

Attached Table 4 **Assisted reproduction institution permit renewal review items, standards, and point distribution table**

Review Item and Standard	Designated Point	Review Principles	Score
1. Regular assessment of the work performance of employees	8 points	1. An assessment is conducted at least once every three months; procedure is duly documented, and results are reviewed and analyzed. Active corrective action has been implemented.	8 points
		2. An assessment is conducted at least once every three months; procedure is duly documented.	6 points
		3. Assessment is not conducted at least once every three months, or documented records are incomplete.	0 point
2. Records of laboratory equipment maintenance and repair conducted by assigned personnel	8 points	Regular maintenance, calibration, and records are conducted on laboratory equipment items 3, 4, 5, 6, 10, 11, 15, and 16 as set forth in the attached Table 2	1 point will be deducted for every missing item.
3. Laboratory quality control	84 points		
(1) Records of relevant operation procedures	6 points	1. Personal information of recipient couples	If data of each record stated in the left column is complete, a 1.5-point credit
a. Personal information of recipient couples,		2. Various examination records 3. Assessment data (including case indications)	

<p>the examination records, the assessment data (including case indications), the surgical procedures and results, and the surgery consent form (photocopy)</p>		<p>4. Surgery consent form</p>	<p>is given; a 1-point credit is given for incomplete records, and no point is given where no record is available.</p>
<p>b. Personal information of donors and recipient couples, the examination records, the assessment data, the surgical procedures and results, and the embryo preservation and destruction conditions (Note 1)</p>	<p>6 points</p>	<ol style="list-style-type: none"> <li>1. Personal information of donors and recipient couples</li> <li>2. Various examination records</li> <li>3. Assessment data (including case indications)</li> <li>4. Letter of consent</li> </ol>	<p>If data of each record stated in the left column is complete, a 1.5-point credit is given; a 1-point credit is given for incomplete records, and no point is given where no record is available.</p>

c. Culture medium preparation or quality testing related data	2 points	Score assessment is based on the integrity of the records submitted or the presence or absence of records.	Credit point is halved if records are incomplete; no point is given where no record is available.
d. Induced ovulation method (including types of ovulation medicine used)	4 points		
e. Inspection of the follicle aspirated substances and identification of oocyte	1 point		
f. Oocyte count and oocyte quality and maturity assessment	1 point		
g. Sperm preparation (including collection, analysis, washing, and recycling procedures)	1 point		
h. Insemination of oocytes and determination of the oocyte fertilization status	2 points		
i. Incubation and implantation of fertilized oocytes	1 point		
j. Embryo incubation, status of embryo division, and	3 points		

identification of embryo grade			
k. Embryo implantation (via uterus or Fallopian tubes)	1 point		
l. Cryopreservation of sperm, oocytes, or embryos	2 points		
m. Number of pregnancy cases, miscarriages, and number of live births	1 point		
n. Sex and weight of infant, delivery method, and records of congenital deformity and other abnormalities	2 points		
(2) Control of the operation outcomes			
a. Records of cryopreservation and thawing of human embryos	4 points	1. Cryopreservation, thawing, and implantation procedures were implemented and duly documented;	4 points
		2. Cryopreservation procedures were implemented and duly documented;	2 points
		3. No cryopreservation records documented.	0 point
b. Live birth rate of cryopreserved human	3 points	1. $\geq 10\%$	3 points
		2. 1%-9%	2 points

embryos recorded in the last three years or current valid period (Notes 2 and 3).		3. Successful pregnancy but no live birth	1 point
c. The cumulative live birth rate of treatment cycles of women less than 38 year old within the last three (3) years of valid period (Notes 2 and 3).	26 points	1. Above 25% 2. 20% – 24% 3. 15% – 19% 4. 10%-14% 5. 1%-9% 6. 0%	26 points 23 points 20 points 16 points 5 points 0 point
d. Technical experiences and records of intracytoplasmic sperm injection into human oocytes	2 points	Surgeries were performed and duly documented. No surgical procedure performed and documented	2 points 0 point
e. The ratio of women under the age of 35 who have had less than two embryos implanted within current permit period (Note 3).	8 points	1. Above 55% 2. 30%-54% 3. 20%-29% 4. 1%-19% 5. 0	8 points 4 points 2 points 1 point 0 point
f. The monitoring, improvement plans and records of moderate and severe ovarian hyper stimulation syndrome.	2 points	1. The monitoring, improvement plans and records were carried out. 2. The monitoring was carried out without, improvement plans and records.	2 points 1 point

