sample and the correct way to handle them.
4. Detailed description for each lab method step by step.
5. Methodology of cultures preparation, liquids, reagents, and other substances prepared in a lab.
6. A list and calibration methodology of all the devices and equipment in the lab.
7. Methods of quality control and quality assurance in the lab and how to apply them.
8. Methods to handle and act when examination and inspection results do not correspond with expected readings.
9. The system used to secure and accredit results.
10. Determining the deficiency in application and the measures to overcome it.
11. List of accredited sources and references.
12. A clear mechanism to identify the identity of the couples at each stage in treatment.
13. Prohibit handling of more than one sample at the same time.
14. Substances and materials are to be used only once.

15. A clear mechanism for annual review for all the documented results in the internal system.
16. To ensure that the procedures to clean and maintain the cryopreservation chambers are based on the manufacturing company's guidelines.

Article (11)

Conditions for Human Embryo Lab Preservation

Taking into account Article (9) of the Law, the Health Facility must provide a mechanisms to preserve ova, embryos, sperm, or gametes, for the purpose of transfer or future fertilization, and commits to the following:

1. Ensuring that there is a valid marriage contract certified by the relevant authority, when starting the cryopreservation treatment and when using the samples in the treatment.
2. Ensuring the written agreement of the couples to preserve the sample and to renew the duration of the cryopreservation and the disposal method at the end of the duration, and for them not to be used for purposes other than fertilization.
3. There is a clear mechanism and policy to record and document the details of storage, including the following:

a. Ensuring the identity of the couple with the recorded identities when starting cryopreservation.
b. The type and quantity of the cryopreserved samples.
c. The number of cryopreserved samples remaining since starting to use them.
d. The date and method of storage.
e. The type and number of cryopreserved embryos.
f. Provide the required tests before cryopreservation (HIV, HBV, HCV, VDRL).

4. There is a clear mechanism to check the samples during cryopreservation, and that with the certification of two embryo specialists.
5. Provide a clear system to follow-up and determine the location of the cryopreserved sample, with clear labeling and record matching.
6. Provide a mechanism and clear system to observe the samples.

7. Provide a sensor, in every store, with a high quality alarm system and clear voice to alert the person in charge of any fault in the system or containers, and a list of people involved who are committed to inform the lab director of any fault.
8. Provide a clear policy to inform the medical director to take the necessary procedures in case of an emergency.
9. Provide appropriate envelopes to preserve, so that the samples are not exposed to infections, radiations, or chemicals that can cause harm.
10. Provide a safe place, with authorized access, with constant surveillance.
11. Ensure the safety of devices used in cryopreservation.
12. Provide a system to preserve samples of patients with STIs in separate storage adhering to conditions of the cryopreservation lab, and to clearly indicate the area to The Authority's inspectors.
13. Provide a policy to deal with cryopreservation emergencies, such as a leak or decrease in medical gases or a failure in storage, and a clear system to transport samples in these cases.
14. Provide a system to evaluate and audit the storage, on a regular and random basis to ensure the correct method of storage.
15. Provide a clear policy to deal with patients wanting to renew their storage,
16. Provide a system that documents that a couple was informed that their samples are to be destroyed before the storage duration ends, and later that the samples were destroyed.
17. Provide a policy to act if unable to reach a couple regarding renewing their storage duration.
18. Provide a written policy that includes the requirement of having the couples written consent to destroy the samples when necessary.
19. Provide a clear policy to transfer cryopreserved samples between Health Facilities within The Kingdom, especially including:

a. The written consent of the couple, with the attendance and confirmation of the lab director or their representative, and documenting the risks that could result from the transfer.
b. Detailed documentation of the storage process from the way, the dates, the number of samples, the types of samples, and the required tests before

cryopreservation (HIV, HBV, HCV, VDRL). Committing to a clear policy within the Health Facility to act when the tests are not available.

c. Get prior written approval from the moving company and the one receiving the sample.
d. Contract with a licensed Health Facility in the specialty in The Kingdom, to care for the patients during completion of their treatment cycle and to handle the cryopreserved samples.
e. Coordinated with the relevant department in The Authority to place coordination methods with The Authority's CEO.

