Minutes of the 11th Institutional Review Board Meeting in FY2023 (Expedited Review)

Date Wednesday, October 11, 2023, 10:00-12:00

Place [Hiroshima] Auditorium, [Nagasaki] The 3rd conference room (teleconference)

Participants *IRB co-chairpersons*: Dr. Tanabe and Ms. Shinohara; *IRB members*: Dr. Hida and Ms. Ogawa

Review of research involving human subjects

	Department	Study title	Review result	Summary minutes
1	Epidemiology	CR180: Cancer risk projection for the UNSCEAR report concerning Epidemiological Studies of Radiation and Cancer (Furukawa et al.)	Approved	I. Application □ In "I-2. Collaborative research by multiple entities (p. 1)", check Yes for “If yes, is collective review desired?”. □ In "I-3. Purpose, significance, and basis demonstrating scientific validity of research (p. 1)", revise “using the risk estimates derived from published LSS papers” into “using the cancer incidence risk estimates derived from published LSS papers.” In addition, revise “to project risks of cancer incidence from the LSS to reference populations” into “to project risks of cancer incidence in reference populations based on the LSS data”. (Same revision in the Information Disclosure Form) □ In "I-4. Duration and methods" (p. 1), revise “study period will be from the date of approval by RERF IRB” into “study period will be from the date of approval by RERF IRB and the Executive Committee.” □ In "Within RERF" of "I-7-3) Safeguarding" (p. 2), include a comment to the effect that research assistants of RERF Epidemiologic Analysis Laboratory will create and pseudonymize the dataset for analysis, and replace “subject’s ID number” with “system ID number” (same modifications on p. 11 of RP). Regarding “the new ID number will be generated randomly only for this study” (p. 2), add a comment to the effect that the key table prepared by the research assistants will not be kept (same modification on p. 11 of RP). □ In "When providing information outside RERF" of "I-7-3) Safeguarding" (p. 2), clarify who will encrypt data, record data provision, and store the record of provision, and clarify also how the record is stored (same modifications on p. 11 of RP). 2. Research protocol (RP) □ Line 203 (p. 10): Revise “… Department of Epidemiology provides the following personal information to the relevant cancer registries” into “… Department of Epidemiology provided the following personal information to the relevant cancer registries and thereby obtained the following information”. □ Line 211 (p. 10): Replace “… obtained by previous RERF surveys” with a clearer expression such as “… obtained by interviews or mail surveys.” □ Line 252 (p. 12): Add an explanation to the effect that data will be stored until the completion of the project in “Only pseudonymously processed individual level data will be stored in the RERF internal secure network folder …”. □ Line 254 (p. 12): Indicate who will report in “Regular updates on study progress will be reported to the primary investigator and other investigators at RERF via e-mail …".

				□ Line 256 (p. 12): In “all coefficients and variance-covariance matrices … will be discarded,” explain how discarding is made, such as “electronic files are irreversibly deleted and paper documents are shredded.” □ Line 258 (p. 12): Indicate the period such as “indefinitely” in “Datasets used for analysis, results, and documents will be archived at ITD of RERF for the purpose of scientific verification in the future. 3. Information Disclosure Form (Form 1-5-2) □ Enter the research starting date in “Period” (p.1). □ Explain the “reference populations throughout the world” in “Objective and method of using specimens/information” (p. 1). □ In “Specimens/information items to be used or provided,” replace “Used by RERF investigators” with “Information to be used.” Also, revise the “city, town, and village” into the “city at the time of bombing.” (P. 1) □ Include a comment to the effect that based on RP18-61 and RP29-60 information is obtained from the cancer registry and tumor/tissue registry (p. 2). □ Make the entry of “ABCC autopsy program” separate from the cancer registry information (p. 2). (Same in "Items on specimens/information" of Form 1-6-2) 4. Records on provision of samples-data □ Form 1-6-1: In “How specimens/information were obtained,” include a comment based on excerpt from the RP such as “Using person-year tables generated from the pseudonymized individual-level data, dose-response analyses will be conducted for computation”. □ Form 1-6-1: In “When to prepare the record to provide” under “Other items to be included in RP”, enter a comment such as “within (how many) days from the day of provision” or “the month in which provision was made”. Specify the type of record like a paper document or an electronic file in “Recording medium of the record to provide.” Include a location of a file cabinet, a server, *etc*. in which the recording medium is stored in “Place to store the record to provide” (same modification in Form 1-6-2). In “Method for the party to be provided to confirm the detail of informed consent of the party to provide,” delete “RP’s consent statement” and enter a comment like “By viewing the Information Disclosure Form”. □ Form 1-6-2: In “Method for the party to be provided to confirm the detail of informed consent of the party to provide,” enter a comment like “Informed consent has not been obtained.”

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

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