

International Clinical Research Professional Certification System Rules

Chapter 1 General rules

Article 1 (Purpose)

The International Society of Clinical Medicine International Clinical Research Professional Certification System (hereinafter referred to as *the System*) certifies human resources who have acquired the knowledge and research ethics necessary for international clinical research as international clinical researchers, thereby enabling international joint clinical research. It aims to be implemented widely and smoothly, and to contribute widely to society through the development of international medical care.

In English, such professionals shall be referred to as International Clinical Research Professionals (ICRP).

Article 2 (Purpose)

The International Society of Clinical Medicine (hereinafter referred to as *the Society*) shall certify International Clinical Research Professionals in accordance with these regulations in order to achieve the purposes outlined in the preceding Article.

In order to operate and maintain this system, an International Clinical Research Professional Training Certification Subcommittee (hereinafter referred to as *the Subcommittee*) will be set up within the Certification System Committee of the International Society of Clinical Medicine. The Subcommittee president, secretary, and members shall be selected by the Board of Directors.

Article 3 (Work of the Certification Subcommittee)

The Certification Subcommittee will operate and manage the system in general, and carry out the following duties.

- (1) Formulation and accreditation of international clinical researcher certification training course.
- (2) Authentication and evaluation of the International Clinical Research Professional certification examination
- (3) International Clinical Research Professional certification and renewal review
- (4) Other matters necessary for the system

Chapter 2 Certification rules

All of the following must be satisfied to receive International Clinical Research Professional certification

- (1) Experience in clinical research

Participation in one or more clinical studies* or one or more years of relevant experience

* Includes both domestic and international clinical research

- (2) Completion of training course on international joint clinical research using the International Clinical Research Professional Certification e-Learning System of the International Society of Clinical Medicine
- (3) Passing the authentication test attached to the above e-learning system
- (4) Being a full member of the International Society of Clinical Medicine
- (5) Attending at least one International Clinical Research Professional certification training course within two years of commencement of training

Article 5 (Certification method)

As a rule, a certification review shall be conducted once a year.

2 The date of the certification examination and other matters necessary for conducting the certification examination will be announced on the official website of the Society.

Article 6 (The application)

Applicants who wish to undergo accreditation review must submit the documents listed in the following items to the Society by the designated date.

(1) International Clinical Research Professional certification application with the following attachments:

- Detailed description of clinical research experience
- Documents attesting to clinical research experience
- Written proof of eligibility

(2) Copy of a certificate of attendance at training course on international joint clinical research offered by the International Clinical Research Professional Certification e-learning System of the International Society of Clinical Medicine

(3) Copy of International Clinical Research Professional certification training course offered by the International Society of Clinical Medicine

Article 7 (Certification review)

Based on the certification requirements stipulated in Article 4, the Certification Committee will conduct a certification review, certifying and registering the International Clinical Research Professional after approval by the Board of Directors.

Article 8 (Issuance of the certificate)

The Chair will issue a certificate to any individual who has paid the certification registration fee and has been certification and registered.

Article 9 (Effective period of the certificate)

The certificate will be effective for a period of four years from the time it is issued.

Article 10 (Renewal of the certificate)

In order to claim to be an International Clinical Research Professional, the International Clinical Research Professional must renew this certification five years after the year of certification.

2 Information concerning the application for renewal of certification will appear for review in Society announcements and on its website.

Article 11 (Renewal eligibility)

Applicants for renewal of certification must satisfy all of the following conditions.

(1) The annual membership fee of the Society must be paid in full from the time of certification to the time of application for renewal.

(2) Attendance at a Research Professional accreditation seminar designated (implemented) by the International Society of Clinical Medicine at least once between the time of registration for certification and the time of application for renewal

Article 12 (Suspended renewals)

If it is difficult for the individual applying for renewal of certification to meet the requirements of Article 11, Paragraph 2 due to maternity leave, childcare leave, study abroad, long-term medical treatment, or for similar reasons, the individual may petition the Certification Committee to suspend his or her license. However, the individual may not be referred to as an International Clinical Research Professional during the suspension period.

Article 13 (Suspended renewals)

An International Clinical Research Professional may lose his or her qualifications for the following reasons.

(1) When declining to be certified as an International Clinical Research Professional

(2) When certification is not renewed

(3) Upon withdrawal from the Society

Article 14 (Revocation of eligibility)

If the International Clinical Research Professional is found to have acted in an inappropriate manner, or to have made a false statement in the application documents, certification may be revoked after deliberation by the Certification Committee and approval by the Board of Directors.

Chapter 3 training

Article 15 (training)

(1) After applying for the start of training, take a training course (including e-learning system) related to international clinical research accredited by the Society, and pass the confirmation test for each unit.

(2) After applying for the start of training, attend a seminar on international joint clinical research conducted or designated by the Society.

Article 16(Training content and others)

Standards for training content and other necessary matters are determined by the Accreditation Subcommittee. In addition, the accreditation section will recognize as an accredited training course of the Society among the training courses related to international joint clinical research provided by other organizations that meet the accreditation requirements for training courses stipulated by the accreditation section.

Chapter 3 Amendments to the regulations

Article 17 (Training content and others)

Revisions to these rules may be made through resolutions of the Certification Committee and the Board of Directors.

Supplementary provisions

These regulations will come into effect from November 3, 2022.