Regulations for Artificial Reproduction Information Notification andAdministration

Promulgated by Shu-Sho-Guo-Tzu Order No.0960400731 on August 8, 2007
Article 5、11、12 amended by Shu-Sho-Guo-Tzu Letter No.1000400497 on April 7, 2011.
Article 14 amended by Bu-Sho-Guo-Tzu Letter No.1020410297 on September 18, 2013.
Attached Form 2 and Attached Form 7 amended by Bu-Sho-Guo-Tzu Letter No.1040400687 on April 20, 2015.

Article 1 These Regulations are prescribed pursuant to Article 27, Paragraph 2 of the Artificial Reproduction Act (hereinafter referred to as "this Act").

Article 2 An artificial reproduction institution (hereinafter referred to as "Institution") shall notifythe following artificial reproduction information to the competent authority:

1. Health examination and assessment of reproductive cell donor;
2. Results of operations involving donated reproductive cells;
3. Information concerning the incomplete donation, return, destruction, or transfer of reproductive cells or embryos created from donated reproductive cells;
4. Information concerning all the initiated cycles with or without the use of ovulation induction drugs in artificial reproduction cases;
5. Artificial reproduction cases data;
6. Information concerning destruction of recipient couples' reproductive cells or embryo.

Article 3 An Institution shall fill out and submit a Reproductive Cell Donation Checking Application Form (Attached Form 1) and apply to the competent authority for checking prior to receiving reproductive cells donation.

Article 4 The competent authority shall record the donor data to an artificial reproduction database after it receives a checking application as described in the proceeding article.Where the donor data complies with the regulations of Article 8, Paragraph 1,Subparagraph 4 of this Act, it shall be classified as control data for subsequent management。

Where the competent authority discovers that the donor in question is already listed by another Institution when processing a checking application, it shall notify the applicant Institution in writing that it shall not accept a donation from that donor, and that any reproductive cells already obtained from that donor must be destroyed.

Article 5 After the donor’s qualification to donate sperm is confirmed by the checking process, the Institution may obtain the donor's sperm on separate occasions within six months upon the first obtainment of the donor’s sperm.The Institution must confirm that the donor's health status is suitable

for donation, and shall not simultaneously provide sperm from a single donor to two or more recipient couples.

Article 6 The donor’s information classified as control data under Article 4 shall not be removed from control unless one of the following conditions is satisfied:

1. The donor has not actually completed donation procedures, and the competent authority has been notified.
2. The donor's reproductive cells or embryos created from donated reproductive cells have been completely destroyed, and the competent authority has been notified.
3. The donor's reproductive cells or embryos created from donated reproductive cells have been used but did not result in a live birth and were not stored after the operation, and the competent authority has been notified.

Article 7 An Institution shall fill out and submit a Reproductive Cell Donor Health Examination and Assessment Notification Form (Attached Form 2) within 14 days after the date of completion of health examination and assessment as provided in Article 7, Paragraph 1 of this Act.

Article 8 Where the performance of artificial reproduction for a recipient couple uses donated reproductive cells or embryos created from donated reproductive cells, the Institution shall fill out and submit the first leaf of a Donated Reproductive Cell Operation Results Notification Form (Attached Form 3) within 12 weeks after the date of the operation,and shall fill out and submit the second leaf of the same form within two months after the estimated date of childbirth.

Article 9 Where one of the following conditions is satisfied, the Institution shall fill out and submit a Notification Form for Failure to Complete Donation, Return, Destruction, or Transfer of Reproductive Cells or Embryos Created from Donated Reproductive Cells (Attached Form 4) within two months after the date of its satisfaction:

1. A donor whose data is classified as control data under Paragraph 1 of Article 4 fails to complete donation.
2. The Institution returns undestroyed donated reproductive cells to a donor as provided in the proviso to Article 19 of this Act.
3. The Institution destroys donated reproductive cells or embryos created from donated reproductive cells as provided in Article 21, Paragraphs 1 through 4 of this Act.

When donated reproductive cells or embryos created from donated reproductive cells are transferred as provided in Article 20 and Article 21,

Paragraph 4 of this Act, the transferring Institution shall provide photocopies of attached forms 1 through 3 for the case, the written consent forms of the donor or recipient couple, and the competent authority's response to the transferee Institution for preservation, and the transferee Institution shall sign Attached Form 4 as confirmation.

The transferring Institution as described in the proceeding paragraph shall notify the competent authority by submitting Attached Form 4 within two months after the date of completion of transfer.

Article 10 An Institution shall fill out and submit a weekly Case Report Form for All the Initiated Cycles with the Used of Ovulation Induction Drugs in Artificial Reproduction (Attached Form 5) for the cases receiving treatment during the previous week.

The Institution shall conduct a health examination and assessment of recipient couples in accordance with the items listed in Attached Form 6, and shall record the results in Attached Form 5.

Article 11 An Institution shall file an Artificial Reproduction Case Data Form (Attached Form 7) quarterly for the previous quarter via a reporting system designated by the competent authority.

Article 12 An Institution shall file a Notification Form for Destruction of Reproductive Cells or Embryos from Recipient Couples (Attached Form 8) annually for the previous year via a reporting system designated by the competent authority.

Article 13 The competent authority may inspect an Institution's artificial reproduction data whenever necessary.

