

Assisted Reproduction Act

Promulgated under Presidential Decree Hua-Tsong 1 Yi No.09600035251 on March 21, 2007
Amended Article 3, Article 31 and Article 36, and promulgated by Presidential Order Hua Tsung (1) Yi Tzu No. 10600158851 on January 3, 2018

Chapter 1 General Principles

Article 1 This Act is enacted for the purpose of fostering the sound development of assisted reproduction, maintaining social ethics and health, and protecting the rights and interests of infertile couples, children conceived through assisted reproduction, and donors.

Article 2 The terms used in this Act are defined as follows:

1. Assisted reproduction: refers to the use of assisted means not involving sexual intercourse to achieve conception and birth with assistance from reproductive medicine.
2. Reproductive cell: refers to sperm and oocytes.
3. Recipient couple: refers to a husband and wife receiving assisted reproduction, where the wife's uterus can carry a fetus and give birth to a child.
4. Embryo: refers to a fertilized oocyte that has undergone division for less than eight weeks.
5. Donor: refers to a person who provides sperm or oocytes for fetal development and birth without compensation to a recipient couple.
6. Cloning: refers to techniques that produce an offspring from a single cell without the union of sperm and oocyte.
7. Mutual donation of sperm and oocytes: refers to an agreement between two identified recipient couples under which both women conceive via the union of sperm provided by the man in one couple and oocytes provided by the woman in the other couple.
8. Assisted reproduction institution: refers to medical care institutions and public interest judicial persons licensed by the competent authority to practice assisted reproduction.

Article 3 The competent authority of this Act is the Ministry of Health and Welfare.

Article 4 The competent authority shall call together relevant scholars, specialists, and representatives of private groups to establish an advisory committee, which shall consider the development of social ethics and medicine and maintenance of public health, and deliberate on the status of implementation of this Act on a regular basis.

The number of female members on the committee as prescribed in the preceding paragraph shall not be less than half of all the committee members.

Article 5 This act shall not apply to assisted reproduction where the oocyte and sperm are from the husband and wife, except for Article 16, Subparagraph 3 of this Act and related penal provisions as provided in this Act.

Chapter 2 Administration of Medical Care Institutions Performing Assisted Reproduction

Article 6 A medical care institution shall not perform assisted reproduction or accept, store, or provide donated reproductive cells unless and until submitting the application to and a permit is issued by the competent authority.

A public interest judicial person shall not accept, store, or provide donated sperm unless and until submitting the application to and a permit is issued by the competent authority.

The permit as prescribed in the proceeding Paragraph 1 and 2 is valid for three years. Application for renewal shall be filed within three months prior to the expiration with the competent authority if continued performance of the services as described in the proceeding

paragraphs after the expiration is desired. Regulations governing the conditions of permits, application procedures, and other binding matters shall be prescribed by the competent authority.

Article 7 Assisted reproduction institutions shall perform the following tests and assessments of recipient couples and donors before performing assisted reproduction or accepting donated reproductive cells.

1. General psychological and physiological state.
2. Family disease history, including records of hereditary diseases of the person in question and blood relatives within the fourth degree of kinship.
3. Suspected hereditary or infectious diseases affecting ability to give birth.
4. Other matters designated and announced by the competent authority.

Assisted reproduction institutions shall make records of the testing and assessment as prescribed in the proceeding paragraph.

Article 8 An assisted reproduction institution shall not accept reproductive cells donation unless the donor meets the following criteria :

1. Men at least 20 and less than 50 years of age; women at least 20 and less than 40 years of age.
2. The results of testing and assessment as prescribed in the proceeding article confirm the suitability of the donor.
3. The donor agrees to donate without compensation.
4. The donor has never donated sperm or oocytes before, or the donor's previously donated reproductive cells never helped any recipient couple complete live birth and were not stored.

A recipient couple may, within the monetary amount or price limit set by the competent authority, commission the assisted reproduction institution to provide a nutrition allowance or nutrition products to the donor, or may pay for the donor's necessary testing, medical, and transportation expenses and loss of working time.

An assisted reproduction institution shall check with the competent authority concerning the criteria as prescribed in Paragraph 1, Subparagraph 4, and shall not use the donor's sperm or oocytes until the competent authority provides confirmation.

Article 9 Before accepting donated reproductive cells, an assisted reproduction institution shall explain to the donor related rights and responsibilities, and obtain the donor's understanding and written consent.

