Attached Table 3 **Assisted reproduction institution permit renewal application review item form**

1. Photocopy of practice license;
2. Personnel roster and qualification certificates specified in Article 2; (Those whose qualification has been approved by the competent authority are not required to provide qualification certificates.)
3. Training completion certificates of operating physicians, technicians, and counselors as required in Articles 3, 4, and 5;
4. Personnel work performance assessment;
5. List of facilities and equipment prescribed in the attached Table 2;
6. Records of laboratory equipment maintenance and repair conducted by assigned personnel;
7. The following operation manuals:

(1) Preparation of culture medium;
(2) Sperm and oocytes preparation and insemination;
(3) Grading of oocytes and embryos;
(4) Micro-manipulation;
(5) Cryopreservation and thawing procedures, and operating procedures of computer-controlled freezer or equivalent embryo freezing equipment;
(6) CO_2 incubator testing specifications;
(7) Embryo room quality control measures

8. Laboratory quality control

(1) Records of relevant operation procedures; (AR Institutions handling 20 or more cases within the three-year permit validity period shall submit records of 20 cases; however, AR Institutions handling less than 20 cases within the three-year permit validity period shall submit records of all cases.)

a. Personal information of recipient couples, the examination records, the assessment data (including case indications), the surgical procedures and results, and the surgery consent form (photocopy)
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)

c. Culture medium preparation or quality testing related data

d. Induced ovulation method (including types of ovulation medicine used)

e. Inspection of the aspirated substances of ovarian follicle, and identification of oocytes

f. Oocyte count and oocyte quality and maturity assessment

g. Sperm preparation (including collection, analysis, washing, and recycling procedures)

h. Insemination of oocytes and determination of the oocyte fertilization status

i. Incubation and implantation of fertilized oocytes

j. Embryo incubation, status of embryo division, and identification of embryo grade

k. Embryo implantation (via uterus or Fallopian tubes)

l. Cryopreservation of sperm, oocytes, or embryos

m. Number of pregnancy cases, miscarriages, and number of live births

n. Sex and weight of infant, delivery method, and records of congenital deformity and other abnormalities.

(2) Control of the operation outcomes

a. Frozen and thawed records of cryopreserved human embryos

b. The live birth rate of cryopreserved human embryos in the last three (3) year valid period (Notes 2 and 3). Calculation method: The numbers of live birth cycle of cryopreserved human embryos ÷the numbers of implanted cycle of cryopreserved human embryos.

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

d. Technical experiences and records of intracytoplasmic sperm injection into

human oocytes

e. The effectiveness and accuracy of assisted reproductive data report during the current permit period.

(i) The effectiveness of stipulated report forms for assisted reproduction cases entering into treatment cycle after starting using ovulation drugs and information list of assisted reproduction cases.

(ii) 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.

f. The ratio of women under the age of 35 who have been implanted with less than two embryos.

g. The monitoring, improvement plans and records of moderate and severe ovarian hyper stimulation syndrome.

h. The monitoring and records of sex ratio at birth.

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 accumulative cryopreserved human embryos live birth rate of treatment cycles of women under age 38 in the latest three years of valid period;

(2) The ratio of women under the age of 35 who have been implanted with less than two embryos within current permit period.

(3) The effectiveness of stipulated report forms for assisted reproduction cases entering into a treatment cycle after starting to use ovulation drugs, and information list of assisted reproduction cases.

(4) The effectiveness of stipulated report form of donations germ cell operation results.