Cabinet Decision No. (36) of 2009
Issuing the Implementing Regulation of Federal Law No. (11) of 2008 Concerning the Licensing of Fertilization Centers in the State

The Cabinet,

Upon consideration of the Constitution,

And Federal Law No. (1) of 1972, concerning the Jurisdictions of Ministries and the Powers of Ministers, as amended,

And Federal Law No. (7) of 1975, concerning the Practicing of the Human Medicine Profession, as amended,

And Federal Law No. (5) of 1984, concerning the Practicing of some Medical Professions by other than Physicians and Pharmacists,

And Federal Law No. (5) of 1985, concerning the Civil Transactions, as amended,

And Federal Law No. (3) of 1987, concerning the Penal Code, as amended,

And Federal Law No. (11) of 1992, concerning the Civil Proceedings, as amended,

And Federal Law No. (35) of 1992, concerning the Penal Proceedings, as amended,

And Federal Law No. (2) of 1996, concerning Private Health Facilities,

And Federal Law No. (10) of 2008, concerning Medical Liability,

And Federal Law No. (11) of 2008, concerning the Licensing of Fertilization Centers in the State,

And based upon the proposal of the Minister of Health and the approval of the Cabinet,
Has decided as follows:

Article 1
In applying the provisions of this Regulation, the following words and expressions shall have the meanings set forth opposite each one, unless the context determines otherwise:
State: the United Arab Emirates.
Ministry: the Ministry of Health.
Minister: the Minister of Health.

Law: Federal Law No. (11) of 2008 concerning the Licensing of Fertilization Centers in the State.
Health Body: Ministry of Health; any federal or local government bodies dealing with health affairs in the emirates.
Committee: the Fertilization Centers Oversight and Control Committee.
Centre: the fertilization center where assisted reproductive techniques are performed, including all clinical and biological procedures that are necessary to effectuate extracorporeal conception.
Assisted: the medical procedures that are Reproductive necessary to effectuate extracorporeal Techniques conception and reproduction.

Article 2

a. The provisions hereof shall apply to the fertilization Centers operating in the State, and to centers applying for licenses to operate in the State according to the Law and this Regulation.
b. The Health Bodies may issue a preliminary license for the establishment or operation of the Centre according to the controls and conditions specified under the Law and this Regulation. The license must be approved by the Ministry in order to be final and valid.

Article 3

A technical committee called " the Fertilization Centers Oversight and Control Committee" shall be formed by a Cabinet decision upon the proposal of the Minister and its office shall be located in the Ministry. The Committee's membership shall comprise the Ministry's director general, as chairman, and a number of physicians whose ranks shall not be below the rank of a consultant specialist in the fields of andrology, infertility, gynecology and obstetrics or embryology, from each of the following Bodies:

1) The Ministry of Health.
2) Health Authority – Abu Dhabi.
3) Dubai Health Authority.
4) College of Medicine and Health Sciences of the UAE University, where the member shall have the rank of professor.
5) The private health sector.

The Committee shall also comprise a Sharia adviser from the General Authority of Islamic Affairs and Endowments and a legal adviser to be selected by the Minister of Health.
No member of the Committee may attend the Committee's meetings or express their opinions in any matter presented to the Committee if such member or any of his relatives up to the fourth degree has any personal interest in the presented matter.

Article 4

Subject to the responsibilities of the Committee under the Law, the Committee shall perform the following responsibilities:

1- To oversee the implementation of the conditions and standards for licensing fertilization centers in accordance with the Law and this Regulation.
2- To update the conditions, standards and controls for licensing fertilization centers, have these approved by the Minister and consider them a part of this Regulation.
3- To study modern Assisted Reproductive Techniques and infertility treatments, make recommendations on the applicability of these techniques in the State and establish implementation conditions and standards, and have these approved by the Cabinet.
4- To establish appropriate quality conditions and standards required for the continuing licensure of Centers among which – as an indicator - is a live birth as a result of treatment at every Centre, with a success ratio as determined by the Committee.
5- To exercise control over fertilization Centers through performance evaluation reports to verify the extent to which they are applying the established quality standards, in accordance with the control mechanism determined by the Committee.
6- To provide specialized fertilization consulting, being the competent fertilization authority in the State.
7- To examine the offences detected by the investigation officers and make appropriate and relevant recommendations.
8- To examine the complaints referred to it by the Minister or the chairman of the Committee and make appropriate recommendations.
9- To review the consent forms attached hereto and update them by addition or deletion as necessary.
10- To form subcommittees in the local Health Bodies to oversee and control the fertilization Centers, within their geographic jurisdiction, provided that these subcommittees shall notify the Committee of their findings.
11- To perform any other duties assigned to it under the Law and this Regulation.
12- The Committee shall exercise the technical responsibilities hereinabove mentioned upon the recommendation of the technical committee referred to in the Law. The Committee may seek the assistance of experts, institutions or specialized expertise houses or research centers.