Article 14 The competent authority shall assign its subordinate Health Promotion Administration or commission a relevant group to perform any of the matters prescribed in these Regulations and in Article 27, Paragraph 1 of this Act.

Article 15 These Regulations shall take effect on the date of promulgation.

Attached Form 1

Reproductive Cell Donation Checking Application Form

I. Institution name:___ Institution code: □□□□□

II. Application date:___ (y)___ (m)___ (d)

III. Donor data

1. Name:___ 2. Date of birth:___ (y)___ (m)___ (d)

3. National ID card number: □□□□□□□□□□

4. Alien resident certificate ID number (Note 1): □□□□□□□□□□

5. Foreigner passport number: □□□□□□□□□□

6. Sex: □1.M □2.F

7. Registered address (Note 2): _____ (county/city) _____ (city/township/district) _____ (village) _____ (road/street) _____ (section) _____ (lane) _____ (alley) _____ (no.) _____ (floor) _____

8. Nationality and ethnicity:

(1) ROC

Please check □1. Fukien □2.Hakka □3.Native

□4. Mainland Chinese □9.Other

(2) Foreigner (nationality: _____)

9. Skin color: □1.Yellow □2.White □3.Black

□4. Brown □9.Other _____)

Operating physician:___

Date received: ____(y)____(m)____(d) Accepted by:_____

Note 1: Foreigners who do not have a national ID card shall fill out items 4 and 5; foreigners with no alien resident certificate ID may submit equivalent identification documents from their country of origin, and fill in the serial number on those documents.

Note 2: Foreigners shall fill in their address in Taiwan.

Instruction: The first leaf of this form shall be sent to the competent authority by registered mail; the competent authority shall review and respond to this form in accordance with Article 8, Paragraph 1, Subparagraph 4 of the Artificial Reproduction Act. The Institution shall preserve the second leaf.

Attached Form 2

Reproductive Cell Donor Health Examination and Assessment Notification Form

I. Institution name: _____ Institution code: ☐☐☐☐☐

II. Donor data:

1. Name: _____ 2. Date of birth: _____(y) _____(m) _____(d)
3. National ID card number: ☐☐☐☐☐☐☐☐☐☐
4. Alien resident certificate ID number (Note): ☐☐☐☐☐☐☐☐☐☐
5. Foreigner passport number: ☐☐☐☐☐☐☐☐☐
6. Case history number: _____

III. To be filled out by donor:

1. Skin color: ☐1.Yellow ☐2.White ☐3.Black ☐4.Brown ☐9. Other _____
2. Hair color: ☐1. Black ☐2. Brown ☐3.Blond ☐4. Red ☐9. Other _____
3. Are you an intravenous drug user? ☐0. No ☐1.Yes
4. Are any of your sex partners members of an AIDS risk group? ☐0. No ☐1.Yes ☐9. Don't know
5. Have you had more than one sex partner during the last six months? ☐0. No ☐1.Yes
6. Have you experienced difficult urination during the last six months? ☐0. No ☐1.Yes
7. Have you had urethral secretions during the last six months? ☐0. No ☐1.Yes
8. Have you had any ulcers of the reproductive organs during the last six months? ☐0. No ☐1.Yes

*9. Do you have a history of chromosomal abnormalities ☐0.No ☐1.Yes

*10. Do you have a history of hemophilia ☐0.No ☐1.Yes

*11. Epilepsy ☐0.No ☐1.Yes

12. Dwarfism ☐0.No ☐1.Yes
13. Congenital deafness ☐0.No ☐1.Yes
14. Marfan's syndrome ☐0.No ☐1.Yes
15. Family history of color blindness ☐0.No ☐1.Yes
16. Other hereditary diseases ☐0.No ☐1.Yes
17. Have you or any family member to the fourth degree of kinship obtained a disability handbook?

    ☐0.No ☐1.Yes: Relationship: _____ Type of disability: _____

    Disability level: _____ Reason for occurrence: _____

18. Do you or any family member to the fourth degree of kinship suffer from a

hereditary disease?

☐0.No ☐1.Yes: Relationship: _____ Name of disease: _____

19. Have you obtained a major sickness and injury card?

☐0.No ☐1.Yes Name of disease: _____

I hereby certify that the information provided above is truthful and correct. I am willing to bear all legal responsibility for any falsehood or fabrication.

Signature and seal of donor:_____Date filled out:___(y)___(m)___(d)

IV. Health assessment items [to be filled out by the institution]

General physiological examination: ☐No ☐Yes	Other major diseases:
Mental illness: ☐No ☐Yes	Diabetes ☐No ☐Yes Test items: _____
Infectious disease:	Thalassemia ☐No ☐Yes Test items: _____
* AIDS ☐No ☐Yes Test items: _____	Chlamydia ☐No ☐Yes Test items: _____
* Syphilis ☐No ☐Yes Test items: _____	Cervical Smear test results: _____
* Gonorrhea ☐No ☐Yes Test items: _____	Other (please state) _____
Hepatitis B surface antigen ☐No ☐Yes Test items: _____	ABO blood type Results: _____
Hepatitis C ☐No ☐Yes Test items: _____	RH(+) or (-) Results: _____

V. Health examination and assessment results: ☐ 1. Suitable for donation ☐2. Not suitable for donation, reason: _____

I hereby certify that I have discussed the foregoing questions with the donor and have explained to him/her related rights and responsibilities; the donor's understanding and written consent have been obtained.

