

## **Radiation Effects Research Foundation Regulations for Protection of Study Subjects**

(Objective)

**Article 1** - The objective of these regulations is to provide for the protection of study subjects at the Radiation Effects Research Foundation (hereafter referred to as “this juristic person”), in accordance with Paragraph 2 of Article 66, Articles of Incorporation.

(Employees’ responsibilities)

**Article 2** - Individuals stipulated in Article 2 of the Rules of Employment, as well as all individuals engaged in activities at this juristic person by this juristic person’s direction and order (hereafter referred to as “employees”), in conducting research involving human subjects, pledge to strive for the protection of study subjects, in line with their roles in such research, giving due attention to the following basic matters:

- (1) Compliance with applicable domestic and foreign laws and guidelines concerning the protection of study subjects in such research;
- (2) Ensuring the appropriateness of research by developing and complying with research protocols, and by preliminary review and approval of such research protocols by an institutional review board;
- (3) Protection of personal information of study subjects;
- (4) Provision of sufficient prior explanation to study subjects and securing their consent of their own free will (informed consent), in cases in which such efforts are required;
- (5) Reporting to the persons, the institutional review board, and the Director(s) in charge of such research when a problem related to the protection of study subjects has occurred.

(Compliance with laws and guidelines)

**Article 3** - Laws and guidelines applicable to this juristic person’s research in Item 1 of Paragraph 1 of the preceding Article are as follows:

- (1) Research on the atomic bomb survivors and their children
  - 1) Japanese ethical guidelines for medical research: Ethical Guidelines for Life-Science and Medical Research Involving Human Subjects
  - 2) The U.S. ethical guidelines for medical research: The U.S. Code of Federal Regulations: Title 45 Public Welfare Part 46 Protection of Human Subjects
- (2) Research on human subjects other than (1) above
  - 1) Japanese ethical guidelines for medical research: Ethical Guidelines for Life-Science and Medical Research Involving Human Subjects

(Institutional review board)

**Article 4** - This juristic person shall establish an institutional review board (IRB) to perform ethical and scientific review of its research. Duties of the IRB shall typically be the following:

- (1) Advance review of research protocols; approval or other such decisions on said

- research protocols;
- (2) Periodic review of ongoing research programs; submission of modification, cancellation, or other such opinions on said research programs;
- (3) Items separately prescribed as necessary in addition to the preceding items.
2. RERF Chairman must determine the approval or disapproval of all research protocols or proposals for changes with due respect to the decision of the IRB. Any research not approved by the IRB will not be allowed to be implemented.
  3. The IRB must be appropriately composed and operated in order to pursue impartial and neutral reviews, in accordance with domestic and applicable foreign laws and guidelines related to protection of study subjects in each research program conducted by this juristic person.
  4. Members of the IRB must not reveal any information obtained from the performance of their duties without reasonable justification. This shall also apply after resignation from their positions.
  5. Matters pertaining to the operation of the IRB will be determined separately.

(Education and training programs concerning protection of study subjects)

**Article 5** - The Chairman shall be responsible for taking necessary measures to ensure that employees receive education and training programs concerning the protection of study subjects.

(Punishment)

**Article 6** - If an employee violates Article 2 and/or Paragraph 4 of Article 4, he or she will be disciplined in accordance with the provisions of the Rules of Employment or his or her contract.

(Revision and abolition of the regulations)

**Article 7** - Revision and abolition of these regulations will be implemented by decision of the Board of Directors.

### **Supplementary Provision**

These regulations shall take effect on the date of approval by the Board of Directors (June 4, 2014).

### **Supplementary Provision**

These regulations shall take effect on the date of approval by the Board of Directors (March 4, 2016) and be implemented from April 1, 2016.

### **Supplementary Provision**

These regulations shall take effect on the date of approval by the Board of Directors (June 3, 2021) and be implemented from June 30, 2021.