Article 5

1. The Committee shall meet regularly at least once every two months upon the invitation of the chairman of the Committee or vice-chairman. It may hold its meeting at a different time upon the request of its chairman, vice-chairman or three of its members.
2. At its first meeting, the Committee shall select a vice-chairman who will replace the chairman in his absence.
3. A Committee meeting must be attended by the chairman or vice-chairman and a majority of the members. A vote of a majority of those present shall be required for any recommendations. In the event of an equal number of votes, the side on which the chair of the meeting voted shall prevail.
4. The Committee membership shall be for a three-year renewable term.

5. If a member is absent from the Committee meetings for two consecutive times or three non-consecutive times in a year, or if he fails to attend the Committee meetings regularly due to his work conditions or for any other reason, he shall be replaced.
6. The director of the medical licensing department in the Ministry shall serve as Committee rapporteur but without voting rights with regard to Committee recommendations.
7. The Committee rapporteur shall prepare registers for recording the meeting minutes and recommendations of the Committee.
8. The Committee shall submit its minutes of meeting with its recommendations regarding the matters presented to it to the Minister for approval.
9. The Committee's recommendations shall be implemented through the competent authorities according to the nature of these recommendations and the type of respective subjects. The licensing department shall, in coordination with the competent authorities, follow up the implementation of the recommendations approved by the Committee.
10. A Minister's decision approving the Committee recommendation may be appealed by means of a petition submitted to the Minister within fifteen days from the date that the decision is notified to the party concerned. Appeals must be ruled on within fifteen days from the date that they are submitted, and the aggrieved party may seek judicial recourse within thirty days from the date that the rejection of appeal is notified to him, or the date that the time prescribed for ruling on the appeal has elapsed.
11. The compensation of the Committee chairman and members shall be determined by a Cabinet decision upon the recommendation of the Minister.

Article 6

The undertaking of any activity involving Assisted Reproductive Techniques inside any health facility is conditional upon obtaining a license according to the controls and conditions for the licensing of Centers stipulated by the Law and this Regulation, regardless of the license of the health facility where such activity is performed.

Article 7

The licensing of the Centre is conditional upon fulfilling the technical conditions and specifications and the availability of the medical equipment and devices as follows:

First: 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, with consideration for the environmental and health conditions of the site of the Centre.

Second: Contents of the Centre

The Centre shall contain at least the following:

a- Clinic: it shall contain the following:

1. A reception area;
2. Two (2) waiting rooms (one for men and one for women);

3. Two (2) water closets (one for men and one for women);
4. An examination room for each physician;

b- Treatment, operating and laboratory rooms: they shall contain the following:

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
    c. A sperm freezing room
    d. An embryo laboratory / fast hormone analysis room
    e. A storeroom for surgery devices / solutions / laboratory equipment.

These rooms shall fulfill all the required ventilation specifications by installing filters in the cooling systems and determining the humidity percentage at the laboratory (20%) and the temperature at the laboratory and its enclosures (22 – 24ºC), and shall ensure adjacency between the operating room and the embryo laboratory room and audio or visual contact.

4. Storeroom.
5. Sterilization room.
6. Auxiliary rooms (garbage room / water closets / offices/ break rooms for visitors and workers)

Third: Medical Equipment and Devices that must be available in the Centre

Each Centre shall contain the equipment stated in table (1) attached hereto in addition to office supplies and other medical equipment.

Article 8

Every person applying for a license to operate a fertilization center in the State shall ensure the availability of medical, technical and administrative staff licensed to work in the center. The license shall be subject to the availability of the qualifications and experiences set forth opposite each one as per the evaluation adopted in the State:

a- Technical director of the Centre, provided that:

1. He shall be a consultant gynecologist and obstetrician.
2. He shall have the highest professional degree in the field of gynecology and obstetrics.
3. He shall have at least (8) years of experience in the same field after obtaining the highest professional degree, of which at least (5) years of experience at fertilization centers accredited by the Ministry.
4. He shall pass the personal interviews and technical evaluation by fertilization specialists.

b- A specialist gynecologist - obstetrician, working under the supervision of the technical director of the Centre, provided that:

