

Registration and Regulation of ART in Taiwan

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Assisted Reproduction Law (draft)

Chapter I – General Provisions

Article 1

This Law is enacted in order to achieve a sound development of medically assisted procreation, to protect the rights and interests of infertile husbands and/or wives, and children borne through assisted reproduction, and to maintain the moral relationship and health of nationals as a whole. With regard to matters not provided for in this Law, the provisions of other relevant laws and regulations shall govern.

Article 2

The term "competent authority" as used in this Law shall refer to the Department of Health under the Executive Yuan.

Article 3

The following terms as used in this Law shall have the meanings as defined herein below:

1. Assisted reproduction: shall mean the technology to achieve the objective of pregnancy by means of artificial method other than sexual intercourse.
2. Husband and wife receiving Assisted reproduction: shall mean the husband and the wife receiving the Assisted reproduction.
3. Gamete: shall mean the spermatozoon and the ovum.
4. Embryo: shall mean a fertilized ovum.
5. Donor: shall mean the person who contributes the spermatozoon or the ovum to a husband or a wife receiving assisted reproductive procedure for him/her to conceive and to give birth to a fetus.
6. Surrogate mother: shall mean any female who has agreed with the husband and the wife receiving the assisted reproduction to provide her womb for nourishing and delivering the fetus on behalf of them.
7. Asexual reproduction: shall mean the technology used to give birth of offspring(s) by means of single cell nourishing rather than through the union of a spermatozoon and an ovum.

8. Infertility: shall mean sterility, or the case in which the wife were unable to become pregnant within one year or more after her wedding even if the husband and the wife have a normal sexual life and without using any contraception.

9. Mutual sperm and ovum donation: shall mean the arrangement for cross combination of the sperm and ovum of two or more married couples undergoing assisted reproduction.

10. Within-spouse assisted reproduction: shall mean the assisted reproduction to be effected using the sperm and ovum of married couple undergoing assisted reproduction.

Article 4

The provisions of this Law save the provisions set out in Item 7 of Article 17 and in Article 32 shall not apply to the within-spouse assisted reproduction to be effected by placing the sperm provided by the husband into the body of the wife.

Chapter II – Administration of Medical Institutions Engaging in Assisted Reproduction

Article 5

Assisted reproduction shall be performed by specifically qualified physicians of a medical institution permitted by the competent authority.

Regulations governing the conditions for granting the permission to a medical institution, under the preceding Paragraph, the permission application procedures, the specific qualification requirements for the physicians, and other matters subject to the administration shall be prescribed by the competent authority.

Any medical institution other than that as set forth in Paragraph One of this Article shall not accept, store or provide the gametes to be donated by any person.

Article 6

A medical institution engaging in Assisted reproduction shall establish its own assisted reproduction database management system, and shall appoint a staff to be exclusively in charge of the management of such data system.

Regulations governing the establishment and management of the database management system required in the preceding Paragraph, the use of the data stored therein, and other matters subject to database management shall be prescribed by the competent authority.

Article 7

The medical institution should conduct screening tests on the donated gametes and shall make the records of such screening tests.

Items of the screening tests of gametes referred to in the preceding Paragraph shall be designated by the competent authority.

Gametes may not be put to use unless otherwise qualified through screening tests thereof.

Article 8

The medical institution shall, before performing assisted reproduction, explain to the husband and wife receiving the operation the method of performance and the possibility of success of, and the complication (s) and danger which may occur from the assisted reproduction, and shall have such explanation reduced to writing for the consent of them.

The format of the written explanation as required in the preceding Paragraph shall be specified by the competent authority.

Article 9

The medical institution shall, after the wife receiving assisted reproduction has become pregnant, assist her in receiving routine prenatal examination and necessary prenatal diagnosis for any hereditary disease.

Chapter III – Performance of Assisted Reproduction

Article 10

The medical institution shall, before the husband and wife are ready to receive assisted reproduction or to accept the gamete donated by a donor, conduct the following examination and assessments:

1. General psychological, physiological, familial and social conditions;
2. Family history of diseases, including the records of hereditary diseases, and those of their respective lineal relatives by blood within the second degree of relationship, and the brothers and sisters;
3. The existence or non-existence of any hereditary disease or infectious disease which is detrimental to their health; and
4. Other matters requiring examination and assessment as required in a public notice published by the competent authority.

Regulations governing the scope of matters to be examined and assessed, the qualification of examiners, the procedures and records, and other mandatory rules for compliance in conducting the examinations and assessments set forth in the preceding Paragraph shall be defined by the competent authority.