Assisted reproduction institutions shall make records of the following information when accepting donated reproductive cells:

1. The donor's name, address, national ID card number or passport number, date of birth, height, body weight, blood type, skin color, hair color, and ethnicity.
2. The donated items, quantity, and date.

Article 10 Assisted reproduction institutions shall not provide reproductive cells donated by a single donor to two or more recipient couples at the same time, and shall immediately cease providing reproductive cells from the same donor after a recipient couple successfully achieves pregnancy; Article 21 of this Act shall be complied with after that recipient couple completes a live birth.

Chapter 3 Implementation of Assisted Reproduction

Article 11 A medical care institution shall not perform assisted reproduction for a married couple

unless all the conditions in the following subparagraphs are satisfied:

1. The results of testing and assessment implemented in accordance with Article 7 confirm suitability to receive assisted reproduction.
2. The husband or wife of the married couple has been diagnosed as suffering from infertility, or has been diagnosed as suffering from a major hereditary disease designated by the competent authority, and it is suspected that natural conception and birth will cause abnormal children.
3. At least one member of the married couple possesses healthy reproductive cells, and that person has no need accepting donated sperm or oocytes.

Where the condition prescribed in Subparagraph 2 of the proceeding paragraph is not met but the married couple has a legitimate medical reason, they may receive assisted reproduction after reporting to and obtaining approval from the competent authority.

Article 12 A medical care institution must explain the necessity of assisted reproduction, the implementation technique, the success rate, any possible complications or hazards, and possible alternative treatment methods to the recipient couple, and obtain the couple's understanding and written consent of both persons before performing assisted reproduction.

Where the implementation of assisted reproduction involves the recipient couple's acceptance of sperm donated by a third party, the performing medical care institution shall obtain the husband's written; where the procedure involves the acceptance of oocytes donated by a third party, the medical care institution shall not perform assisted reproduction unless and until obtaining the written consent of the wife.

The written consent as prescribed in the proceeding paragraph shall be notarized by a notary public.

Article 13 A medical care institution performing assisted reproduction shall not use a specific donor's reproductive cells as requested by the recipient couple; a medical care institution shall not use donated reproductive cells for a specific recipient couple as requested by the donor.

Medical care institutions shall provide information concerning the donor's ethnicity, skin color, and blood type for the reference of the recipient couple.

Article 14 A medical care institution performing assisted reproduction shall make the following information recorded:

1. The name, address, national ID card number or passport number, date of birth, height, body weight, blood type, skin color, and hair color of the husband and wife of the recipient couple.
2. The donor's national ID card number or passport number and case history number at the medical care institution.
3. Progress of assisted reproduction performance.

When a medical care institution provides a copy of the medical records as prescribed in the proceeding paragraph at the recipient couple's request, the information prescribed in Subparagraph 2 of the proceeding paragraph shall not be released.

Article 15 Where a donated sperm and oocytes are used for assisted reproduction, sperm and oocytes from the following relatives shall not be united:

1. Direct blood relatives.
2. Direct relatives by marriage.
3. Collateral blood relatives within the fourth degree of kinship.

The competent authority shall make regulations governing applicants for kinship verification, the responsible agency, the verification method, content items, verification procedures, and other binding matters concerning kinship verification as prescribed in the proceeding paragraph in conjunction with the central household registration competent authority.

Article 30 of this Act shall not apply where violation of Paragraph 1 of this article is due to missing or erroneous information derived by following the regulations prescribed by the competent authority as provided in the proceeding paragraph.

Article 16 Any of the circumstances or methods prescribed in following subparagraphs is prohibited while performing assisted reproduction:

1. Using reproductive cells or embryos provided exclusively for research purposes.
2. Creating a human embryo other than by fertilisation.
3. Selection of the embryo's sex. This restriction shall not apply, however, when there is a reason connected with hereditary disease.
4. Mutual donation of sperm and oocytes.
5. Using embryo cultured in vitro for more than seven days.
6. Implantation of more than five embryos at a time.
7. Using of mixed semen.
8. Using of donated reproductive cells imported from outside the country.

Article 17 Where assisted reproduction implemented by a medical care institution constitutes a human subject research as provided in the Medical Care Act, the regulations of the Medical Care Act shall be complied with.

