Summary minutes of the 6th Institutional Review Board Meeting in FY2023 (Expedited review)

Date & time	Monday, Jun 26, 2023, 14:00 – 15:30
Place	Auditorium (Hiroshima) and the 3rd Conference Room (Nagasaki)
Participants	IRB co-chairpersons: Dr. Tanabe and Ms. Shinohara IRB members: Dr. Hida and Ms. Ogawa

< Review of research involving human subjects >

	Dept.	Study title	Review result	Summary minutes
1	Clinical Studies	CR179: “Collaboration in a multicenter project with a Japanese cohort” (Tatsukawa *et al.*)	Approved	1. Application ・Ⅰ. 2: Select “No” for the question “Is collective review desired?” In item (2) and the subsequent items, provide information on all collaborative research institutions other than Toho University, and complete the “Roles/Responsibilities” fields. ・Ⅰ. 4: Delete “schedule” from the phrase “... we schedule to participate in the multicenter project,” and add a statement that IRB approval will be obtained again when providing new data. In the “Research duration” on page 2, the projected period of 4-5 years should be specified in terms of month and year. (The same applies to the Research Protocol (RP) on page 27 and the information disclosure document on page 43.) ・Ⅰ. 7: Also select “a) Personal information” in section (1) “Types of information used in research” on page 3. ・VII-2-2: For item ② “Period” in section (2) “Yes, the information will be stored,” provide a specific explanation, such as “until the completion of the participation in the Japanese Cohort Multicenter Collaborative Project (EPOCH-JAPAN),” on page 13. (The same applies to section g-2) in the RP on page 26.) ・VII-2-2: In section (3) “Disposal of the information” on page 14, select “Disposal is planned” and specify that electronic data will be physically deleted and paper will be shredded. ・IX-1: For the question “Will research results be explained to research subjects?” provide a justification for not doing so, such as the lack of sufficient clinical usefulness for estimating individual risk, on page 14. (The same applies to the RP on page 26.) 2. RP ・Replace “provided after anonymizing” with “provided after pseudonymizing” in the section “Large-scale integrated data management in EPOCH-JAPAN project” on page 25. ・Add “Toho University” to the phrase “those in charge will carry out statistical analysis

				within Shiga University of Medical Science or other institution of each cohort” in section f-3) “Statistical analysis” on page 25. ・Add the following to section g-2) “Ethical considerations for RERF data”: The potential risks or harm to the subjects involved in this project are minimum, and it is difficult to obtain consent again. Therefore, a simplified procedure will be implemented, and an opportunity to opt out will be ensured through the information disclosure document. Additionally, specify the staff member in charge as the contact person in the phrase “include information such as the contact information for RERF” on page 26. 3. Information disclosure document ・Revise the phrase “data to be provided will be pseudonymized at RERF” in the filed “Objective and method of using samples/information” to something like “to be provided after removing names and addresses” or “to be provided after deleting personal information” on page 43. ・In the field “Samples/information items to be used or provided” (page 43-44), explain how RERF has obtained the “death information” and “radiation exposure information.” 4. Items to be included in the RP (Form 1-6-1) ・Enter “RP1-75,” “RP2-75,” and “the vital statistics from the MHLW,” etc. in the field “How specimens/information were obtained” under “Recording Item A,” and update the field “Name of head of organization to provide” under “Recording Item C” on page 45.
2	Epidemiology	Revisions to RP 18-61 & RP 29-60: “Tumor registry study in Hiroshima and Nagasaki” and “Detection of leukemia and related disorders” (Sugiyama *et al*.)	Approved	1. RP ・List the researcher’s names under the title of the Attachment. Also, update the reference to the “Ethical Guidelines for Medical and Health Research Involving Human Subjects” and its effective date in the preamble. ・In the section 1) “Purpose” (page 11), in addition to “to estimate the number of subjects,” indicate that the data will also be used for analysis, as described in Section 10 on page 14. ・Explain how records of data transferred to or received from other organizations will be maintained. ・Clarify that the “IRB” mentioned in Section 1 of item 4) “Ethical procedures ...” refers to the IRB of RERF. Also, revise the phrase “necessary information will be disclosed on the RERF website in compliance with the ethical guidelines” in Section 2 on page 15 to clarify that the opportunity to opt out is ensured through the information disclosure, and to identify a staff member as the contact person.

				・In Section 6 of item 4) “Ethical procedure ...,” on page 16, add to the phrase “figures can be very small, but ...” that the figures may be lower than 10. (The same applies the Application on page 3 and the information disclosure document on page 22.) 2. Information disclosure document ・Replace “Form 1-5-1” on page 18 with “Form 1-5-2” for the opt-out procedure.

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.