Article (12)

Maintenance of Devices in Human Embryo Lab

The Health Facility in maintaining its human embryo lab devices must:

1. Keep a list of all the devices in the labs, including the country of origin of the device, date of manufacture, and the serial number.
2. The maintenance and calibrations of all devices regularly, and for the maintenance specialist to records the dates in a separate log.
3. Record all the malfunctions of the devices and the dates they were fixed in a separate log.
4. Record all the relevant information from the daily routine check for the incubators, including the temperature, humidity, levels of CO2, and levels of gas in the support canisters.
5. Check the level of liquid nitrogen in the main storage regularly.
6. Ensure there is enough liquid nitrogen in the embryo storage canisters and the gamete storage canisters.
7. Provide enough incubator gas pipes depending on the absorption capacity of the Health Facility.
8. Provide a backup generator for all devices and special equipment (incubators, cryopreservation storage, and others).
9. Keep records of checkups, maintenance, and fixes to provide the relevant authorities when asked.

Article (13)

Conditions for Daycare Hospitals

Taking into account Appendix (1) attached to the Health Facilities Decision, daycare hospitals specialized in the treatment of delayed childbearing through the use of artificial fertilization and assisted reproductive techniques should:

1. Be independent, specialized only in receiving couples with delayed childbearing, and equipped with the necessary equipment to treat them.
2. Have a contract between it and a general hospital with the intensive care unit, to transfer patients if needed.
3. The daycare hospital anesthesiologist must be licensed by The Authority and responsible for:

a. Check list Theatre.
b. Anesthesia.
c. Discharge.

4. Have a 24 hour availability of emergency care for critical conditions during or after the treatment cycle.
5. Have a 24 hour availability of an ambulance.
6. Not include inpatient admission for more than 24 hours.
7. Have a contract between it and a licensed hospital by The Authority to care for multiple pregnancy cases and premature births.

Chapter V

Administrative Staff

Article (14)

Conditions and Responsibilities of the Administrative Staff

Taking into account Appendix (4) attached to the Health Facilities Decision, each Health Facility must have a medical director, an embryo lab director, an administrative director, and may have a scientific director, according to the following conditions:

First: Medical Director:

The medical director in the Health Facility must:

1. Be a consultant physician licensed in gynecology and obstetrics, with practical experience of at least 5 years in artificial fertilization and assisted reproductive techniques, with an accredited certificate according to The Authority's specifications.
2. Be aware of the teachings of Islam and to have ethical, social, legal, medical, and scientific understanding to manage the Health Facility, according to The Authority's licensing procedures.
3. To prove his medical fitness by the concerned medical body according to The Authority's licensing procedures.

In addition, the Health Facility must have another physician that fulfils the above criteria, who will be assigned by the medical director to replace him in his absence and to notify the Authority in such case.

If there is no one available to replace the medical director, a physician is assigned temporarily, provide that he/she fulfil The Authority's licensing criteria.

Second: Medical Director's Responsibilities:

The medical director is in charge of the Health Facility, and manages the medical, nursing, and technical staff, and is responsible for all licensed treatment activities, and any violations of the policies and approved standards, especially the following:

1. Manages and supervises the Health Facility technical work flow to ensure achieving its purpose with high standards, and ensure the quality of the health services provided.
2. Represents the Health Facility at The Authority and provide it with what its request of files, records, logs, documents, data, and health information, during the period The Authority specifies.
3. Checks the qualifications and conditions of all medical, technical, and nursing staff employed in the Health Facility, and continue to provide support and training programs for them.

4. Ensures that there is enough consultants, specialist and health care professionals according to the capacity of the Health Facility.
5. Ensures the availability of the necessary equipment for treatments provided.
6. Ensures the existence of correct and proper arrangements to preserve embryos and gametes and the existence of correct and proper arrangements to destroy them.
7. Ensures the Health Facility's commitment to all the conditions and procedures necessary for its license.
8. Informs The Authority when the Health Facility stops providing any of its health services, or if there is any change to the data or information the Health Facility provided The Authority with to get or renew its license, and that is within 30 days of the stop or change.
9. Reports any incidents that occurs in the Health Facility.
10. Allows The Authority's specialized or authorized employees to conduct inspections, evaluations, and audits to check that the law is applied.

Third: Embryo Lab Director:

The embryo lab director supervises and is directly responsible for all the lab activities, and is responsible for the lab technicians' activities, and should:

1. Be Muslim and aware of the teachings of Islam and to have religious, ethical, social, and legal understanding to manage the treatment labs, according to The Authority's licensing procedures.
2. Be a physician with a sub specialty in embryology or biological labs, with a specialty in fertilization labs, or has a PhD in a biological science, with practical experience of at least 5 years in fertilization labs.
3. Have an MSc in either biological sciences or lab technologies, with a minor in fertilization lab sciences.
4. Have practical experience of at least 5 years in all necessary applications for fertilization procedures, such as growing tissues, preparing cultures, preparing sperm, cryopreservation techniques, and applying quality standards of a fertilization lab.
5. Have experience in device regulation and maintenance.
6. Have experience in cryopreservation techniques.

