Ethics Regulations for Medical Research Involving Human Subjects

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(Objective)
Article 1
The objective of these regulations is to ensure that the Research and Education Promotion Foundation (hereinafter referred to as "R.E.P.") complies matters to be observed from an ethical point of view in conducting medical research involving human subjects, respect human dignity and human rights, obtain societal understanding and cooperation, and conduct research smoothly.

(Definition of terminology)
Article 2
The definitions of the terminology used in these regulations are as follows.

(1) Medical Research Involving Human Subjects

An activity involving human subjects (including specimens and information acquired from them) to be carried out for the purpose of obtaining knowledge contributing to maintain and promote people's good health or to recover from injury and disease and improve quality of life for patients, through understanding the cause of diseases and their pathology and through improving measures to prevent injury and disease as well as diagnostic and treatment measures in medical care or through verifying those measures' validity.

(2) Invasiveness

To cause injuries or distress to research subjects' body and/or mind by conducting a procedure for investigational purpose, such as puncture, incision, administration of drugs, irradiation and questions related to the subject's mental trauma, etc. Of various types of invasiveness, one causing minor injury and/or distress on the research subjects' body and/or mind is called "minor invasiveness."

(3) Intervention

A practice for investigational purpose to control the presence or absence of factors, which can affect a variety of events occurring in relation with human health (including activities to maintain and promote good health and medical practices such as medication and examinations for prevention, diagnosis and treatment of the patients), or the degree of such factors. The above-defined intervention also includes medical technique beyond usual medical practice that is conducted for investigational purpose.

(4) Human Biological Specimen

A part of human body (including that of deceased individuals) to be utilized (or which has been utilized) in research, such as blood, body fluids, tissues, cells, excrement and DNA extracted from these, etc.

(5) Specimen and/or Information

The above-defined human biological specimen and/or the above-defined information utilized in research.

(6) Head of the Research Institution

This refers to the president of R.E.P.

(7) Principal Investigator

An individual who is engaged in implementing of research and directing overall research work at R.E.P.

(8) Investigators, etc.

People responsible for research at R.E.P., as well as other people involved in conducting research, including people conducting operations involving the provision of specimens and information and activities related to personal information protection.

(9) Informed Consent

Consent to be given voluntarily by research subjects or their legally acceptable representative, etc. to investigators, etc. or individuals providing existing

specimens or information, with respect to whether the research shall be commenced or continued (including how specimens or information shall be handled), having enough understanding after receiving adequate prior information with regard to the purpose and significance of the research, burdens on the research subjects and predicted results of the research (including both risks and benefits), etc.

(Research to be conducted by R.E.P.)

Article 3.

1. R.E.P. aims to support research activities of researchers belonging to research institutions existing in Thailand or Japan, and therefore shall not carry out medical research alone.
2. Medical research carried out by R.E.P. shall be carried out in collaboration with research institutions with which a joint research agreement is signed or under consignment from research institutions.

(Scope of application of these regulations)

Article 4

1. These regulations apply to any medical research involving human subjects which is carried out by R.E.P.
2. When carrying out research inside Thailand with Thailand's research institutions, R.E.P. shall follow these regulations and also adhere to the provisions set forth in laws, ordinances, guidelines of Thailand.
3. When carrying out research inside Thailand collaboratively with foreign research institutions including Japan, R.E.P. shall follow these regulations and also adhere to the provisions set forth in laws, ordinances, guidelines of Thailand and the relevant foreign countries.
4. When the provision(s) set forth in such local laws, ordinances, guidelines, etc. are stricter than the provision(s) of these regulations, in principle research shall be carried out in accordance with the provision(s) of the said local laws, ordinances, guidelines, etc. in place of the relevant provision(s) of these regulations.

(Basic policy)

Article 5.

The basic policy for medical research involving human subjects is as follows.

(1) Respect for human dignity and human rights
(2) Implementation of research with social and academic values
(3) Ensuring of scientific validity suitable to the characteristics in the particular field of research
(4) Comprehensive assessment of the burdens on research subjects and predicted risks and benefits
(5) Review by an independent and fair ethical review committee
(6) Adequate prior explanation and voluntary informed consent of research subjects
(7) Special consideration for vulnerable subjects
(8) Protection of personal information
(9) Ensuring of integrity and transparency of research

(Obligations of investigators)

Article 6

1. Investigators, etc. shall carry out research with the utmost respect for the life, health and human rights of research subjects.

2. Investigators, etc. shall not disclose information obtained while they are engaged in research without justifiable reason. The same shall apply even after investigators, etc. are no longer engaged in the research.

3. Investigators, etc. shall carry out research appropriately, complying with laws, ordinances, guidelines, etc. and in accordance with the research protocol reviewed by the ethical review committee and approved by the chief executive of the research implementing entity.

4. Investigators, etc. shall receive education and training on the ethics of research and on knowledge and skills necessary to carry out the research prior to its implementation. They shall also receive education and training during the research period on a regular basis as necessary.

(Obligations of principal investigator)

Article 7

1. The principal investigator shall prepare an appropriate research protocol prior to any

implementation of research. In the same manner, the principal investigator shall revise the research protocol prior to any implementation of a changed conduct of research.
2. The principal investigator shall endeavor to take action in order that his/her research shall be carried out appropriately and the reliability of results of the research can be secured, for example, by collecting information necessary in carrying out the research.
3. When research is finished, the principal investigator of the research shall report to the head of the research institution with respect to matters required.
4. When conducting research collaboratively with other research implementing entity(s), the principal investigator shall share relevant information to the research with the principal investigator of such other research implementing entity(s).

(Obligations of the head of the research institution)
Article 8.
1. The head of the research institution shall exercise necessary supervision over the research he/she approved for implementing, in order that it shall be carried out appropriately, and shall take ultimate responsibility for it.
2. The head of the research institution shall arrange systems and procedures necessary for the appropriate implementation of research.
3. When the head of the research institution is asked by principal investigator for approval for any implementation of research or revision of the approved research protocol, the head of the research institution shall submit the matter to ethical review committee for deliberation and make decision on relevant measures, such as approval, disapproval, etc., to the matter with due respect to opinions presented by the ethical review committee.

(Ethical review committee)
Article 9
1. When the head of the research institution asks for any opinion with regard to the appropriateness of implementing research or other matters, the ethical review committee shall make reviews on the matter, in accordance with these regulations, neutrally and fairly as well as from ethical and scientific viewpoints, and shall present its opinions in writing.
2. The composition of committee members and other details required for ethical

committee are prescribed in the Research Ethics Committee Regulations.

(Audit)
Article 10
1. The principal investigator shall endeavor to secure the reliability of research and when carrying out research which involves invasiveness (not including minor invasiveness) and intervention, shall perform monitoring and, as necessary, audit, in accordance with the specifications prescribed in the research protocol approved by the head of the research institution.

(Revision of these regulations)
Article 11
Revision of these regulations shall be determined by the president, after the meeting of the executive board of R.E.P.

(Effective date)
Article 12
These regulations are effective as of November 15, 2017.