Physician: _____

Assessment completion date: (y) (m) (d)

Date received: ___(y)___(m)___(d) Accepted by:_____

Note: Foreigners who do not have a national ID card shall fill out items 4 and 5; foreigners with no alien resident certificate ID may submit equivalent identification documents from their country of origin, and fill in the serial number on those documents.

Instruction:

1. Disease items marked with an "*" absolutely rule out donation.
2. This form shall be sent to the competent authority by registered mail within 14 days from the assessment completion date (based on postmark date); the Institution shall preserve the second leaf.

Attached Form 3

Donated Reproductive Cell Operation Results Notification Form

I. Institution name: _____ Institution code: □□□□□

II. Donor data:

1. Name: _____ 2. Date of birth: _____(y) _____(m) _____(d)

3. National ID card number: □□□□□□□□□□

4. Alien resident certificate ID number (Note): □□□□□□□□□□

5. Foreigner passport number: □□□□□□□□□□

6. Sex: □1.M □2.F

III. Acquisition of donated reproduction cells

□ Sperm, date obtained: _____(y) _____(m) _____(d),

Date of completion of follow-up HIV test: ___(y) ___(m) ___(d),

Test results: □negative □ positive

Was the sperm transferred from a sperm bank? □1.Yes □2.No

□ Oocytes, date obtained: _____(y) _____(m) _____(d)

IV. Operation (implantation) date: _____(y) _____(m) _____(d)

V. Recipient woman data:

1. Name: _____ 2. Date of birth: _____(y) _____(m) _____(d)

3. National ID card number: □□□□□□□□□□

4. Alien resident certificate ID number (Note): □□□□□□□□□□

5. Foreigner passport number: □□□□□□□□□□

VI. Recipient man data:

1. Name: _____ 2. Date of birth: _____(y) _____(m) _____(d)

3. National ID card number: □□□□□□□□□□

4. Alien resident certificate ID number (Note): □□□□□□□□□□

5. Foreigner passport number: □□□□□□□□□□

VII. Following this operation, are any of the donor's reproduction cells or embryos

created from the donor's reproductive cells still in storage?

☐ 0. No longer in storage

☐ 1. Still in storage, type of storage: ☐ sperm ☐ oocytes ☐ embryo

VIII. Operation method:

☐ 1. In vitro fertilization and embryo implantation

☐ 2. Sperm and oocyte implantation

☐ 3. Fertilized oocytes/embryo Fallopian tube implantation

☐ 4. Artificial insemination (frozen sperm) ☐ 5. Frozen embryo

IX. Result to recipient woman 12 weeks after operation:

☐ 1. Not pregnant ☐ 2. Pregnant ☐ 3.Pregnant but miscarried

☐ 9. Other (please state): _____

Notification date: ____(y) ____(m) ____(d) Operating physician: _____

Date received: ____(y) ____(m) ____(d) Accepted by: _____

(First leaf)

X. Pregnancy of recipient woman:

☐ 1. Ectopic pregnancy ☐ 2. Miscarriage ☐ 3. Dead fetus or stillborn ☐ 4.Live birth ☐ 9. Other (please state):

Date of occurrence: _____(y) _____(m) _____(d)

Live born infant data

Date of birth: _____(y) _____(m) _____(d) Weeks of pregnancy : _____ weeks

Number of births: ☐1.Single birth ☐2. Twins ☐3.Triplets or above (please fill in the following infant data in accordance with birth order)

Sex	Body weight	Health situation
☐ M ☐ F	Aprox._____ g	☐ normal ☐ malformed

☐ M ☐ F	Aprox._____ g	☐ normal ☐ malformed
☐ M ☐ F	Aprox._____ g	☐ normal ☐ malformed
☐ M ☐ F	Aprox._____ g	☐ normal ☐ malformed

Notification date: (y) (m) (d) Operating physician: _____

Date received: (y) (m) (d) Accepted by: _____

Note: Foreigners who do not have a national ID card shall fill out items 4 and 5; foreigners with no alien resident certificate ID may submit equivalent identification documents from their country of origin, and fill in the serial number on those documents.

Instruction: The first leaf of this form shall be sent to the competent authority within 12 weeks after the date of operation; the second leaf shall be sent to the competent authority by registered mail within two months after the estimated date of birth (based on postmark date); the Institution shall preserve the third leaf.

(Second leaf) (Third leaf)

Attached Form 4

Notification Form for Failure to Complete Donation, Return, Destruction, or Transfer of Reproductive Cells or Embryos Created from Donated Reproductive Cells

I. Institution name: _____ Institution code: □□□□□

II. Donor data:

1. Name: _____ 2. Date of birth: _____(y) _____(m) _____(d)

3. National ID card number: □□□□□□□□□□

4. Alien resident certificate ID number (Note): □□□□□□□□□□

5. Foreigner passport number: □□□□□□□□□

III. Recipient woman data:

1. Name: _____ 2. Date of birth: _____(y) _____(m) _____(d)

3. National ID card number: □□□□□□□□□□

4. Alien resident certificate ID number (Note): □□□□□□□□□□

5. Foreigner passport number: □□□□□□□□□

IV. Recipient man data:

1. Name: _____ 2. Date of birth: _____(y) _____(m) _____(d)

3. National ID card number: □□□□□□□□□□

4. Alien resident certificate ID number (Note): □□□□□□□□□□

5. Foreigner passport number: □□□□□□□□□

V. Notification types and reasons:

Type	Reason
□ Failure to complete	□ 1. Health assessment results not suitable for donation