Article 18 After a recipient woman becomes pregnant, the performing medical care institution shall recommend that the woman receive routine pre-birth check-ups and, if needed, recommend that the woman receive a prenatal diagnosis.

Chapter 4 Protection of Reproductive Cells and Embryos

Article 19 Donors shall not request the return of any donated reproductive cells. But where a donor is diagnosed or proven as having a functional impairment of reproduction by a physician, that donor may request the return of any reproductive cells that have not been destroyed.

Article 20 Donated reproductive cells accepted by an assisted reproduction institution may be transferred to another assisted reproduction institution for use in assisted reproduction if the donor's prior written consent is obtained.

Article 21 An assisted reproduction institution shall destroy donated reproductive cells where one of the following conditions is satisfied:

1. The recipient couple has completed one live birth using the donated cells.
2. The cells have been preserved for more than ten years.
3. It has been discovered after donation that the cells are unsuitable for use in assisted reproduction.

An assisted reproduction institution shall destroy a recipient couple's reproductive cells where one of the following conditions is satisfied:

1. The providers of the reproductive cells have asked for their destruction.
2. The providers of the reproductive cells have died.
3. The reproductive cells have been preserved for more than ten years. But the preservation period may be extended to the date assigned by the providers of the reproductive cells if their written

consent is obtained.

An assisted reproduction institution shall destroy an embryo created for a specific recipient couple where one of the following conditions is satisfied:

1. The marriage of the recipient couple is invalid or annulled, the couple divorces, or one spouse dies.
2. The embryo has been preserved for more than ten years.
3. The recipient couple has given up attempting assisted reproduction.

The reproductive cells or embryos preserved by an assisted reproduction institution should be destroyed if the assisted reproduction institution terminates its business operations. But such donated reproductive cells may be transferred to another assisted reproduction institution with the donor's written consent. A recipient couple's reproductive cells or embryos may be transferred to another assisted reproduction institution for continued preservation with the recipient couple's written consent.

Any reproductive cells or embryos that should be destroyed as provided in the proceeding four paragraphs may be preserved for research purposes, provided that the written consent of the donor or recipient couple is obtained and permission of the competent authority is granted .

Article 22 An assisted reproduction institution shall not use reproductive cells donated in accordance with this Act, the reproductive cells of the recipient couple, or embryo produced by a recipient couple for any purposes other than assisted reproduction, except for research purposes as provided in Paragraph 5 of the proceeding article.

Chapter 5 Status of Children Conceived through Assisted Reproduction

Article 23 Any child born to a married woman and conceived through the use of donated sperm with the consent of her husband shall be considered a child born in wedlock.

Where the husband can prove that his consent as described in the proceeding paragraph was obtained by fraud or coercion, he may bring a law suit for denial of paternity not later than six months after the fraud or coercion has ceased. But where his consent was obtained by fraud, such a law suit is barred after three years of the child's birth.

Article 1067 of the Civil Code shall not apply to any part of this article.

Article 24 Any child born to a married woman and conceived through the use of her husband's sperm and donated oocytes with her consent shall be considered a child born in wedlock.

Where the wife can prove that her consent as described in the proceeding paragraph was obtained by fraud or coercion, she may bring a law suit for denial of her parental status not later than six months after the fraud or coercion has ceased. But where her consent was obtained by fraud, such a law suit is barred after three years of the child's birth.

Article 25 If a marriage is annulled or found to be invalid after a wife has conceived, a child or children born to that wife shall be considered a child or children born to the recipient couple in wedlock.

Chapter 6 Preservation, Management, and Utilization of Data

Article 26 Records as prescribed in Article 7, Paragraph 2; Article 9, Paragraph 2; and Article 14, Paragraph 1 shall be produced and preserved in compliance with regulations as provided in the Medical Care Act.

Article 27 Assisted reproduction institution shall notify the following information to the competent authority, and the competent authority shall establish an assisted reproduction database to

manage such information:

1. Testing and assessment performed in accordance with the regulations of Article 7, Paragraph 1.
2. The donations of donors performed in accordance with the regulations of Article 9, Paragraph 1.
3. Assisted reproduction implemented in accordance with the regulations of Article 12, Paragraph 1.
4. The destruction of reproductive cells or embryos in accordance with the regulations of Article 21, Paragraphs 1 through 4.
5. An assisted reproduction institution shall actively report relevant information including the number of persons receiving assisted reproduction, success rate, reasons for infertility, and assisted reproduction techniques used on an annual basis. The competent authority shall make regular public reports containing the foregoing data.