7. Regularly contact the medical director, science director, and administrative director to follow-up on treatments, coordination, and development.

Fourth: Administrative Director:

The administrative director is only responsible for the administration of the Health Facility, and is prohibited from interfering in the facility's work flow except for the administrative aspect of the Health Facility, and is also prohibited from reviewing patient files and being in treatment areas unless licensed as a member of the treatment staff.

Fourth: Scientific Director (if available):

The medical director or the embryo lab director can be the scientific director for the Health Facility, and is responsible for the research and scientific activities, in addition to the conditions for the medical director or the embryo lab director, the scientific director should:

1. Be aware of all prohibitions in the field of work according to Islamic Sharia.
2. Have experience in research design and statistics, and published studies and scientific research published in notable scientific journals or presented in regional or global scientific conferences.

Chapter VI

Written Consent

Article (15)

Conditions of Written Consent

The written consent the Health Facility receives from a couple should fulfil the following:

1. Have the consent of the husband and wife together, along with the medical staff, and the signature of witnesses to corroborate the statements.

2. Ensuring that there is a valid marriage contract certified by the relevant authority, before starting the treatment and during.
3. The written consent, before starting treatment, should include all the procedures of every treatment phase before its start, and all complications and possible side effects during handling the gametes and embryos and the chances of treatment success.
4. To repeatedly obtain the written consent by the couple separately, at the start of each phase of treatment, and the medical staff must check the identity of the couple before the start of each phase of treatment.
5. Include the storage of sperm, ova, and tissue for a period not more than 10 years, and storage of embryos for a period not more than 5 years, specifying the amount allowed to transfer.
6. Commitment to code of professional conduct in obtaining the written consent.

Chapter VII

Private Records and Files

Article (16)

Private Records and Files Regulations

Taking into account the law, the Health Facility commits to open special records to note all information and procedures that were undertaken with their reasons and results, as well as opening a medical record for each case to note test results, procedures, and prescriptions, with all the relevant diagnosis, according to the following regulations:

1. Recording all cases of conception difficulty, when starting treatment, in a registration form, and save each couple's copy in their own file.
2. Recording the CPR of the husband and wife when opening the conception difficulty patient file, and keeping a copy of the valid marriage license in the file when starting treatment.

3. Obtaining written consent from the couple and attending physician that includes all information necessary to start treatment, and at each new phase of treatment, and keeping a copy of the consent in the patient medical file.
4. The attending physician documenting all private information when starting treatment, and at each new phase of treatment, and keeping a copy in the patient medical file.
5. Keeping copies of tests results of hepatitis (B&C), AIDs, STIs, and any new tests for the couple before starting treatment, and regularly every 6 months.
6. Keep a special registration form for the ovulation stimulation phase of treatment showing the treatment plan, the name of the stimulation drug and the dosage, development of serum and follicle, and the name and dosage of the drug used to induce ovulation.
7. Keep a special registration form for the ova suction phase of treatment showing the name of the couple and their CPR, the name of the witness, the name of the attending physician and their license number, the name of the direct embryo technician, and the number of ova and drugs used during the procedure.
8. Keep a special registration form for the embryo transfer phase of treatment showing the name of the couple and their CPR, the name of the attending physician and his/her license number, the number of embryos transferred to the uterus, their stages, their quality, the name of the direct embryo technician, and a signature on the form from another embryo technician as a witness.
9. Keep a special registration form for the cryopreserved samples in storage showing the date of storage, and signed by two embryo lab technicians.
10. Provide a separate, secure room to preserve paper records, with access only by the patient's attending physician, the professionals licensed by The Authority for fertilization treatment, and those authorized by the Health Facility's medical director or from The Authority upon request.
11. Commit to save electronic copies of patient private records, in accordance to Appendix (3) attached to the Health Facilities Decision.
12. Preserve patient files, documents, information, and their special procedures either in electronic or paper form, in a confidential and secure manner and protected from damage, available to be presented to the relevant authorities when

requested, and for all the records to be presented to the relevant authorities if the Health Facility closes.

Chapter VIII

General Provisions

Article (17)

Scope

Taking into account the law, the provisions of this Decree apply to public and private Health Facilities, and any who practice any activity related to the use of artificial fertilization and assisted reproductive techniques.

Article (18)

Reconciliation

All Health Facilities who practice the use of artificial fertilization and assisted reproductive techniques must abide by this Decree, and to apply to The Authority within 6 months to reconcile its provisions.

Article (19)

Enforcement of the Provisions of the Decree

The CEO of The Authority shall implement this Decree, to be adopted as of the first day of the month following the date of its publication in the Official Gazette.