Type	Reason
donation	☐ 2. Donor calls off donation ☐ 3. Loss of contact with donor ☐ 4. Institution terminates business ☐ 9. Other _____
☐ Return	☐ Due to impaired procreative function, donor requests return of reproductive cells that have not been destroyed.
☐ Destruction	☐ 1. Has enabled recipient couple to complete one live birth. ☐ 2. Preserved for more than ten years. ☐ 3. Reproductive cells found to be unsuitable for artificial reproduction after donation. ☐ 4. Recipient couple have an invalid or annulled marriage, are divorced, or one party has died. ☐ 5. Recipient couple give up artificial reproduction. ☐ 6. The institution has terminated business. ☐ 9. Other _____ Destruction type: ☐ sperm ☐ oocytes ☐ embryo created from donated reproductive cells
☐ Transfer	☐ 1. The institution has terminated business. ☐ 2. Transferred to another medical care institution for use. ☐ 3. Recipient couple has requested transfer. ☐ 9. Other _____ Transferring institution: _____ Transfer type: ☐ sperm ☐ oocytes ☐ embryo created from donated reproductive cells Is sperm still being stored after the sperm bank has provided it? ☐ Yes ☐ No Handed-over documents: ☐ 1. Reproductive Cell Donation Checking Application Form (photocopy) ☐ 2. Reproductive Cell Donation Checking Response Form (photocopy) ☐ 3. Reproductive Cell Donor Health Examination and Assessment Notification Form (photocopy) ☐ 4. Donated Reproductive Cell Operation Results Notification Form (photocopy) ☐ 5. Letter of consent (photocopy) ☐ 9. Other _____ Transferee institution: _____(please affix confirming seal)

Date on which the facts occurred: __(y)__(m)__(d)

Date of completion of transfer: _(y)__(m)__(d)

Notification date: ____(y)____(m)____(d) Notification provided by: _____

Date received:____(y)____(m)____(d) Accepted by: _____

Instruction: Foreigners who do not have a national ID card shall fill out items 4 and 5; foreigners with no alien resident certificate ID may submit equivalent identification documents from their country of origin, and fill in the serial number on those documents.

Please note: The first leaf of this form shall be sent to the competent authority by registered mail within two months of the date of failure to complete donation, return, or destruction, or within two months of the date of completion of transfer (based on postmark date); the Institution shall preserve the second leaf.

Attached Form 5

_____(y)_____(m)_____(d) (Sunday) to _____(y)_____(m)_____(d) (Saturday)

Case Report Form for All the Initiated Cycles with or without the Use of Ovulation Induction Drugs in Artificial Reproduction

Institution name: _____

Institution code: _____

Name of recipient woman	National ID card number/alien resident certificate ID/passport number (Note)	Case history number	Date of birth y/m/d	Initiated Date y/m/d	Already performed health examination and assessment in accordance with Article 7, Paragraph 1 of the Artificial Reproduction Act (please check)	Explanation made to recipient couple and consent form obtained in accordance with Article 12, Paragraph 1 of the Artificial Reproduction Act (please check)

Instruction: Foreigners with no national ID card shall provide both the alien resident certificate ID and passport number.
Please note: Cases from the previous week must be filled in on this form by Tuesday of each week.

Notification provided by:_____

Notification date:_____

Attached Form 6

Recipient Couple Health Examination and Assessment Form

Recipient woman	Recipient man
I. Basic information 1. Name: _____ 2. Date of birth:_____(y/m/d) 3. National ID card number: ☐☐☐☐☐☐☐☐☐☐ 4. Alien resident certificate ID number(Note): ☐☐☐☐☐☐☐☐☐☐ 5. Foreigner passport number: ☐☐☐☐☐☐☐☐☐☐	**I. Basic information** 1. Name: _____ 2. Date of birth:_____(y/m/d) 3. National ID card number: ☐☐☐☐☐☐☐☐☐☐ 4. Alien resident certificate ID number(Note): ☐☐☐☐☐☐☐☐☐☐ 5. Foreigner passport number: ☐☐☐☐☐☐☐☐☐☐
II. Skin color _____, Hair color _____ Height:_____cm, Weight: _____kg Blood type: ABO blood type Results:___	**II.** Skin color _____, Hair color _____ Height:_____cm, Weight: _____kg Blood type: ABO blood type Results:____
III. General psychological conditions: Mental illness: ☐ 0.No ☐ 1.Yes, condition: _____	**III. General psychological conditions:** Mental illness: ☐ 0.No ☐ 1.Yes, condition: _____
IV. General physiological conditions: Systemic disease: ☐ 0.No ☐ 1.Yes, disease:_____	**IV. General physiological conditions:** Systemic disease: ☐ 0.No ☐ 1.Yes, disease:_____
V. Family disease history: ☐ 0.No ☐ 1.Yes, disease:_____	**V. Family disease history:** ☐ 0.No ☐ 1.Yes, disease:_____
VI. Hereditary disease history of recipient and relatives within the fourth degree of kinship: ☐ 0.No ☐ 1.Yes, disease:_____ Relationship: _____	**VI. Hereditary disease history of recipient and relatives within the fourth degree of kinship:** ☐ 0.No ☐ 1.Yes, disease:_____ Relationship: _____
VII. Infectious disease test results: 1. Syphilis ☐ 0.No ☐ 1.Yes 2. AIDS: ☐ 0.No ☐ 1.Yes 3. Other infectious disease history: ☐ 0.No ☐ 1.Yes, disease:_____	**VII. Infectious disease test results:** 1. Syphilis ☐ 0.No ☐ 1.Yes 2. AIDS: ☐ 0.No ☐ 1.Yes 3. Other infectious disease history: ☐ 0.No ☐ 1.Yes, disease:_____

Note: Foreigners who do not have a national ID card shall fill out items 4 and 5; foreigners with no alien resident certificate ID may submit equivalent identification documents from their country of origin, and fill in the serial number on those documents.