Article 11

The medical institution may perform Assisted reproduction only for the husbands and wives who conform to any of the following requirements:

1. Where the husband's age is under 60, and the wife's age is under 50;
2. Where the results of examination and assessment conducted under the provisions of the preceding Article reveal that the husband and the wife are suitable for assisted reproduction;
3. Where either the husband or the wife has suffered from infertility which is not curable, or any other serious hereditary disease to the extent likely to give birth of abnormal son or daughter;

4. Where at least one of the married couple has health gametes and needs not or needs only to accept the sperm or the ovum donated by a third party;
5. Where the wife's womb is able to nourish and to give birth to a child; or
6. Where neither the husband nor the wife has already a son or a daughter developed from his/her own gamete.

Within-spouse assisted reproduction or an assisted reproduction using the embryo described in Paragraph Two, Article 21 of this Law based on the purpose of causing a second time live-birth shall be exempt from the restrictive condition set out in Item 6 of the preceding Paragraph.

Article 12

The medical institution may accept the gametes to be donated by a donor conforming to any of the following requirements:

1. A male of the age over 20 but under 50; or a female of the age over 20, but under 40;
2. A person suitable for donating his/her gametes as confirmed by the results of an examination and assessments conducted under Article 10 hereof;
3. A person making gratuitous donation of his/her gametes; or
4. A person who has not donated or has donated his/her gametes but without neither resulting in any live birth before nor having any retained storage of gametes.

Article 13

Before obtaining the consent of a donor to donate his/her gametes, the medical institution shall explain to him/her the scope of his/her rights and obligations; and shall obtain the consent of his/her spouse, if any.

The medical institution shall establish a file to maintain the personal data of each gamete donor, including his/her name, date of birth, serial number of his/her identity card or passport, and other relevant information of him/her as required for performance of assisted reproduction; and shall have such data/information reported to the competent authority for recordation.

The consent of a donor to be obtained in Paragraph One of this Article shall be reduced to writing in the format to be prescribed by the competent authority.

Article 14

In performing Assisted reproduction, the medical institution shall neither use the gametes of a specific donor as requested by the husband and/or wife receiving assisted reproduction, nor accept the gametes of a donor for exclusive use to any specific husband or wife as designated and requested by the husband or wife receiving the operation; except in the case where the gamete donor is a collateral relative by blood of the same rank and the same sex and within the fourth degree of relationship of the husband or the wife requiring to receive assisted reproduction.

The information regarding the race, skin color and blood group of the gamete donor shall be provided by the medical institution to the husband and wife receiving assisted reproduction for their reference.

Article 15

No assisted reproduction by means of combining the sperm and the ovum provided by the following relatives shall be performed:

1. Lineal relatives by blood;
2. Lineal relatives by marriage; or
3. Collateral relatives by blood within the sixth degree of relationship.

Article 16

Gametes donated by the same donor shall not be provided for use by two or more wives receiving assisted reproduction and the medical institution shall cease the use of such gametes after one wife receiving such gamete has successfully become pregnant.

Article 17

No assisted reproduction may be performed by any of the following means:

1. Using the gametes or an embryo provided for use in experimental or research activities
2. Using a surrogate mother;
3. By way of asexual reproduction;
4. By way of selecting the gender of the offspring;
5. By way of mutual donation of sperm and ovum;
6. Using an embryo which has been cultivated for a period over 14 days;
7. Using mixed sperms; or
8. Using frozen sperms imported from abroad.

Chapter IV – Protection of Gametes and Embryos

Article 18

After donation of gametes, the donor shall not demand for return thereof.

Article 19

A medical institution shall not make use of the gametes donated in accordance with this Law for any purpose other than for assisted reproduction.

Article 20

Under either of the following circumstances, the gametes donated shall be destroyed by the medical institution:

1. Where such gametes have been preserved for a period over 10 years; or
2. Where the use of such gamete by a husband and a wife receiving assisted reproduction has resulted in

a successful live birth

Article 21

Under any of the following circumstances, the gametes or embryos deposited in the medical institution by a husband and a wife desiring to receive assisted reproduction using such gametes shall be destroyed:

1. Where the wife desiring to receive the assisted reproduction has attained the age of fifty;
2. Where the husband desiring to receive the assisted reproduction has attained the age of sixty;
3. Where the husband and the wife desiring to receive assisted reproduction are divorced or either of them is deceased; or
4. Where such gametes have been preserved for a period over 10 years.

Where a embryos set forth in the preceding Paragraph were formed from the sperm or the ovum donated by other persons, such embryos shall also be destroyed, after they have been used successfully in achieving live-birth twice.

Article 22

The medical institution shall, after having destroyed the gametes or embryos under the provisions of the preceding two Articles, report such process to the competent authority for its recordation. Regulations governing the procedures, the deadline and other rules for compliance in connection with the destruction and reporting processes shall be prescribed by the competent authority.

