Chapter 1 "Certified Clinical Embryologist" Internal regulations of application for certification

Article 1 The review of Certified Clinical Embryologist will be performed by the committee of certified qualification, and certified by the board.

2 The Japanese Society of Clinical Embryologist (thereafter, "JSCE") will announce the schedule of the review, the procedures, the certification method, the review fee, and others for certifying the qualification through the academic journals, the web site or others.

Article 2 A person who will apply the review of certifying the qualification of "Certified Clinical Embryologist" is required to meet each of the following items.

(1) A member of JSCE

(2) Experience with more than a year of the ART laboratory work

* The ART laboratory work here means a sequence of process for all of the works in the incubation room, including the conditioning of sperm, the handling of embryo from ovum collection to embryo transfer by the applicant oneself. The experience with at least 30 cases in each process is required.

(3) Academic background shall be met either of followings.

- a) A bachelor who mastered the subject relating to biology in a science-related department of a university or an equivalent educational institution.
- b) A person who was graduated from a technical college accredited under the School Education Act and obtained a qualification of a clinical laboratory technologist or a registered nurse.
- c) A person with the associate degree who majored a subject relating to genesiology in a junior college, and, in case that the course term was 3 years, with the experience of the ART laboratory work for more than 2 years. If the course term was 2 years, the over-3-year experience of the ART laboratory work is required.

(4) A person who participated workshops (those held continuously on the examination day can be included) hosted by JSCE and received a certification of completion twice or more, or a person who received a certificate of completion once and participated ART-related academic conferences including JSCE twice or more, in the recent 3 years. For the latter, copies of a participation certificate for the academic conferences should be attached as an evidence.

Article 3 A person who wants to apply for the review of certifying the qualification of "Certified

Clinical Embryologist" should submit the following documents with the review fee by the end of every October to the JSCE head office.

(1) Certificate

- 1. Application for the exam/the renewal
- 2. One copy of a resume. (Any formats are acceptable, only if in A4-size papers with horizontal writing.)
- 3. A certification of clinical work experience by a head of an institution or a department
- 4. Documents to certify participation of academic conferences. (Any formats are acceptable.)
- 5. A copy of a license if having a license certified by the Minister of Health, Labour and Welfare, or, in place of the license, a completion certification of biology or the equivalent subject from a university or a technical college (A copy of a certification is available).
- (2) Regarding a DVD to submit for application, followings shall be defined.
 - An unedited DVD which recorded from sperm immobilization to sperm injection in the intracytoplasmic sperm injection (ICSI) implemented by the applicant will be acceptable (Continuous shooting without a momentary pause is preferred.). Note that a scene that ICSI was being implemented continuously for 2 or more ova should be recorded (Recording time: 5 – 30 minutes).
 - An unedited DVD which recorded from freezing to thawing in the rapid-freeze method (vitrification) implemented by the applicant will be acceptable (Continuous shooting without a momentary pause is preferred.). Record the following contents to be showed clearly (Recording time: 10 – 30 minutes).

• [Freezing] Movie which recorded from immersion into equilibrium solution with a pipette for handling embryo to carrying on an equipment for freezing.

• [Thawing] Movie which recoded from putting a cryogenically-preserved embryo into thawing solution to carrying the embryo to a culture medium for generation after completion of thawing.

*An oocyte which approved by an institution is to be used including immature oocytes, polyspermy oocytes, or lab animal oocytes.

*Not a movie recorded at hand of a practitioner for all of ICSI, freezing/thawing, a micro movie (a movie of a microscope monitor) should be submitted to check the status of an oocyte, a zygote, or an embryo.

*During equilibrating under freezing/thawing, record everything as it was without pausing.

- 3. Be careful of the specification for recording (either of DVD-VIDEO, mpg, avi, wmv, or mov), as resubmission is required sometimes if the DVD cannot be played by a DVD player or a PC. Submitted DVDs will not be returned to applicants and disposed by the committee of certified qualification with its responsibility.
- 4. If there is no function to record for a microscope itself, record an image of a monitor with a home-video recorder or others (If a movie cannot be prepared because there is no microscope with a monitor, the review for certification is not available.).
- 5. For the blind-review, do not describe any information to specify an applicant or a patient in a DVD itself, but attach a sticky note with the name of an institution and an applicant on a DVD.
- 6. A DVD to be submitted should be DVD-R or DVD-WR with the image quality to evaluate a procedure.

Article 4 The review to certify the qualification of "Certified Clinical Embryologist" will be carried out once a year.

- 2 The exams will be a paper exam, an interview, and a practical exam with submission of a DVD.
- 3 The exam fee will be JPY 30,000.

For payment: Postal transfer account No. 00800-5-22536 The Japanese Society of Clinical Embryologist

Chapter 2 Renewal of the qualification of "Certified Clinical Embryologist"

Article 5 Renewal of the qualification of "Certified Clinical Embryologist" shall be renewed every 5 years.

Article 6 The review for renewal of the qualification will be carried out by the committee.

Article 7 A person who applies the renewal should meet the followings.

