Research Ethics Committee Regulations

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(Objectives)
Article 1
The objective of these regulations is to examine the appropriateness of medical research involving human subjects which is conducted by the Research and Education Promotion Foundation (hereinafter referred to as “R.E.P.”), in accordance with the "Ethics Regulations for Medical Research Involving Human Subjects" formulated by R.E.P., from an ethical and scientific perspective.

(Establishment of ethics committee)
Article 2
For the purpose of the preceding article, R.E.P. establishes an ethics committee for medical research (hereinafter referred to as "the Committee").

(Composition of Committee members)
Article 3
1. The Committee shall be composed of five or more members with the following standpoints.
   (1) Expert in the medical science or life science
   (2) Expert in the humanities or social sciences, including ethics and law
   (3) Those who can provide opinions of the general public, including viewpoints of research subjects.
2. The Committee shall have at least two members who do not belong to R.E.P.
3. The Committee shall be composed of at least one member with Japanese nationality and at least one member with Thailand nationality.
4. The Committee shall have both male and female members.
5. In addition to members described in the preceding paragraph, the Committee may add any person who the Committee considers necessary as a member
6. The tenure of the Committee members shall be two years, and members may be reappointed at the end of this term. The term of the substitute Committee members in

the event of vacancy shall be the remaining term of the predecessor.

(Appointment of committee members)
Article 4
1. The Committee members shall be appointed by the president of R.E.P. (hereinafter referred to as "the President ")
2. The Committee chair and deputy Committee chair shall be decided by mutual election of the Committee members, and appointed by the President.

(Submission of research protocol)
Article 5
1. When principal investigator intends to carry out any research (including the case in which research is implemented after revision(s) in the research protocol), the principal investigator shall prepare the research plan composed of following documents beforehand and receive approval of the President.

(1) Research protocol
(2) Research subject information sheet to obtain consent
(3) Consent form
(4) Other materials required by the Committee

2. When principal investigator intends to conduct any research collaboratively with other research implementing entity(s), the principal investigator shall clarify the role and responsibility of the principal investigators of each of other collaborative research implementing entity(s), in the course of the preparation of a research protocol. In addition, principal investigator shall provide the Committee with information necessary for making reviews, including information on approval for the implementation of research at other collaborative research implementing entity(s), results of the review by other ethical review committee(s) and the progress status of the research.

(Contents of research protocol)
Article 6
1. Contents of research protocol shall, in principle, include the items below. Any of those items may be omitted, however, when the President gives approval for that after the Committee deliberation. In addition, with respect to work that R.E.P. does not

engage directly, it can be replaced by attaching a research plan submitted by the collaborating research institution to the ethics review committee of the research institution.

(1) Title of the research
(2) Site-specific information for the research (including names of the research implementing entity(s) and the investigator(s), etc.)
(3) Objectives and significance of the research
(4) Method and time period of the research
(5) Enrolling Criteria of research subjects
(6) Basis of scientific validity for implementing the research
(7) Procedures pursuant to the provisions for obtaining informed consent, etc.
(8) Handling of personal information, etc. (including process of anonymization, when anonymization is conducted)
(9) Burdens to be caused on the research subjects and predicted risks and benefits, including comprehensive assessment of such burdens, risks and benefits as well as measures to minimize those burdens and risks
(10) Means for storage and disposal of specimens and information
(11) Matters to be reported to the chief executive of the research implementing entity and procedures for such reports
(12) Status of research-related conflicts of interest of the research implementing entity, such as research fund resources, as well as research-related conflicts of interest of each investigator, etc., such as his/her individual income
(13) Means to disclose information on research
(14) Means to respond to the consultation, etc. made by the research subjects, etc. and other individuals concerned
(15) When the research involves any financial expenditure on or remuneration for the research subject, etc., a statement to the effect that and details of such
(16) When the research involves invasiveness (not including minor invasiveness), means to respond in cases of serious adverse event
(17) When the research involves any invasiveness, whether or not compensation will be offered for research-related injury and detail of such compensation;
(18) When the research involves any medical technique beyond usual medical practice, response related to the healthcare delivery to the research subjects after

the research

(19) When any significant finding concerning the research subject's health or genetic characteristics which may be inherited by his/her offspring, etc. may be obtained through implementing the research, handling of the research results related to the research subject (including incidental findings);

(20) When a part of work related to the research is entrusted, the content of work to be entrusted and means of supervision over the contractor(s)

(21) With respect to specimens and information acquired from the research subject, when any of those may be utilized or provided to other research implementing entity(s) for the research in future that is not identified at the time of obtaining consent from the research subject, etc., a statement to that effect and the contents of utilization assumed at the time of obtaining consent

(22) When monitoring or audit is performed pursuant to the provisions, organizational framework and procedures for such.