Attached Form 7

Artificial Reproduction Case Data Form

Notification provided by：_____

Notification date：_____

I. Institution code: _____

II. Recipient woman data:

1. Name: _____ 2.Date of birth: □□□□(y) /□□(m)/□□(d)

3. National ID card number:_____ 4. Nationality: _____

5. Alien resident certificate ID (Note):_____ 6. Foreigner passport number:_____

7. Case history number: _____

III. Recipient man data:

1. Name: _____ 2.Date of birth: □□□□(y) /□□(m)/□□(d)

3. National ID card number:_____ 4. Nationality: _____

5. Alien resident certificate ID (Note):____ 6. Foreigner passport number:_____

IV. Date of initiation □□□□(y) /□□(m)/□□(d)

V. Data concerning artificial reproduction:

1.□□ Length of infertility (years, number round off)

2.□□Number of times using artificial reproduction

3.□Reason for infertility:

(1) Fallopian tube factors (2) Ovarian factors (3) Endometriosis (4) Other uterine factors(5) Other female factors (Please specify_____) (6) Male factors (7) Multiple factors (9) Reason Unclear

4.□Method of artificial reproduction

(1) IVF/ET (2) GIFT (3) ZIFT/TET (4) AID (5) IVF/ET+GIFT

(9) Other (if multiple selection, please specify embryo surgery _____)

5.□Ovarian stimulation method:

(1) Natural period (2) Oral drug stimulation (3) Short cycle drug stimulation (4) Long cycle drug stimulation (5) Ultra-long cycle drug stimulation (6) GnRH antagonist drug stimulation (7) Other (Specify_____)

6.□Ovulation stimulation results, were oocytes obtained?

(1) Yes (2) No, reason: _____

7.□ Micro-manipulation technique

(1) ICSI (2) Assisted ovulation (3) ICSI + assisted ovulation (4) PGS (5) PGD

(9) Other (Please Specify if multiple selection _____)

8.□Source of sperm/oocytes:

(1) Donated sperm (2) Donated oocytes

Donor's national ID card number: _____ Nationality: _____

Alien resident cerfificate ID (Note):_____ Foreigner passport number:_____

(3) Sperm and oocytes from couple

□Own sperm □MESA □TESE □Other (Please specify _____)

9.□□Number of oocytes obtained? (Including immature oocytes)

10.□□Number of normal fertilized oocytes

11.□□Number of implanted oocytes (GIFT)

12.□Number of implanted fertilized oocytes (embryos)

□Number of fertilized oocytes/embryos implanted on Day 2 of cultivation

□Number of fertilized oocytes/embryos implanted on Day 3 of cultivation

□Number of fertilized oocytes/embryos implanted on Day 4 of cultivation

□Number of fertilized oocytes/embryos implanted on Day 5 of cultivation
□Number of fertilized oocytes/embryos implanted on Day 6 of cultivation

13.□□ Number of fertilized oocytes (embryos frozen)

14.□□ Number of frozen oocytes

15.□ Was sperm still in storage after this operation? (1) Yes (2) No

16.□Embryo type (1) Fresh (2) Frozen (3) Both

17. Implantation date □□□□(y) /□□(m)/□□(d)

18.□Ovarian hyperstimulation syndrome
(1) None (2) Mild (3) Moderate (4) Severe (9) Unclear

19.□Clinical pregnancy □□□□(y) /□□(m)/□□(d)
(1) Yes: □Number of embryo sacs, □Number of fetal hearts, □Ectopic pregnancy
(2) No

20.□□Reduction in embryos

21. Result of pregnancy □□□□(y)/□□(m)/□□(d)
□ (1) Number of natural miscarriages (< 20 weeks)
□ (2) Number of ectopic pregnancies
□ (3) Number of induced miscarriages, reason_____
□ (4) Number of stillborn fetuses (20 - 27 weeks)
□ (5) Number of stillborn fetuses (>28 weeks)
□ (6) Number of live births

22.□ Number of abnormal stillborn or miscarried fetuses; Please specify_____

23. Live born infant data

	Sex	Weeks to birth	Weight	Birth method	Physical conditions
(1)	_____	_____	_____	_____	_____
(2)	_____	_____	_____	_____	_____
(3)	_____	_____	_____	_____	_____
(4)	_____	_____	_____	_____	_____

*Codes for birth method and physical condition of live infant

(I) Birth method code
(1) Vaginal birth (2) Vaginal forceps birth (3) Vaginal vacuum suction birth (4) Vaginal birth with caesarean birth history (5) First caesarean birth (6) Caesarean birth with caesarean birth history

(II) Physical condition code
(1) 000 No special condition: normal
(2) Obvious visible congenital defect
101 Nervous system 102 Eyes/face 103 Cardiovascular disease
104 Digestive system 105 Kidney/urinary system
106 Musculoskeletal system 107 Chromosomal abnormality
108 Other(please specify_____)
(3) Other abnormality
201 Suspected infection 202 Jaundice requiring treatment
203 Breathing difficulty (use of respirator>30 minutes)
204 Birth injury 206 other (please specify) 207 Death of newborn

24. Operating physician:_____

Note: Aliens with no national ID card must fill out items 4 and 5; aliens with no alien resident certificate ID shall submit equivalent identification documents from their country of origin, and fill in the serial number on those documents.

