(TRANSLATED BY THE TRANSLATION OFFICE)

Summary minutes of the 4th Institutional Review Board Meeting in FY2023 (Expedited review)

Date & time	Wednesday, May 10, 2023, 9:30–11:12
Place	Auditorium (Hiroshima) and the 3rd Conference Room (Nagasaki)
Participants	IRB co-chairpersons: Dr. Tanabe and Ms. Shinohara IRB members: Dr. Yamada, Dr. Satoh, Dr. Sugiyama, Dr. Hida, Ms. Ogawa, Ms. Dodo, and Mr. Fuchi

< Review of research involving human subjects >

	Dept.	Study title	Review result	Summary minutes
1	Molecular Biosciences	CR175: "Study of the association between parental radiation exposure and occurrence of de novo germline mutations in their offspring" (Uchimura *et al.*)	Approved	**1. Application Form** ・ Select "Research with interventions" for I. "9. Category of research" (2) (p. 4). ・ In (2) of "VII-1. Storage and disposal of samples related to this research," the phrase "In addition, this research will use existing samples" should be deleted (p. 13). ・ In "VII-2. Storage and disposal of samples related to this research," if samples will be stored at a collaborating research institution, write that the "[2] Duration" will be "until the end of the research period" or "until what month, what year" (p. 14). ・ Delete "due to unavoidable reasons" under "Disposal of data", and state that if a collaborating research institution will have summarized data or the like in the conduct of the study, it will be disposed of at the end of the research period (p. 15) (the same applies to p. 40 of the Research Protocol). **2. Research Protocol** ・ Under "Benefits and disadvantages for the research subjects," describe the "maximum volume of blood to be collected" for physical examinations of persons who are not AHS/FOCS subjects (p. 37, p. 38-[1]). ・ Add "in addition" before "those who are not members of AHS/FOCS" (p. 38-[1]). ・ In the "registration with a public database" section, mention "if another study is conducted using this database, it will be published on RERF's official website" (p. 41). ・ In the "Reporting to the RERF Chair" section, add "such as the occurrence of adverse events" to the phrase "(3) Unforeseen issues" (p. 41). ・ Use consistent terminology for "data including non-anonymized personal information" and "non-anonymized data" (p. 46). **3. Explanatory Document and Other Materials** ・ Delete "up to now" in "records of physical examinations at RERF up to now" (p. 54

				and p. 55). ・ Indicate in the “What you are requested to provide” section that you will be using stored cells from previously donated blood (p. 54). ・ Change “mortality follow-up studies” to “life span studies” (p. 55). ・ In the “Rights of those who will undergo genetic analyses” section, either delete “no personal information will be included in such published information” or revise the language to state that names and contact information will not be disclosed (p. 57). ・ Either delete “(5) We will ensure that your personal information is not leaked” or revise the language to state that names and contact information will not be disclosed (p. 59). ・ Revise “domestic” in “domestic public genome database” to “of Japan” (p. 60, p. 61, p. 63). ・ In 2–4) on the Consent form, mention that registered genomic data will be shared not only in Japan but also overseas (p. 61). ・ Specify the volume of blood to be collected for physical examinations, e.g., "how many mL at the maximum" (p. 64-[2]). **4. Information Disclosure Document** ・ In (2) of “Information to be used,” add “health information of parents and children (acquired from physical examinations for the RERF Adult Health Study and the Clinical Study of the F_1 Offspring of A-bomb Survivors, other physical examination, and the life span studies)” (p. 67). ・ Add “cancer registry organizations” to “Provision of specimens/information to external institution(s) (p. 67).

Approved by confirming that the aforementioned revisions have duly been made.

To prevent the spread of COVID-19, the IRB members at the meeting maintained sufficient distances from each other.