Cabinet Resolution No. (64) of 2020

Concerning the Implementing Regulation of Federal Law No. (7) of 2019

Concerning Medically Assisted Reproduction

The Cabinet:

- After perusal of the Constitution;
- Federal Law No. (1) of 1972 on the Jurisdictions of the Ministries and the Competences of the Ministers, and its amendments;
- Federal Decree Law No. (4) of 2016 On Medical Liability;
- Federal Law No. (7) of 2019 Concerning Medically Assisted Reproduction;
- Cabinet Resolution No. (20) of 2017 Adopting Unified Standards for the Licensing of Health Professionals at the Country Level, and its amendments;
- And pursuant to the proposal of the Minister of Health and Prevention and approval of the Cabinet;

Has issued the following Resolution:

Article (1)
Definitions

The definitions contained in Federal Law No. (7) of 2019 referred to herein shall apply to this Resolution, other than that, the following words and expressions shall have the meanings indicated opposite each of them, unless the context requires otherwise:

Reproductive Cloning	:	The process entailing the creation of a human being by transferring a nucleus from a human somatic cell to an enucleated egg, and the resulting cell reproduces, forming an embryo that is a genetically identical copy of the original somatic cell.
Law	:	Federal Law No. (7) of 2019 Concerning Medically Assisted Reproduction

Conditions and Controls for Licensing Centers

Article (2)

Subject to any conditions or controls determined by the health authority, the following conditions and controls are required for licensing a Center:

First: Conditions and Controls Related to the Center's Location:

The Center's location must be in line with the nature of its activity and the services it provides, preferably on the ground floor. If it is located on other than the ground floor, an elevator is required to transfer the patients, subject to the environmental and health conditions of the location.

Second: Conditions and Controls Related to the Center's Contents:

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The Center must include, as a minimum, a clinic, rooms for treatment, operations and laboratory, in accordance with the specifications and requirements determined by a decision of the Minister in coordination with the rest of the health authorities.

Third: Conditions and Controls Related to the Center's Medical Equipment and Devices

The Center must contain the medical equipment and devices that are determined by a decision of the Minister in coordination with the rest of the health authorities.

Article (3)

Conditions for the Staff Working in the Center

Every natural or legal person applying for a license to establish a center in the Country must commit to providing the relevant health, technical and administrative staff necessary for the work of the Center. The Center's staff must meet the following conditions:

First: General Conditions:

a. He/ she should not have been sentenced to a freedom-restricting penalty for a crime involving moral turpitude or dishonesty, unless he/ she has recovered his/her civil rights;
b. He/ she should not have been dismissed from his job by a court ruling or a disciplinary decision was issued against him/ her to be dismissed from service due to dishonesty;
c. He/ she has not been previously convicted for violating the Medically Assisted Reproduction Technology's regulations and standards with regard to honesty in performing the job;
d. Any other criteria stipulated by the health authority

Second: Conditions for the Health and Technical Staff

In addition to the general conditions mentioned above, health and technical staff must fulfill the following:

a. Obtaining the necessary licenses from the competent health authority;
b. Holding the qualifications and experiences determined by a decision issued by the Minister in coordination with the rest of the health authorities.

Article (4)

Conditions and Controls for Multiple Egg Fertilization

When fertilizing a number of eggs that are sufficient for more than one implantation, Centers must take the maximum possible medical or other measures to prevent mixing the eggs with other samples or using them in contradiction with the provisions of the Law and this Resolution, by providing the following:

1. Schedule showing the steps followed for preservation;

2. A program confirming the location and time of preservation, along with ensuring that there is a special program that defines the procedures to be followed regarding identifying the owner of the samples, and the steps to be taken in the event of failure to find a sample of a person;
3. A program ensuring the success of preservation and the success ratios of such processes, provided that it includes the forms approved by the laboratory, along with indicating the number of years required to preserve the samples;
4. The mechanism followed according to the approved standards regarding the disposal of fertilized eggs through destructing them in the event of the death of one of the spouses or the occurrence of a divorce between them;
5. Separation of samples extracted from persons with an infectious disease from the rest of the preserved samples;
6. Obtaining the consent of the concerned persons to preserve the unfertilized eggs through freezing as per the relevant form;
7. Obtaining the consent of the concerned parties to preserve the semen through freezing as per the relevant form;
8. Adherence to the approved and applicable controls and forms in this area.