Instruction: Artificial reproduction cases and results of confirmed clinical pregnancy for the previous quarter shall be reported online using this form before the end of February, May, August, and November.

Instructions for Artificial Reproduction Case Data Form

I. Institution code: Please provide the institution code assigned by the competent authority after the medical care institution applied to establish an artificial reproduction institution.

II. Recipient woman data:

1. Name: Please provide the name of the recipient woman.
2. Date of birth: Please provide the birth date (Western year in A.D.) of the recipient woman.
3. National ID card number: Please provide recipient woman's ROC national ID card number. Leave this field blank if not an ROC citizen.
4. Nationality: For foreign recipient women, record the country of origin.
5. Alien resident certificate (ARC) ID: A foreign recipient woman without an ROC national ID card must fill in the ARC ID number on a relevant document issued by the ROC; if the woman has no ARC ID number, a relevant document from her country of origin shall be presented to the medical care institution for checking, and the ID number filled in. Leave this field blank if the recipient woman has an ROC national ID card.
6. Foreign passport number: Apart from providing the foregoing numbers, a recipient woman without an ROC national ID card must also provide her passport number. Leave this field blank if the recipient woman has an ROC national ID card.
7. Case history number: Please provide recipient woman's case history number at the operating institution.

III. Recipient man data:

1. Name: Please provide the name of the recipient man.
2. Date of birth: Please provide the birth date (Western year in A.D.) of the recipient man.
3. National ID card number: Please provide recipient man's ROC national ID card number.
   Leave this field blank if not an ROC citizen.
4. Nationality: For foreign recipient men, record the country of origin.
5. Alien resident certificate (ARC) ID: A foreign recipient man without an ROC national ID card must fill in the ARC ID number on a relevant document issued by the ROC; if the man has no ARC ID number, a relevant document from his country of origin shall be presented to the medical care institution for checking, and the ID number filled in. Leave this field blank if the recipient man has an ROC national ID card.
6. Foreign passport number: Apart from providing the foregoing numbers, a recipient man without an ROC national ID card must also provide his passport number. Leave this field blank if the recipient man has an ROC national ID card.

IV. Date of initiation: Please provide the Western date on which the recipient woman began use of ovulation induction drugs. If the recipient woman has not used ovulation induction drugs, but has used frozen embryos or calculation of natural period, please provide the date on which the recipient woman received a reproductive system examination and entered a treatment cycle.

V. Data concerning artificial reproduction:

1. Period of infertility: Period during which a woman who has a normal sex life

and does not use birth control fails to become pregnant. Calculated in years; please round off.

2. Number of times using artificial reproduction: Number of times using artificial reproduction prior to this instance of use of ovulation induction drugs (or treatment cycle); does not include number of instances of artificial insemination (AIH) between spouses.
3. Reason for infertility: Please provide the following reason codes:

   (1) Fallopian tube factor (2) Ovarian factors (3) Endometriosis (4) Other uterine factors (5) Other female factors (Please specify_____)(6) Male factors (7) Multiple factors(9) Reason unclear

   Please provide code (7) if there is more than one reason for infertility; do not write code for primary reason.
4. Method of artificial reproduction: This field must be filled in for each case and each treatment cycle (including treatment cycles completed without acquisition or implantation of oocytes). The field may be filled as soon as a case enters a treatment cycle and the method of artificial reproduction is known. If the method is changed during this treatment cycle at the time of implantation, please change to show the method actually employed. Please provide the relevant assisted reproduction technique code:

   (1)IVF/ET; (2)GIFT; (3)ZIFT/TET; (4)AID;(5) IVF/ET+GIFT; (9) Other (please specify __)
5. Ovarian stimulation method: Please provide ovarian stimulation method code for recipient woman (or oocyte donor):

   (1) Natural period (2) Oral drug stimulation (3) Short cycle drug stimulation (4) Long cycle drug stimulation (5) Ultra-long cycle drug stimulation (6) GnRH antagonist drug stimulation (7) Other (Specify____)
6. Were oocytes obtained: Please provide code indicating whether oocytes were obtained after recipient woman (or oocyte donor) was injected with ovulation induction drugs:

   (1) Yes; (2) No.

   Please provide the following reason code if no oocytes were obtained:

   (1) Poor ovarian stimulation.
   (2) Sperm could not be obtained.
   (3) Reason attributable to the female patient, such as high fever, discomfort, failure to give injection, etc.
   (4) Ovulation had already occurred.
   (5) Other.
7. Micro-manipulation technique: Please provide the combination of sperm and oocytes, and the use of micro-manipulation techniques, during the current cycle; fill out 0 if no micro-manipulation technique was used.