1. He shall have a Clinical Master’s Degree or its equivalent in gynecology and obstetrics.
2. He shall have (3) years of experience after obtaining the Clinical Master’s Degree, at fertilization centers accredited by the Ministry.
3. He shall pass the personal interviews and technical evaluation by fertilization specialists.

c-An andrology and infertility specialist surgeon (optional),provided that:

1. He shall have a Clinical Master's Degree or its equivalent in one of the following medical specializations c- An andrology medicine and surgery, urology surgery and dermatology and venereology. andrology medicine and surgery, urology surgery and dermatology and venereology.
2. He shall have clinical and surgical experience of at least (3) years in one of the areas stated in paragraph (1) hereinabove 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, dealing shall take place with a center or a hospital where this specialization is available.

d- A specialist in anesthesia, provided that:

1. He shall have a Master's Degree or its equivalent in the field of anesthesia.
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 anesthesia specialists.

e- A genetics specialist (optional)

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 experience, after obtaining the Doctorate, at fertilization centers accredited by the Ministry;
2. A Clinical Master's Degree or its equivalent in addition to at least (6) years of experience, after obtaining the Clinical Master's Degree, at fertilization centers 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 shall have a Bachelor's Degree in Biology or Medical Science.
2. He shall have at least (5) years of experience, after obtaining the Bachelor's Degree, at fertilization centers accredited by the Ministry.
3. He shall pass the personal interviews and technical evaluation by fertilization specialists.

h- An anesthesia technician, provided that:

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

i- A radiologist (optional)

j- At least four registered nurses, including an operating room nurse

k- Administrative staff consisting of:

1. An administrative and financial director.
2. A social researcher (optional)

3. A receptionist
4. A medical records clerk
5. A storekeeper
6. A building security guard
7. Two cleaners

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 honor.

Article 9

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 or research purposes, introducing genetic modifications to the features of fetuses, taking the unfertilized or fertilized ova and sperm specimens that have been prepared inside the State abroad and bringing such specimens into the State if they have been prepared abroad or dealing with embryo banks.
vi. The husband and wife are prohibited from authorizing the
vii. Centre to donate their embryos, ova or sperms to other spouses.
viii. The maximum embryo transfer limits authorized according to para (1) Article (13) of the Law.

Article 10

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.

Article 11

The Centre shall 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 statement.

Article 12

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

a. Performing of Assisted Reproductive Techniques, as per attached form (1).
b. Embryo transfer into the uterus or the fallopian tube, as per attached form (2).
c. Sperm injection into the uterus, as per attached form (3).

Article 13

For the purpose of storing unfertilized ova and sperm, 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 or sperm 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 and sperm in storage.
4. The approach to be adopted in case of demise of one of the spouses or the occurrence of a legal separation.
5. Separating the unfertilized ova and sperm extracted from a couple or an individual who is infected with a contagious disease from the rest of the unfertilized ova and sperm in storage.
6. Obtaining the husband and wife's consent 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).

Article 14

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. They shall especially observe the following:

1. To adopt modern preventive methods against germs and viruses that might cause contagious diseases, and sterilize all the tools and containers used.
2. To verify that the embryo culture media are microbe-free, sterilized and capable of producing healthy genes.
3. To use a form for recording the ova maturity level and evaluating the quality of the embryo and how the unfertilized or fertilized ova are handled.
4. To use a form for determining the quality and quantity of sperm intended to be used to complete the fertilization process.
5. To record in the medical file of each customer 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.
6. To have the name and signature of the laboratory technician, director and attending physician recorded in the file of every patient undergoing treatment.
7. 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.
8. There shall be a coordination between the technical staff and the attending medical staff to determine the fate of the transferred embryos and record these results in the relevant records.
9. 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.
10. To ensure awareness of the characteristics and properties of the gas used in the incubators and to verify that the incubators fulfill the required medical specifications.

11. To verify the gas concentration percentages and the temperature of the internal environment of the incubators and record these percentages every day.
12. 12. To ensure awareness of the procedures to be taken in case a certain gas concentration degree cannot be attained in the incubators.
13. To provide a backup generator to be used in case of sudden electrical shutdown.
14. To install an alarm system in the incubators in case of a sudden failure and to explain how to respond to these alarms.
15. The Centre shall only fertilize the required number of ova for implantation at any given time to avoid having a surplus of fertilized ova. In case there is a surplus of fertilized ova in whatever manner, the Centre shall leave these ova without medical care until they perish naturally.

Article 15

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.