Article (5)

Conditions and Controls for Performing the Techniques of Medically Assisted Reproduction

When performing any of the Techniques of Medically Assisted Reproduction and preparing the implantable eggs, the Center must adhere to the following:

1. The number of times of ovarian stimulation to obtain eggs for the purpose of fertilization should not exceed 6 (six) times per year;
2. The number of embryos transferred to the uterus should not exceed two.

Article 6

Conditions and Controls for Conducting Research and Experiments

Subject to the provisions of Federal Decree-Law No. (4) of 2016 referred to herein, the Center may conduct research or experiments on unfertilized or fertilized eggs and sperms, in accordance with the following conditions and controls:

1. Refraining from conducting research or experiments for reproductive cloning;
2. Refraining from conducting research or experiments for selecting genetic features for a reproductive purposes;
3. Refraining from conducting research or experiments for commercial purposes;
4. Refraining from conducting research or experiments involving any kind of alteration of the human genome;
5. Obtaining a prior approval from the authority concerned with health research in the Ministry or the competent health authority before commencing the search;

6. The purpose of the scientific research should be one of the following:
   a. Increasing the knowledge regarding serious cases or diseases or other;
   b. Developing medications for serious cases or diseases or other;
   c. Developing medications for fertility problems;
   d. Increasing knowledge regarding problems leading to miscarriage;
   e. Developing the methods for detecting chromosomal abnormalities or genetic or mitochondrial disorders in embryos prior to implantation into the uterus;
   f. Increasing knowledge regarding embryonic development;
   g. Increasing knowledge regarding the processes of freezing gametes or embryos;
   h. Developing methods for detecting chromosomal abnormalities or genetic or epigenetic disorders in eggs and sperms (Epigenetics);
7. Fulfilling the conditions of scientific research legally established and approved by the Ministry or health authority;
8. Obtaining a written consent of each of the spouses or concerned parties, as the case may be;
9. The spouses or concerned parties may abstain from agreeing to or revoking conducting the research. Further, it is permissible to request its amendment at any stage of the research, and the Center must stop or amend the research once it is notified of the same, provided that this does not negatively affect the treatment of the spouses or concerned parties in the Center;
10. Before obtaining approval, the following information must be provided to the spouses or concerned parties:
    a. Clarifying to the spouses that abstaining from agreeing to the research will not negatively affect their treatment at the Center;
    b. Clarifying the purpose of the scientific research to be performed, and the impact that this research will have;
    c. The expected period to complete the research.
11. The principal researcher and the scientific research body must ensure that there is no conflict of interest between the Center and the spouses or the concerned parties;
12. When using gametes or embryos in research, the following should be taken into consideration:
    a. Refraining from using them in the search for other than the specific purpose of the search;
    b. The consent of the spouses or the concerned parties to conduct the research should not be the result of financial or in-kind consideration, or the result of physical or moral coercion, or that this consent is based on fraud or deception;
    c. Adhering to the previously approved search protocol and refraining from introducing any change thereto without new approval from the competent authority;

13. In the event that the search uses eggs or sperms taken from incapacitated persons, the prior written consent of the legal guardian or legal representative must be obtained for using these persons' eggs or sperms in this research;
14. Any other conditions and controls stipulated by the health authority

Article (7)

Obligations of the Center's Staff

The Staff of the Center shall perform their work as per the protocols applied regarding the Techniques of Medically Assisted Reproduction, adhere to strict organization in dealing with unfertilized sperms, eggs and embryos, exercise the utmost care and caution to prevent their use, exploitation or replacement in a way that leads to intermixing of genealogical lines, and in particular they must adhere to the following:

1. Adopting modern preventive measures against germs and viruses that cause infectious diseases, sterilizing all tools and bowls used, separating samples that are proven to be carrying communicable and infectious diseases to ensure that they are not mixed with sound samples at all stages of treatment in the embryology laboratory;
2. Ensuring that the nutrient medium does not contain any microbes, sterile and able to produce healthy genes;
3. Recording the degree of egg maturation, embryo assessment, and how to deal with immature and mature eggs;
4. Determining the quality and quantity of sperm to be used to complete the fertilization process;
5. Writing down full information about the treatment course in the medical file for each of the Center's clients, to include the following, as the case may be:
   a. The number of eggs taken from the ovary;
   b. The fate of each egg taken;
   c. The number of fertilized eggs;
   d. Characteristics of each fetus, the number of fetal cells, and gender of the fetus;
   e. The fate of each fetus (implantation, destruction, freezing, use for scientific research purposes, or any other action taken in its regard);
   f. Characteristics of the semen sample and the fate of unused samples;
   g. Writing down the name of the laboratory technician, director and treating physician along with their signature in the record of each patient undergoing treatment;
   h. Writing down the source of the nutrient medium and the source of the protein fluid used in the implantation process and the record must be signed by the laboratory technician and director;
   i. Coordinating between the treating technical and the medical staff to identify the fate of the transferred embryos and writing down these results in the relevant records;