2. Contents of the research protocol for operating research work acquiring specimens or information from research subjects or being provided from other entities, and retaining and providing such specimens or information to other research implementing entities repeatedly and continuously (hereinafter referred to as "collection and provision") shall, in principle, include the items below. Any of those items may be omitted, however, when the President gives approval for that after relevant ethical review committee deliberation.

(1) Organizational framework for the collection and provision of specimens or information (including name(s) of the organization collecting and providing specimens or information and the investigator(s), etc.)

(2) Objectives and significance of the collection and provision of specimens or information

(3) Method and time period for the collection and provision of specimens or information

(4) Types of specimens or information to be collected and provided

(5) Procedures pursuant to the provisions for obtaining informed consent, etc. (including information to be provided and consented to pursuant to the relevant provisions, when obtaining informed consent)

(6) Handling of personal information, etc. (including process of anonymization, when anonymization is conducted);
(7) Burdens to be caused on the research subjects and predictable risks and benefits, including comprehensive assessment of such burdens, risks and benefits as well as measures to minimize those burdens and risks;
(8) Means for storage of specimens or information and for quality control of them
(9) Handling of specimens or information after the end of collection and provision
(10) Status of research-related conflicts of interest of the organization collecting and providing specimens or information, such as fund resources for the collection and provision, as well as research-related conflicts of interest of each investigator, etc., such as his/her individual income
(11) Response to consultation, etc. made by the research subjects, etc. and other individuals concerned
(12) When the research involves any medical technique beyond usual medical practice, a statement to that effect and details of such
(13) When any significant finding concerning the research subject's health or genetic characteristics which may be inherited by his/her offspring, etc. may be obtained through implementing the research, handling of the research results related to the research subject (including incidental findings)
(14) With respect to specimens or information acquired from the research subject, when any of those may be utilized or provided to other research implementing entity(s) for the research in future that is not identified at the time of obtaining consent from the research subject, etc., a statement to that effect and the contents of utilization assumed at the time of obtaining consent.

(Examination)

Article 7

1. The President shall submit research planning documents to the Committee members. The Committee members evaluate the appropriateness of conducting research based on the submitted research planning documents.

2. Committee members may request a hearing to applicant to ensure the appropriateness and reliability of research being conducted. The applicant shall respond to a hearing.

3. When the applicant is the Committee member, the member can not participate in the judgment of the examination. The President can not participate in the deliberations and decision of the Committee.
4. The Committee may invite nonmembers with expertise in special areas for assistance.

(Resolution method)
Article 8
1. In principle, Committee resolutions should be determined unanimously by all members present. However, in the event that opinion is divided, resolutions shall be determined by agreement of two-thirds of the members. In this event the dissenting opinions shall be submitted to the President.
2. Decisions shall be of the following five types.
(1) Approval
(2) Conditional approval
(3) Non-approval
(4) Re-evaluation: To be evaluated again following revision of the plan
(5) Not applicable
3. The Committee chair must report the Committee's evaluation results to the President without delay.
4. The President must respect the Committee's decisions and make necessary decisions on items pertaining to the conduct of research in accordance with these decisions. The President may not perform research that the Committee has deemed inappropriate.

(Expedited evaluation)
Article 9
Under any of the following circumstances the Committee may delegate reviews to member(s) designated by the Committee (hereinafter referred to as "expedited review") and adopt their opinion. The result of such an expedited review shall be considered as the conclusion of the entire ethical review committee and shall be reported to other members of the Committee.
(1) Review of research to be conducted collaboratively with other research implementing entity(s), the entire scope of which has already been reviewed by the ethical review committee to which the collaborative research entity(s)

submitted it for deliberation and opinions to indicate the appropriateness of such research have already been presented;

(2) Review of minor revisions of research protocol;

(Saving of evaluation records)

Article 10

Evaluation records approved by the Committee shall be stored for a period of the date of reporting the completion of such research. However, evaluation materials related to intervention in research that is invasive (excluding minimally invasive) shall be stored for a period of five years following the date of reporting the completion of such research.

(Confidentiality)

Article 11

Neither Committee members nor personnel conducting related office work may disclose information obtained in the course of their duties. This provision shall apply after such duties have ended.

(Revision of the regulations)

Article 12

Revision of these regulations will be determined by the President, after the meeting of the executive board.

(Effective date)

Article 13

These regulations are effective from November 15, 2017.