The Centre shall also obtain a quality accreditation/ certification from a specialized body in the same field, accredited by the Ministry, and such within three years from the date of obtaining the license for the first time. The Centers existing on the date that this Regulation is issued shall obtain the accreditation certificate within three years from the date that this Regulation is published in the official gazette.

Article 16

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

a- ID card, 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.
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 or family book.
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 stated 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.

d- The Centre technical director's record:

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

e- The medical file:
It shall include all the data stated 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 stated 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 stated 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.

Article 17

Prior to commencing its operations, the Centre shall undertake to develop an internal by-law with regard to its operation system, the prices and the total and detailed costs, all stated clearly and in both Arabic and English. This by-law shall be placed visibly on the notice board at the Centre. Copies of the by-law 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 by-law 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.
The internal by-law shall not include any pictures or expressions that violate public decency.

Article 18

Without prejudice to para (12) Article (4) of this Regulation, the government Health Bodies may establish their own fertilization Centers, and this shall be regarded as license, provided that they shall be subject to all the conditions, controls and standards required for obtaining a license, and the applicable rules for control and oversight provided for under the Law and this Regulation. The punishments stipulated under the law shall apply to the offences committed by the government Centers.

Article 19

1. The Minister shall issue a decision to determine the specialized fertilization Centers concerned with performing the pre-implantation genetic diagnosis intended for hereditary disease detection, in accordance with the international standards and as per the Committee's recommendation.
2. The 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.

Article 20

The following indicators are regarded as standards for evaluating the Center'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 bylaw.
13. The extent to which the Centre is committed to implementing the internal bylaw.
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.

Article 21

The Minister may cancel the license of the Center 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.

Article 22

1. 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.
2. The Minister may as well order the provisional suspension for a maximum period of (60) days for the following reasons:
    a. If the license expires and is not renewed.
    b. If the Centre violates any of the controls and standards stipulated under the Law and this Regulation.
    c. If the Centre violates any of the prohibitions under the Law and the Regulation.
    d. If the Centre commits any of the offences listed in the private health facilities law and any other laws related to the health sector.

In case of the provisional suspension of the Centre, the customers 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.

Article 23

The Minister may cancel or suspend the Center's operation upon the recommendation of the 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 customers.

Article 24
The Centre shall undertake to obtain the licenses and other authorizations stipulated by other laws. Obtaining a license according to the Law and this Regulation shall not exempt the Centre from this undertaking.

Article 25
The Centers already established in the State at the time of issuance of the Law shall adjust their status according to the Law and this Regulation by applying to the Ministry for approval of license. They shall handle the frozen embryos in their possession and dispose of the remainder thereof within six months from the date that the Law is published in the official gazette.

The government health Bodies shall adjust the status of their Centers that exist at the time of issuance of the Law and this Regulation within the said period.

Article 26
This Decision shall be published in the Official Gazette and shall come into effect on the next day of publication.

Mohammad Bin Rashed Al Maktoum
Prime Minister
Issued on:12 Shawwal 1430 H
corresponding to 1 October 2009

Tables and Forms Attached to
Cabinet Decision No. (36) of 2009 Issuing the Implementing Regulation of Federal Law No.(11) of 2008 Concerning the Licensing of Fertilization Centers in the State

1	Table (1) Medical Equipment and Devices Required at the Centre
2	Form (1) Performing of Assisted Reproductive Techniques
3	Form (2) Transfer of embryos into the uterus or the Fallopian Tube
4	Form (3) Injection of Sperm into the uterus
5	Form (4) Preservation of Unfertilized Ova by Freezing
6	Form (4) Preservation of Unfertilized Ova by Freezing

Table (1) Medical Equipment and Machines Required at the Center

1- Machine and Quantity in IVF Laboratory and Andrology Unit

Machine	Qty.
CO2 incubator	2
Laminar Hood	1
Inverted Microscope	1
Stereomicroscope	1
Micromanipulator	1
Centrifuge	1
Centrifuge	1
Freezing tanks	1
Electrical pipettes	2
Variable pipettes	2
Mackler cell	1
Fyrite analyzer	1
Fridge	2
Camera + monitor	1
Computer	1
UPS back-up	1
Warm plate	1
Digital weighting media	1

2- Machine and Quantity in Operating Room

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

3- Generator

Form (1)

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 anesthesia 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, fetal 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 anesthesia 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 anesthesia.

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 abovementioned 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, fetal 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 center, 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 State 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)

Couple's 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 donor……..
Date……...
ID/Passport No…….
Type…….