CFM Resolution - Federal Board of Medicine # 1957/2010

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CFM Resolution no. 1358/92 after 18 years of effectiveness has been amended regarding assisted reproduction, which has given rise to this resolution, which replaces it *in totum*.

THE FEDERAL BOARD OF MEDICINE, exercising the powers granted by Law no. 3.268, dated September 30, 1957, changed by Law no. 11.000, dated December 15, 2004, governed by Decree no. 44.045, dated July 19, 1958, and

WHEREAS the importance of human infertility as a healthcare issue, with medical and psychological implications, and the legitimacy of the desire to overcome it;

WHEREAS the advancement of scientific knowledge allows us to solve several human reproduction issues;

WHEREAS the assisted reproductive techniques have enabled the procreation under several circumstances, which was not possible through traditional procedures;

WHEREAS the need to conciliate the use of these techniques with the medical ethical principles;

WHEREAS, finally, the decision made in the plenary session of the Federal Board of Medicine on December 15, 2010,

DOES HEREBY RESOLVE

Article 1 - To adopt the ETHICAL RULES TO EMPLOY ASSISTED REPRODUCTIVE TECHNIQUES, attached hereto as a deontological device to be followed by all physicians.

Article 2 - This resolution is effective as of its publication, revoking CFM Resolution # 1.358/92, published in the DOU, section I, on November 19, 1992, page 16053.

Brasília-DF, December 15, 2010.

ROBERTO LUIZ D'AVILA	**HENRIQUE BATISTA E SILVA**
Chairman	**General Secretary**

SOLE ANNEX TO CFM RESOLUTION # 1.957/10

ETHICAL RULES TO EMPLOY ASSISTED REPRODUCTIVE TECHNIQUES

I - GENERAL PROVISIONS

1 - Assisted reproductive techniques (AR) are here to help us in solving human reproduction issues, enabling the procreation process when other therapeutics has proved to be ineffective or inappropriate.

2 - AR techniques can be employed as long as the actual probability of success exists and no serious risk to the patient's health or the potential offspring's health may exist.

3 - The informed consent is mandatory for all patients submitted to assist reproductive techniques, including donors. Medical issues involving the circumstances of application of an AR technique shall be provided in details, as well as the results obtained in that treatment site with the proposed technique. Information must also reach biological, legal, ethical, and economic level data. The informed consent shall be written in a special form and shall be deemed completed with the agreement, in writing, by those to be submitted to the assisted reproductive techniques.

4 - AR techniques must not be applied in order to choose the gender (sex selection) or any other biological characteristic of the future child, except to avoid diseases related to the gender of the child to be born.

5 - Fecundation of human oocytes is forbidden when with any purpose other than human procreation.

6 - The maximum number of oocytes and embryos to be transferred to the womb cannot exceed four. Regarding the number of embryos to be transferred, the following shall be observed: a) women of up to 35 years of age: up to two embryos; b) women between 36 and 39 years of age: up to three embryos; c) women over 40 years of age: up to four embryos.

7 - In the event of multiple pregnancies, arising from the employment of AR techniques, the use of procedures that intend to minimize embryos is forbidden.

II - AR TECHNIQUE PATIENTS

1 - All those capable who have requested the procedure and the indication of which does not fall far from the boundaries hereof, can receive the AR techniques as long as they are in agreement and fully aware about the subject, as per the applicable law.

III - REGARDING CLINICS, SITES, OR SERVICES EMPLOYING THE AR TECHNIQUES

Clinics, sites, or services employing the AR techniques are responsible for the control of infectious-contagious diseases, collection, handling, storage, distribution, transfer, and discharge of human biological material for the AR technique patient, all of which shall at least count on:

1 - a technical director in charge of all medical and laboratory procedures conducted, who shall obligatorily be a physician duly enrolled with the applicable Regional Board of Medicine.

2 - a permanent record (obtained through information observed or reported from a competent source) of the pregnancies, births, malformations of the fetuses or newborns from different AR techniques employed in the site in question, as well as from lab procedures related to the handling of gametes and embryos.

3 - A permanent record of the diagnostic proofs to which the human biological material to be transferred to the AR technique patients is submitted in order to avoid the transmission of diseases.

IV - GAMETES OR EMBRYOS DONATION

1 - Donation shall never be intended for profit or commercial gain.

2 - Donors cannot know the identity of the receivers and vice versa.

3 - Secrecy about the identity of the gamete and embryo donors and the receivers shall be obligatorily kept. In special situations, information about donors, for medical reasons, can be provided for the physicians only, being the civil identification of the donor kept confidential.

4 - Clinics, sites, or services using donation must kept on a permanent basis a clinical data record of overall issues, phenotypic characteristics, and a sample of the donors' cellular material.

5 - Where the site is located, the birth records shall avoid a donor from producing more than one pregnancy of child of different gender in a one-million inhabitants area.
6 - The choice of donors is under the site's responsibility. As much as possible, the site must make all efforts to assure a phenotypic and immunological resemblance between the donor and the receiver, as well as maximum compatibility potential to the receiver.

7 - The physician in charge of the clinics, sites, or services or the members of a multidisciplinary team working in those places is not allowed to participate as donors of AR programs.

V - GAMETES OR EMBRYOS CRYOPRESERVATION

1 - Clinics, sites, or services can cryopreserved sperm, eggs, and embryos.

2 - Of the total number of embryos produced in a laboratory, the exceeding number of viable embryos shall be cryopreserved.

3 - Upon cryopreservation, spouses or partners must express their will in writing about the destination given to the cryopreserved pre-embryos in the event of divorce, serious diseases, or passing of one of them or both and when they want to donate them.

VI - EMBRYOS DIAGNOSIS AND TREATMENTS

AR techniques can also be used in the preservation and treatment of genetic or hereditary diseases when perfectly indicated and with enough guarantees of diagnosis and therapeutics:

1 - Any intervention on *in vitro* embryos with diagnostic purposes cannot be intended to anything other than evaluate their viability or detect hereditary diseases, being the couple's informed consent mandatory.

2 - Any intervention with therapeutic purposes about in vitro embryos shall not be intended to anything other than treating a disease or preventing its transmission, with actual guarantee of success, being the couple's informed consent mandatory.

3 - The maximum term for development of *in vitro* embryos shall be of 14 days.

VII - REGARDING SURROGATE PREGNANCY (TEMPORARY WOMB DONATION)

Clinics, sites, or human reproduction services can use AR techniques to create a situation known as surrogate pregnancy, as long as there is a medical issue that prevent or contraindicate the genetic donor's own pregnancy.

1 - Temporary womb donors must belong to the genetic donor's family, related up to the second degree, being all other cases subjected to authorization by the Regional Board of Medicine.

2 - Temporary womb donation cannot be used for profit or commerce.

VIII – *POST MORTEM* ASSISTED REPRODUCTION

It does not constitute an unethical act the *post mortem* assisted reproduction as long as previously and specifically authorized by the deceased the use of cryopreserved biological material according to the applicable law.