6. The following information shall be written down by the laboratory official upon receiving a sample of the semen and attaching it to the sample:
   a. Time of receiving the sample;
   b. The way of receiving it;
   c. The time of the last intercourse;
   d. Extreme heat changes;
   e. The bowl does not contain the full sample;
   f. Indicate any problems regarding the sample's liquidity.
7. Identifying the features and characteristics of gases used in incubators and ensuring that they meet the medical specifications;
8. Ensuring the appropriateness of gas concentration ratios and internal environment temperature of the incubators and record these ratios;
9. Being aware of the measures taken in case it is not possible to obtain a certain degree of gas concentration in the incubators.

Article (8)

Conditions and Controls for Bringing Samples From or Sending Them Outside the Country

It is permissible to take samples of unfertilized or fertilized eggs or frozen sperms that were prepared inside the Country to outside the Country or to bring these samples into the Country if they were prepared outside it in accordance with the following regulations and procedures:

1. Bringing and sending fertilized eggs to or from the Country is only allowed for legally married spouses whose marriage is in conformity with the approved marriage contract laws;
2. The Center must obtain the following documents before any transfer:
   a. Copies all licenses and certificates of accreditation of the two centers (the transferor and transferee);
   b. Declarations and approvals signed by the spouses or concerned parties, as the case may be, regarding the procedures for bringing or sending the transferred samples;
   c. Results of the medical examination for infectious diseases of the transferred samples, namely: Hepatitis B, Hepatitis C, and Human Immunodeficiency Virus (HIV), which were performed while freezing, or any other examination determined by the health authority;

   These documents shall be kept in the medical file of the spouses or the concerned parties.
3. Patients wishing to transfer their frozen samples (gametes and/ or embryos) must be notified that the Center has the right to refuse to carry out the transfer for any legal or technical reasons it deems appropriate, and that transferring the sample to or from the Country must be carried out in accordance with the transfer standards approved by the health authority, and that the Center shall not accept any request violating any of the above conditions;
4. Verifying the identity of the spouses or the concerned parties wishing to carry out the transfer process and comparing it to the transfer request;

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5. The spouses or concerned parties wishing to carry out the transfer process shall sign a declaration of approval for the transfer process.

Article (9)

Genetic Diagnosis

Without prejudice to the provisions of Article (14) of the Law, it is permissible to perform the genetic diagnosis process using the techniques of genetic diagnosis of embryos before re-implantation in the uterus as per the following controls and procedures:

1. Determining the need for a genetic test before implantation in the uterus by a geneticist affiliated to or contracting with the Center within the genetic testing laboratories;
2. The Center must ensure that a multidisciplinary team participates in providing the genetic testing service, provided that the team includes specialists in the field of reproduction, an embryologist, and a geneticist;
3. Obtaining the written consent of the spouses wishing to conduct a genetic test, and the Center must ensure that the information that sets out the process is given, provided that it includes clarifications about the points included in the relevant form, in particular the following:
   a. The existence of genetic medical indications in the family or in one of the spouses that requires conducting the testing;
   b. The procedure followed and the risks involved;
   c. Genetic testing does not guarantee the occurrence of pregnancy, nor does it guarantee that there will be no miscarriage in the event of pregnancy;
   d. Financial costs and the psychological implications of pregnancy failure despite the genetic testing of embryos before implantation in the uterus;
   e. The rates and ratios of misdiagnosis with relation to these tests, including the possibility of mistaken or false results;
   f. When performing the genetic testing of embryos for diagnosing HLA-matched embryos, the Center must obtain a medical report from the treating physician of the affected sibling. This diagnosis is recommended for treating the affected sibling.

Article (10)

Action Forms

The forms stipulated in this Resolution shall be issued by a decision of the Minister in coordination with the rest of the health authorities

Article (11)

Executive Decisions

The Minister shall issue the necessary decisions to execute the provisions of this Resolution.

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Article (12)

Abrogation

Any provision that violates or is in conflict with the provisions of this Resolution shall be abrogated.

Article (13)

Publication and Enforcement of this Resolution

This Resolution shall be published in the Official Gazette, and shall enter into force from the day following the date of its publication.

Mohammed bin Rashid Al Maktoum

Prime Minister

Issued by us:

On Safar 14, 1442 A.H.

Corresponding to: October 1, 2020 A.D.

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