Chapter V – Status of Children Borne through Assisted Reproduction

Article 23

The child or children which is (are) borne by a wife receiving the sperm donated by another person with the consent of her husband during the period of persistence of their marriage relationship shall be regarded as the children born within wedlock provided, however, that the husband may institute a denying action, if he can prove that his consent was given under a deception or coercion.

The denying action set forth in the preceding Paragraph shall be instituted within one year after the finding of the end of the deception or coercion claimed. But, no denying action may be instituted after elapse of one full year from the date of his awareness of the date of birth of the son or the daughter or after elapse of six full years from the date of birth of the child at issue.

The husband's consent to be given under Paragraph One hereinabove shall be reduced to writing and duly notarized by a notary public.

Article 24

The child (children) borne by a wife after her consent to receive the embryo formed by the sperm of her husband and the ovum donated by another person during the period of persistence of the marriage relationship between the wife and her husband shall be regarded as the child (children) born within wedlock. But

the wife may institute a denying action if the wife can prove that her consent was given under a deception or coercion.

The denying action set forth in the preceding Paragraph shall be instituted within one year after the finding of the end of the said deception or coercion provided, however, that no denying action may be instituted after elapse of six years from the date of birth of such child (children).

The wife's consent set forth in the preceding Paragraph shall be reduced to writing and duly notarized by a notary public.

If the denying action instituted by the wife under Paragraph One hereinabove is concluded with a final judgment in favor of the said wife, the donor of the ovum shall be entitled to adapt the said child (children) at issue.

Article 25

The provisions provided for in Article 1067 of The Civil Code shall not apply to the cases set forth in the two preceding Paragraphs.

Chapter VI – Preservation and Management of Artificial Reproduction Data or Information

Article 26

In performing Assisted reproduction, the medical institution shall make relevant medical history of each patient receiving such operation. Except for the medical history of a patient having given a live-birth which historical records shall be preserved for a period of 25 years, all other medical history of the patients having received assisted reproduction shall be maintained for the period(s) fixed in the Law Governing Medical Treatments.

The medical history of patient referred to in the preceding Paragraph shall contain the following particulars:

1. The portion relating to the husband and the wife receiving the assisted reproduction:

The name, residence (domicile), uniform number of the identity card or the passport number, the date of birth, the height, weight, blood group, skin color and hair color of the husband and the wife receiving the operation.

The medical examination and assessment records:

The uniform number of identity card or the passport number of, and the medical history of the donor of the gametes registered in the medical institution.

2. The portion relating to the donor of gametes:

The name, residence (domicile), uniform number of the identity card or the passport number, the date of birth, the height, weight, blood group, skin color, hair color, and race of the donor.

Name, quantity and date of donation of the item donated.

The medical examination and assessment records.

The reproduction copy of the medical history to be provided by a medical institution at the request of a husband and a wife receiving assisted reproduction in accordance with the provision of Item One, of the preceding Paragraph shall not contain the information described in Sub-Item Three of the preceding Paragraph.

Upon closedown of the medical institution, the medical history records set forth in Paragraph One of this Article shall be transferred to the competent authority for its preservation.

For custody of the medical history records set forth in the preceding Paragraph, the competent authority may charge the medical institution concerned with a records preservation cost at the rate to be determined by the competent authority.

Article 27

A medical institution engaged in performance of assisted reproduction shall submit to the competent authority the following information within a period to be specified by the competent authority:

1. The date of birth, sex, number of weeks in pregnancy, and the weight of the child (children) born through assisted reproduction.
2. The uniform number of the identity card or of the passport of the husband and the wife as well as of the donor of the gametes.
3. The type, subject, number of times and the possibility of success of the assisted reproduction performed;
4. Other matters as required by the competent authority per its public notice.

Article 28

Under any of the following circumstances, after a child borne through assisted reproduction using the gametes from a male or a female other than a married couple, he/she may, after having consulted a psychologist, apply to the medical institution and the competent authority for obtaining the information pertaining to such assisted reproduction arrangement:

1. Where the strain in his/her counterpart to the marriage is likely contrary to the provisions of Article 983 of The Civil Code;
2. Where the strain in him/her with the strain in his/her adopter or adopted are likely contrary to the provisions of Article 1073 of The Civil Code; or
3. Where the strain in him/her is likely contrary to the provisions regarding restrictions on the scope of relatives as set out in other laws and regulations.

The Regulations governing the definition and scope of the information, the manner and contents of the enquiring procedure and the psychological consultation, and other rules to be complied with in obtaining such information under the preceding Paragraph shall be prescribed by the competent authority.