		3. No monitoring, improvement plans and records were carried out.	0 point
g. The effectiveness and accuracy of assisted reproductive data reports during the current permit period (Note 3)			
(i) The effectiveness of stipulated report forms for assisted reproduction cases entering into treatment cycle after starting to use ovulation drugs and information list of assisted reproduction cases.	2 points	1. 0-1 overdue data report 2. 2-4 overdue data reports 3. $\geq 5$ overdue data	2 points 1 point 0 point
(ii) The effectiveness of stipulated report form on the preservation status of germ cells or embryos and operation results in the report form of donated germ cell	2 points	1. Report is true or accurate 2. Report is not true or accurate	2 points 0 point

operation results.			
h. The monitoring and records of sex ratio at birth	2 points	1. Having monitored and recorded 2. Having not monitored and recorded	2 points 0 point
Total Scores	100 points		

Notes:

1. Where a medical care institution provides no donation services, the requirement of “The personal information of donors, the examination and assessment data, the operational results, the embryo preservation and destruction conditions” provided in Subparagraph b of Paragraph (1) “Records of relevant operation procedures” and “The effectiveness of stipulated report form of the preservation status of germ cells or embryos and operation results in the report form of donations germ cell operation results” provided in Subparagraph 5 of Paragraph 2 “Control of the operation outcomes” shall be excluded from the total score calculation.
2. Statistics of cumulative live birth rate of treatment cycles of cryopreserved human embryo of women under the age of 38 within the latest three (3) years of valid period shall be calculated from one year and three months prior to the expiration of the permit validity period.
3. The following data are established by the competent authority pursuant to the “Assisted Reproduction Database” which are statistically scored within the permit validity period (scores were rounded off to the first decimal point)
  - (1) The live birth rate of cryopreserved human embryos in the last three (3) year valid period. Calculation method: The number of live birth cycles of cryopreserved human embryos ÷ the number of implanted

cycles of cryopreserved human embryos.

- (2) The cumulative live birth rate of treatment cycles of women less than 38 years old within the last three (3) years of valid period.

Calculation method: (the number of live birth cycles of fresh human embryos + the number of live birth cycles of cryopreserved human embryos) ÷ the number of treatment cycles

- (3) The ratio of women under the age of 35 who have had less than two embryos implanted within the current permit period.
- (4) The effectiveness of stipulated report forms for assisted reproduction cases entering into treatment cycle after starting to use ovulation drugs and information list of assisted reproduction cases.
- (5) The effectiveness of stipulated report form on donated germ cell operation results.

4. Where an assisted reproduction institution obtains its first and permit renewal prior to the promulgation and enforcement of the amendment of these Regulations on February 18 of 2014, its data with respect to e. “The ratio of women under the age of 35 who have planted less than two embryos within current permit period”, f. “The monitoring, improvement plans and records of moderate and severe ovarian hyper stimulation syndrome”, g. “The effectiveness and accuracy of assisted reproductive data report during the current permit period” and h. “The monitoring and records of sex ratio at birth” shall be reviewed from the date of amendment.

5. Where the scores given to the AR institution on the review items showed in the attached Table are 85% or higher, said AR institution shall be regarded as having passed review; those receiving scores of 84% or below shall be regarded as having failed the review. The on-site inspection procedure shall be foregone in the subsequent permit renewal application of AR Institutions that have received a score of 90% or above in this review.