The competent authority shall make regulations governing the deadlines, content, format, procedures, and other binding matters for notification as prescribed in the proceeding paragraph.

Article 28 An assisted reproduction institution implementing assisted reproduction, accepting, storing, or providing donated reproductive cells shall assign a specific person to be responsible for information notification as provided in the proceeding article.

Article 29 Children conceived through assisted reproduction, or their statutory agents, may apply to query the competent authority where one of the following conditions is satisfied:

1. Their marriage partner is suspected of violating Article 983 of the Civil Code.
2. An adopted person is suspected of violating Article 1073-1 of the Civil Code.
3. It is suspected that other laws or regulations restricting the scope of relation have been violated.

The competent authority shall make regulations governing the scope of applicable queries, query procedures, content, and other binding matters for queries as provided in the proceeding paragraph.

Chapter 7 Penal Provisions

Article 30 Whoever violates Article 15 or Subparagraphs 1 or 2 of Article 16 shall be punishable with imprisonment for not more than five years, and may additionally be fined not more than NT\$1.5 million.

Article 31 Whoever engages in the business of sale or brokering of reproductive cells or embryos in respect of profit shall be punishable with imprisonment for not more than two years, detained and/or fined between NT\$200,000 and NT\$1 million.

Article 32 Whoever violates Article 10; Article 13, Paragraph 1; or Subparagraphs 3,4,5,6,7, or 8 of Article 16 shall be fined between NT\$200,000 and NT\$1 million.

Article 33 Whoever violates Paragraphs 1 or 2 of Article 6, Paragraph 1 of Article 8, or Article 11 shall be fined between NT\$100,000 and NT\$500,000.

Article 34 Whoever violates Paragraph 1 of Article 7, Paragraph 3 of Article 8, Paragraph 1 of Article 9, Article 12, Article 20, Article 21, Article 22, or any subparagraph of Paragraph 1 of Article 27 shall be fined between NT\$30,000 and NT\$150,000.

Whoever violates Paragraphs 1, 2, 3, or 4 of Article 21 shall be subject to the penalties in the proceeding paragraph and shall also be ordered to make improvement within a prescribed period; failure to comply with such improvement orders within said period may subject to consecutive fines.

Article 35 Physicians in violation of Paragraph 1 or 2 of Article 6, Paragraph 1 of Article 8, Article 10, Article 11, Article 15, or Article 16 shall be subject to disciplinary sanctions as provided in the Physician Act.

Article 36 Whoever obtains consent described in Paragraph 1 of Article 23, or Paragraph 1 of Article 24 by fraud or coercion shall be subject to imprisonment for not more than three years.

Whoever solicits or abets another person to commit the crimes as described in the proceeding paragraph, shall be guilty of the crime and punished.

Any violation of this article shall be indictable only upon complaint.

Article 37 Any permit issued to an assisted reproduction institution pursuant to Paragraph 1 or 2 of Article 6 may be revoked by the competent authority where one of the following conditions is satisfied:

1. The holder of the permit has been punished under Article 32.
2. The representative, an employee, or other working personnel of a medical care institution violated Article 30, and his/her the sentence has been confirmed.

Where an assisted reproduction institution violates Paragraph 1 or 3 of Article 8, Article 11, Article 20, Paragraph 5 of Article 21, or Article 22, the competent authority shall order the institution to cease performing assisted reproduction or accepting, storing, or providing reproductive cells within a prescribed period in addition to imposing the penalties as prescribed in Articles 33 or 34,

An assisted reproduction institution whose permit has been revoked under the proceeding Paragraph 1 may not re-apply for a permit as prescribed in Paragraph 1 or 2 of Article 6 within two years after the effective date of revocation.

Article 38 The fines prescribed in this Act shall be imposed by the special municipality or county or city government.

Chapter 8 Supplementary Provisions

Article 39 Any medical care institutions permitted to perform assisted reproduction by the competent authority under the Regulations Governing Assisted Reproductive Technologies prior to the implementation of this Act shall apply for a permit as provided in this Act within six months after this Act takes effect. Any institutions that fail to apply or obtain a permit prior to the deadline above shall not perform assisted reproduction; violators shall be subject to punishment under Article 33 of this Act.

Article 40 This Act shall take effect on the date of promulgation.