   (1) ICSI; (2) Assisted ovulation; (3) ICSI+ assisted ovulation;(4)PGS; (5) PGD; (9) Other (Please specify if multiple selection)
8. Source of sperm/oocytes: Please provide the sperm/oocyte source code applicable to the current cycle:

   (1)Donated sperm; (2) Donated oocytes; (3) Sperm and oocytes from couple

   If (1) or (2) is selected, enter the ID number of the donor. If the donor is a foreigner, enter his/her country of origin, ARC number, and passport number.

If (3) is selected, please check one of the following ☐ Own sperm ☐ MESA ☐ TESE ☐ Other (Please specify_____)

9. Number of oocytes obtained: Please provide the number of oocytes obtained after ovulation induction drugs were given to the recipient woman (or oocyte donor); includes immature oocytes. Fill in 0 if no oocytes were obtained.
10. Number of normal fertilized oocytes: Please provide the number of normal fertilized oocytes in the current course of treatment.
11. Number of implanted oocytes (GIFT): Please provide the number of implanted oocytes in this field when using the GIFT method.
12. Number of implanted fertilized oocytes (embryos): Please provide the number of implanted embryos or fertilized oocytes of different days of cultivation in the current cycle.
13. Number of fertilized oocytes (embryos) frozen: Please provide the number of embryos or fertilized oocytes that were frozen and not implanted during the current cycle.
14. Number of frozen oocytes: Please provide the number of oocytes that were frozen and not implanted during the current cycle.
15. Was sperm still in storage after this operation: Please check the appropriate code indicating whether sperm was in storage after the cycle:
    (1) Yes; (2) No
16. Embryo type: This field must be filled in for each case and each treatment cycle (including treatment cycles completed without acquisition or implantation of oocytes). The field may be filled as soon as a case enters a treatment cycle and the type of embryo is known. If the method is changed during this treatment cycle at the time of implantation, please change to show the type actually employed. Please provide the relevant code for the type of embryo (fertilized oocyte) implanted or expected to be implanted: (1) Fresh; (2) Frozen; (3) Both
17. Implantation date: Please provide the Western date of embryo, fertilized oocyte, or oocyte and sperm implantation. Please provide the date of the first implantation if two implantations were attempted in the same treatment cycle.
18. Ovarian hyperstimulation syndrome: Please provide the appropriate code indicating whether the recipient woman (or oocyte donor) had ovarian hyperstimulation syndrome:
    (1) No; (2) Mild; (3) Moderate; (4) Severe; (9) Unclear
19. Clinical pregnancy: Please indicate whether clinical pregnancy occurred after implantation, and provide the date of clinical pregnancy or the date on which the treatment cycle was ended following either induction of ovulation but not obtaining any oocytes or obtaining oocytes but not performing implantation. A date must be provided in this field to facilitate computer processing.
    Clinical pregnancy codes and reporting tasks are as follows:
    (1) If clinical pregnancy has occurred, please provide code (1) and date of confirmation of clinical pregnancy.
    Provide the number of embryo sacs, fetal pulses, and ectopic pregnancies. Fill in result of pregnancy fields if the result of pregnancy has been confirmed. Otherwise, fill in the following result of pregnancy in the quarter in which the result of pregnancy has been confirmed.
    (2) Please provide code (2) and date of confirmation of no clinical pregnancy or end of treatment cycles when any of the following three circumstances has occurred:
    ① Implantation, but no clinical pregnancy.

② Induction of ovulation, but the treatment cycles was ended without acquisition of oocytes.

③ Oocytes were obtained, but the treatment cycle was ended without implantation.

Reporting of treatment cycles data ends here in these three circumstances.

20. Reduction in embryos: Please fill in the reduction in the number of embryos; put 0 if there was no reduction.
21. Result of pregnancy: Please fill in the result of pregnancy code, and write the date onwhich the result of pregnancy was confirmed. Also provide the number of pregnancy results in accordance with the result of pregnancy. For instance, write the number ofnatural miscarriages in the appropriate field in the case of natural miscarriage. Apartfrom providing the number of artificial miscarriages, please provide the reason forartificial miscarriage. Multiple responses may be provided.
22. Number of abnormal stillborn or miscarried fetuses: Please provide the number of abnormal stillborn or miscarried fetuses and fill in the appropriate congenital defect code(s).
23. Live infant data: Please provide the sex (male, female), weeks of pregnancy (in weeks, eliminate remainder), weight (in grams), birth method, and physical condition code(s) for live born infants at the time of birth.
24. Operating physician: Please fill in the blank with the name of the physician performing artificial reproduction.

Attached Form 8

Notification Form for Destruction of Reproductive Cells or Embryos from Recipient Couples (excluding destruction of reproductive cells obtained from donation)

Institution name: _____

Institution code: _____

Statistical year: _____ Notification date: _____

Recipient woman		Recipient man		Item destroyed and quantity	Date of destruction	Destruction reason code (Note 2)
Name	National ID card number/ Alien resident certificate ID/ passport number (Note 1)	Name	National ID card number/ Alien resident certificate ID/ passport number (Note 1)			
				☐ ____ sperm vials ☐ ____ oocytes ☐ ____ embryos		
				☐ ____ sperm vials ☐ ____ oocytes ☐ ____ embryos		
				☐ ____ sperm vials ☐ ____ oocytes ☐ ____ embryos		
				☐ ____ sperm vials ☐ ____ oocytes ☐ ____ embryos		
				☐ ____ sperm vials ☐ ____ oocytes ☐ ____ embryos		
				☐ ____ sperm vials ☐ ____ oocytes ☐ ____ embryos		

Note 1: Foreigners who do not have a national ID card shall provide both the alien resident certificate ID and passport number.