- (1) A member of JSCE
- (2) Continuously conducting the ART laboratory work
- (3) Satisfy more than 100 points in total for 5 years by attending the related academic conferences,

presentation in academic conferences, or publication of journals.

Details of points are shown below.

- 60 points Publication of journals: a lead author in the academic journal of JSCE, or other academic journals relating to reproductive medicine in and out of the country. Panelist in national conventions relating to reproductive medicine in or out of the country (as a requested speaker in special lectures, symposiums, workshops, or others)
- 50 points Presenter for general subject of a speech in national conventions relating to reproductive medicine in or out of the country (including a poster presentation)
- 40 points Speaker/presenter for general subject of a speech in a convention of branches relating to reproductive medicine or conferences approved by JSCE
- 30 points Participant/a person who completed workshops hosted by JSCE
- 20 points Participant for academic conferences relating to reproductive medicine (including branch conferences) in and out of the country, co-author of academic journals relating to reproductive medicine, co-speaker in academic conferences relating to reproductive medicine

Article 8 In case that the following procedure to adjourn JSCE was implemented previously by a person who will renew the qualification, the extension of the renewal period can be applied. If the ART work is suspended due to nursing care, delivery, childcare, medical treatment, study abroad, unemployment, or other reasons, submit an application to adjourn JSCE with filling in necessary matters to the head office of JSCE. After that, the extension of the renewal term should be submitted with the designated form to the head office of JSCE. The maximum period to be applied at a time should be 3 years. If the application is approved after the committee of certified qualification reviews, the renewal period for the qualification can be extended up to 3 years in total. However, the period of temporary retirement is more than 3 years in total, the qualification cannot be renewed regardless of circumstances.

Conditions during adjournment are shown below.

- 1. The membership fee is remitted.
- 2. No communication from JSCE.
- 3. The change of address or others during adjournment will be proceeded with a notification of change.
- 4. Participation for academic conferences, seminars, or others hosted by JSCE as a non-member.
- 5. After the period of adjournment, a notification of membership renewal should be submitted immediately.
- 6. If the above mentioned notification is not submitted within a year after the end of the adjournment period, the person will be treated as withdrawal from membership.

7. In case of withdrawal or treated as withdrawal, the qualification will be dissolved at the end of the procedure.

Article 9 A person who wants to apply for the renewal of the qualification of "Certified Clinical Embryologist" should submit the following documents with the review fee by the end of every October to the JSCE head office.

1 Application for the exam/the renewal

2 A copy of the certification of Certified Clinical Embryologist

3 A certification of clinical work experience by a head of an institution or a department

4 Evidences to satisfy more than 100 points in total for 5 years by attending the related academic conferences, presentation in academic conferences, or publication of journals (participation certification of academic conferences, certification of completion, abstracts, or others)

In case that a person qualified before incorporating the review of a practical skill seeks the review of a practical skill, apply to the JSCE head office in accordance with Article 3 (2). The new certification with the description of the review of a practical skill will be issued for people who passed.

Article 10 The review to renew the qualification of "Certified Clinical Embryologist" will be carried out once a year.

2 The review will be conducted by the committee of certified qualification through the documents.

3 The committee of certified qualification will determine whether an applicant passes or not, and, after obtaining the approval from the board, notify the result to the applicant.

4 The board will continuously register people who passed in the original register of "Certified Clinical Embryologist".

5 The renewal fee will be JPY 10,000.

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Chapter 3 Auxiliary provisions

Article 11 The review fee that was once paid will not be returned.

Article 12 If any of this internal regulations is amended, approval of the board should be obtained.

Additional rules

The internal regulation regarding application of the qualification or the renewal that had been implemented form February 11, 2003 was expired as of January 14, 2007.

Additional rules

This internal regulations has enacted from March 22, 2010.

Revised as of July 1, 2013.

Acceptance/rejection criteria for the review of the qualification

Acceptance/rejection criteria for the review of the qualification of Certified Clinical Embryologist is informed as follows.

1. The review of practical skill exam

ICSI

• A sequence of handling sperm immobilization, rupturing oolemma, and injection of sperm into ooplasm can be implemented promptly and correctly.

• Less invasive handling for an ovum can be implemented.

vitrification

• Less invasive handling can be implemented, while immersing an embryo (an ovum) in each solution for appropriate duration.

Remarks: 3 people are in charge per applicant of the exam (the blind-review).

In case that 2 of 3 judges determine to be passed, the applicant will be passed. If the recoded movie is unclear and causes a trouble for determination, it may be notified and the improved movie may be requested.

2. Paper exam

More than 60% of the point rate (including the comparative validation by the difficulty of the exam questions) will be determined to pass the exam.

References: ART essential lab manual, ART-related books, academic journals of JoCE, Back

number of trivia for embryologists (E-news), Human semen test and procedures WHO lab-manual version 5, Society's guidelines of Japan Society of Obstetrics and Gynecology (JSOG) and Japan Society of Reproductive Medicine (JSRM), or others.

3. Determination of pass/fail

Adding the points of an interview to the point rate of a practical skill exam and a paper exam, the passing status will be determined by the determination meeting consisting of advisers and commissioners.