Article 29

The competent authority, the medical institution concerned, and their respective personnel shall keep the confidentiality of the assisted-reproduction-related information which are in their possession or made

known to them while carrying out their respective functional duties, and shall not disclose or deliver such information to any other person, except under the law or upon request of judicial courts. The provisions of this Article shall remain applicable to those personnel after their separation from the competent authority or the medical institution concerned.

Chapter VII – Penal Provisions

Article 30

Any person who has violated the provisions of Article 15 or any of the provisions set out in Items 1 through 3 of Article 17 of this Law shall be punished with imprisonment for a term of not more than five (5) years, and may, in addition thereto, be imposed with a fine of not more than New Taiwan Dollar One Million and Five Hundred Thousand (NT\$1,500,000).

Article 31

Any person who engages in, with the intent to seek profit, the sale of gametes and/or embryo, or in mediating an assisted reproduction arrangement shall be punished with imprisonment for a term of not more than two (2) years, detention with labor service, and in addition thereto or in lieu thereof a fine of not more than New Taiwan Dollar Six Hundred Thousand (NT\$600,000).

The profit on property obtained by an offender of the crime set forth in the preceding Paragraph shall be recouped and confiscated provided, however, that if such profit or property cannot be recovered in full or in part from him, the purchase price of such transaction shall be recouped.

Article 32

Any person who has violated any of the provisions of Paragraph One, Article 14, Article 16, or Items 4 through 8 of Article 17 of this Law shall be punished with imprisonment for a term of not more than two (2) years, detention with labor service, or in addition thereto in lieu thereof a fine of not more than New Taiwan Dollar Six Hundred Thousand (NT\$600,000).

Article 33

Any person who has violated the provisions of provisions of Paragraph One or Paragraph Three, Article 5 of this Law shall be imposed with a fine of not less than New Taiwan Dollar One Hundred Thousand (NT\$100,000) but not more than New Taiwan Dollar Five Hundred Thousand (NT\$500,000). In addition, if he/she is involved in conducting the act of a physician without having the qualification as a physician, he/she shall be dealt with in accordance with the Physician Law.

Article 34

Any person who has violated any of the provisions set out in Paragraphs One through Paragraph Four, Article 26 of this Law shall be imposed with a fine of not less than New Taiwan Dollar One Hundred

Thousand (NT\$100,000) but not more than New Taiwan Dollar Five Hundred Thousand (NT\$500,000).

Article 35

Any person who has violated the provisions set out in Paragraph Three, Article 7; Paragraph One, Article 10; Article 11; Article 12; Article 19; or the Regulations as prescribed by the competent authority in accordance with the provisions set out in Paragraph Two, Article 10 of this Law shall be imposed with a fine of not less than New Taiwan Dollar Thirty Thousand (NT\$30,000) but not more than New Taiwan Dollar One Hundred and Fifty Thousand (NT\$150,000).

Article 36

Any person who has violated the provisions set out in Paragraph One, Article 6; Paragraph One, Article 7; Paragraph One, Article 8; Paragraph One or Two, Article 13; Article 20; Article 21, Article 27; or the Regulations as prescribed by the competent authority in accordance with the provisions set out in Paragraph Two, Article 6; Article 22; or Paragraph Two, Article 28, of this Law shall be imposed with a fine of not less than New Taiwan Dollar Twenty Thousand (NT\$20,000) but not more than New Taiwan Dollar One Hundred Thousand (NT\$100,000).

Article 37

Any medical institution or any physician which/who has violated any provision set out in this Law shall be punished in accordance with this Law, and in addition thereto, the competent authority may invalidate its/his/her permit or prohibit him/her from engaging in the performance of assisted reproduction for a specific period of time.

The medical institution whose permit is invalidated in accordance with the provisions of the preceding Paragraph shall not apply for a new permit within two (2) years from the date of invalidation of its original permit.

Article 38

The fines as fixed in this Law shall be imposed by the competent authority.

Article 39

Where the law violator fails to pay the fine imposed upon it/him/her upon expiry of the time limit fixed by the competent authority, the case shall be referred to the court for compulsory execution.

Chapter VIII – Supplemental Provisions

Article 40

Any medical institution which was previously permitted, prior to the promulgation of this Law, by the competent authority in accordance with the Regulations Governing Man-Aided Reproduction Technology

to engage in the performance of Assisted reproduction shall, within three (3) months from the effective date of this Law, file an application for permission under this Law; and shall not continue to engage in the performance of Assisted reproduction, if it fails to file such application prior to the deadline date set up for such filing, or its application is disapproved.

Article 41

The competent authority may, based on its operational requirement, appoint or entrust a relevant government agency (or an institution) to exercise the power of permitting, administering and supervising the assisted reproduction affairs as well as other relevant activities.

Article 42

The enforcement rules of this Law shall be prescribed by the competent authority.

Article 43

The effective date of this Law shall be fixed by the Executive Yuan.