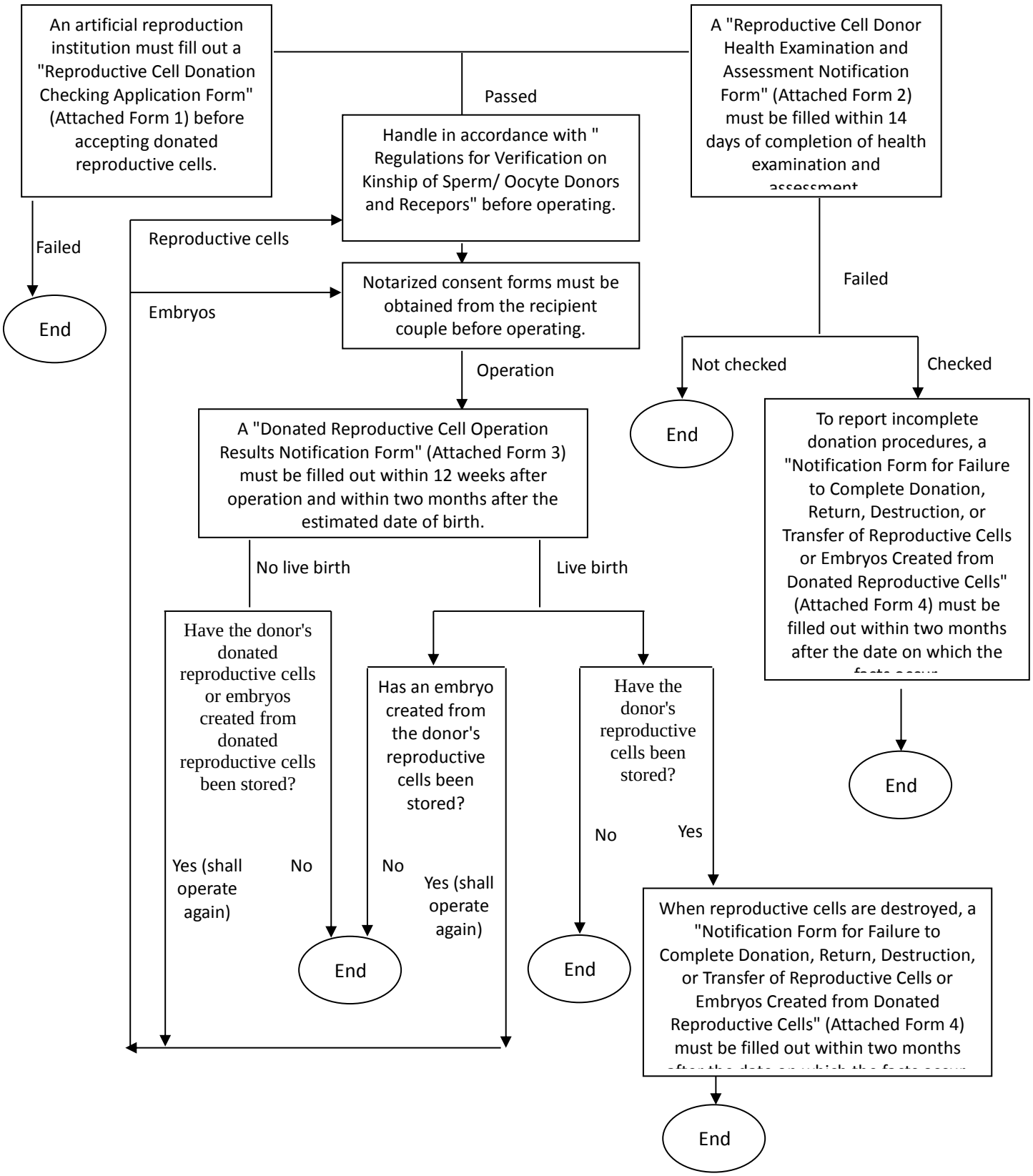
Note 2: Destruction reason codes are as follows:

1. Provider of reproductive cells requests destruction 2. Death of reproductive cell provider 3. Reproductive cells have been preserved for more than ten years
4. Recipient couple have an invalid or annulled marriage, are divorced, or one party has died 5. Recipient couple give up artificial reproduction. 9. Other

Instruction: This form constitutes as an annual report and should be submitted in electronic form before the end of March containing data of destruction of Destruction of Reproductive Cells or Embryos from Recipient Couples annually for the previous year.

Appendix

Process Flowchart for Notification of Reproductive Cell Donation by an Artificial Reproduction Institution



Note: When an artificial reproduction institution returns intact reproductive cells to a donor in accordance with the proviso to Article 19 of the Artificial Reproduction Act, or transfers reproductive cells or an embryo created from donated reproductive cells in accordance with the regulations of Article 20 or Article 21, Paragraph 4 of the Artificial Reproduction Act, the institution must fill out a "Notification Form for Failure to Complete Donation, Return, Destruction, or Transfer of Reproductive Cells or Embryos Created from Donated Reproductive Cells" (Attached Form 4); these situations are not shown in this process flowchart.