Radiation Effects Research Foundation
Operational Procedures of RERF Institutional Review Board

1. Objectives

These operational procedures set forth the composition and operation of the Institutional Review Board (hereinafter referred to as "IRB"), which has been established in accordance with the RERF Regulations for Protection of Study Subjects and Standing Committee Establishment Procedures.

2. Composition of the IRB

(1) The IRB shall have at least five members who are appointed by the RERF Chair. However, the RERF Chair may not appoint him/herself as an IRB member.

(2) The IRB membership shall be composed to meet all of the following requirements. (With regard to 1)-3) below, the same person may not meet multiple requirements.)
   1) The IRB shall include experts in natural science, such as specialists in medical science/medical treatment.
   2) The IRB shall include experts in humanities/social science, such as specialists in ethics/legal science.
   3) The IRB shall include those who express opinions from the perspective of the general public, such as study subjects.
   4) The IRB shall include more than one individual who are not affiliated with RERF. One of such individuals shall not be a spouse, child, parent, sibling or other relative who shares living expenses with a person who is affiliated with RERF.
   5) The IRB shall include members of both genders.

(3) In appointing committee members, due consideration shall be given to the composition of the IRB to maintain balance among all RERF research departments/secretariat.

(4) The IRB shall have a Chairperson and Vice Chairperson, to be appointed by the RERF Chair from among the members of the IRB.

(5) The term of office for IRB members shall be two years, with reappointment possible. In the case of replacement in the middle of a term, the term of office for the IRB member appointed to fill the vacancy shall be the remainder of the predecessor's term of office.

(6) The IRB shall have an executive secretary (ies), to be appointed by the RERF Chair. The executive secretary (ies)'s term of office shall be two years, with reappointment possible.

(7) IRB members and executive secretary (ies) shall not disclose information obtained in the course of their board duties without justifiable reason. The same applies after the members and executive secretary (ies) leave their IRB posts.

(8) The RERF Chair shall take all measures necessary to ensure that IRB members and the executive secretary (ies) receive education and training for reviews and the related work of the board.

3. Convening of the IRB and decision

(1) Convening of the IRB
   1) The IRB Chairperson shall convene the IRB.
   2) The IRB may not convene unless a simple majority of the committee members are in attendance. Furthermore, attendance must fulfill the requirements for committee composition set forth above in 2.(2).

3) The committee members shall participate in IRB reviews and decisions from a fair and neutral standpoint, without consideration paid to their own interests or the interests of their organizations or departments.
4) Investigators and others engaged in conducting a study to be reviewed shall not participate in the IRB's deliberation and decision-making processes. However, such individuals may attend the meeting to present explanations about the study upon the committee's request.
5) The IRB Chairperson may ask for experts' opinions in relation to the contents of a study to be reviewed.
6) When reviewing a research protocol that involves study subjects for whom special consideration is required, the IRB shall ask for opinions from those who have expertise about these subjects.

(2) Decision
1) The IRB shall endeavor to reach a unanimous decision.
2) If unanimity cannot be achieved, decisions by the IRB shall require the consensus of at least two-thirds of the members in attendance.

4. Functions of the IRB

(1) In response to a request from the RERF Chair for an opinion about whether a specific study involving human subjects should be approved or disapproved, the IRB shall conduct reviews in a neutral and fair manner, from both ethical and scientific perspectives, in compliance with all domestic/applicable foreign laws, regulations, and guidelines for protection of study subjects in the relevant study. The IRB will also consider information about possible conflicts of interest involving RERF, its investigators or others, and provide its opinions in writing to the RERF Chair.

(2) The IRB will investigate existing research protocols involving human subjects on an as-needed basis, from both ethical and scientific perspectives, and provide the RERF Chair with recommendations concerning these protocols, including suggestions for modifications or termination.

(3) The IRB may review research protocols involving human subjects upon request from other research institutes. Such reviews shall be predicated on sufficient understanding of the system for conducting research at the relevant research institute.

5. IRB review of research protocols and progress

(1) The IRB review of research protocols and progress shall be conducted in either of the following formats.
1) Regular review (reviews by the IRB in accordance with the provisions of 3.(1) of these operational procedures)
2) Expedited review
a. Regardless of the provisions of 3. (1), the IRB may conduct a review through the IRB Chairperson or through at least one experienced committee member appointed by the IRB Chairperson.
b. The IRB may conduct an expedited review after confirming that the research protocol in question meets the requirements for expedited review stipulated by domestic/applicable foreign laws, regulations, and guidelines for protection of study subjects (Attachment 1 stipulated in the steps for the implementation of ethical review [hereinafter referred to as the "steps"]).
c. Expedited review results shall be presented as the IRB's view and announced to the committee members.
d. Committee members notified of expedited review results have the right to

request, upon submission of justification for the action, that the IRB Chairperson convene the committee to review the item concerned once again. In such cases, when the IRB Chairperson finds reasonable grounds, he/she must convene the committee to re-review the item concerned.

