Summary minutes of the 9th Institutional Review Board Meeting in FY2023 (Expedited review)

Date & time	Friday, Aug. 4, 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. Satoh, Dr. Hida, Ms. Ogawa, Ms. Dodo, and Mr. Fuchi

< Review of research involving human subjects >

	Dept.	Study title	Review result	Summary minutes
1	Clinical Studies	Continued review: CR178 “Thyroid diseases in Hiroshima and Nagasaki atomic-bomb survivors (Renewal of RP2-99)” (Imaizumi *et al.*)	Approved	1. Application nd Method,” enter annd Method,” enter an end date for the thyroid examination in the same manner as in the Research Protocol (p. 2). 2. Research Protocol provide the planned numbers for study provide the planned numbers for study subjects for purposes 1 and 2 and the rationale for the numbers (pp. 30-31). ・In "Close examination" under "f-2) Information to be Used," specify that "multiple ultrasound examinations" means "multiple examination visits" and define the criteria for referral to medical institutions (p. 32). ・In i-4), change “electronic information is initialized physically for disposal” to the effect that electronic information in question will be deleted (p. 42). ・Under "i-5) Details and Methods of Reporting to the RERF Chair," revise “written reports are promptly submitted to the RERF chair” into “written reports are promptly submitted to the RERF chair and IRB.” (p.42) 3. Guideline-based Information Disclosure Document or Provided,” add a comment such as “The or Provided,” add a comment such as “The date to begin using or providing the data is (month date, year) (which is the date of the Vice Chair’s approval) (p. 53). 4. Matters to be Included in Research Protocol (Forms 1-6-1 and 1-6-2) ・ In “Consent provided by study participants” under Entry B, enter “based on written consent or opt-out” (pp. 54 and 57).

2	Clinical Studies	RP-A10-08 Revision to “The risk of disorders in subclinical thyroid dysfunction: an individual participant pooled analysis of large international cohort studies” (Imaizumi *et al.*)	Approved	Research Protocol ・Under "Expenses," give an explanation such as “expenses related to RERF are funded from the RERF General Account” (p. 12). ・In “Ethical Considerations for RERF Data,” add that informed consent will not be obtained and information disclosure will not be made either, because all data provided for research use are anonymized versions of existing information. ・Regarding “Records related to the data provision will be kept for at least 5 years after the completion of this study,” clarify who will create and keep the records and how (p. 13).
3	Clinical Studies	RP-A1-14 Revision to “Association of chronic kidney disease and albuminuria with cardiovascular diseases among A-bomb survivors” (Hida *et al.*)	Approved	Research Protocol ・In "Informed Consent" (p. 13), include when obtaining written informed consent was initiated, and that verbal informed consent was previously obtained. ・Replace "research ID" with "system ID" (p. 14, the same replacement on p. 1, Application). ・In "Handling of Personal Information" under "Ethical Considerations", further explain the pseudonymization procedure in “statistical analysis of data will be conducted following a pseudonymization procedure.” In addition, change “the analytical data will be kept in perpetuity in ITD after review by the Statistics Department” to “the data will be kept indefinitely in ITD after review by the Subcommittee on Data Transformations and Analysis” (p. 14) . ・Under "Expenses", give an explanation such as “expenses related to RERF are funded from the RERF General Account” (p. 15).

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.