(2) Matters to be reviewed

The IRB review of research protocols and progress shall be conducted in any of the following circumstances:

1) Review of new research proposals (Attachment 2 stipulated in the steps)
2) Review of proposals to modify existing research protocols (Attachment 2 stipulated in the steps)
3) Continuing review of progress of existing research proposals (Attachment 3 stipulated in the steps)
   a. All ongoing research protocols involving human subjects shall be subject to at least one continuing review by the IRB each year. The frequency of such reviews shall be determined by the IRB at the first review, based on the degree of the risk.
   b. A principal investigator (hereinafter referred to as "PI") shall prepare documents required for reviews stipulated above in a., and submit them to the IRB.
   c. As part of a continuing review, the IRB may interview the PI and others in charge of the relevant study. To confirm that no material changes in the research protocol have occurred since the previous review, the IRB may also obtain information from sources other than the PI on an as-needed basis for verification.
4) Review of adverse event reports (Attachment 4 stipulated in the steps)
   a. When an investigator or other concerned party finds a case described in any of the following categories or is concerned that a relevant case has occurred, the investigator shall take necessary measures in a timely manner, in accordance with predetermined procedures, and make a report to the PI.
      i. An adverse event that has occurred to study subjects
      ii. Problems that are not anticipated in a research protocol
      iii. Noncompliance with laws, regulations or guidelines for protection of study subjects, or with determinations of the IRB
   b. In response to the report stipulated above in a., the PI shall confirm the presence/absence of the relevant case without delay. When the case is confirmed, he/she shall take all measures necessary, including managing any adverse event that has occurred to study subjects and reporting to the Chief of the Department/Secretariat to which he/she belongs as well as the Chair, and submit an adverse event report to the IRB.
   c. It is necessary to ensure that the person who made such a report set forth above in a. and b. will not receive any disadvantageous treatment by reason of having made the relevant report.

6. Preparation for IRB review and disclosure of records and information

The IRB executive secretary (ies) shall perform the following duties with instructions and/or approval from the IRB Chairperson.

(1) Preparation for IRB review

1) Acquisition of review-related materials and prior confirmation
2) Issuance of acceptance numbers
3) Provision of IRB meeting notification to committee members

(2) Provision of IRB review results, preparation of minutes of IRB meetings, and retention of documents
   1) The executive secretary (ies) shall announce review results to PIs.
   2) The executive secretary (ies) shall summarize the proceedings and prepare minutes.
   3) In addition to the aforementioned minutes of IRB meetings, the executive secretary (ies) shall retain documents received by or dispatched from the IRB.

(3) Disclosure of IRB-related information
   1) Regulations concerning the organization and operation of the IRB and a list of IRB members, identified by name, shall be disclosed on RERF's external website and through the Health, Labour and Welfare Ministry's (MHLW's) IRB reporting system.
   2) Meeting dates for the IRB and review outlines shall be disclosed on the RERF external website and through MHLW's IRB reporting system not less than once a year.

7. Retention period for IRB review materials and disposal procedures

(1) Materials pertaining to the review of research protocols shall be retained for at least five years after the completion of research is reported.

(2) Records shall be retained in an appropriate storage area to prevent damage or loss.

(3) When the retention period for records has expired, they shall be disposed of in accordance with procedures set forth in the RERF regulations.

8. Revision of these operational procedures

These operational procedures shall be revised on an as-needed basis or approximately five years after the date of enforcement, based on a review of the entire contents.

Supplementary Provision

(Effective date)

1. These operational procedures shall take effect from April 1, 2016.

(Old procedures)

2. The Operational Procedures of Human Investigation Committee and the Operational Procedures of Ethics Committee for Genome Research will be abolished on the effective date of the present operational procedures.

Supplementary Provision

1. These procedures will be partially revised with effect from July 1, 2019.

Supplementary Provision

1. These procedures will be partially revised with effect from July 1, 2024.
2. The steps and forms (Attachments, etc.) to implement these procedures will be as set forth in the separately prepared steps for the implementation of ethical review.