Summary minutes of the 2nd Institutional Review Board Meeting in FY2022 (Expedited review)

Date & time	Thursday, June 9, 2022, 14:00 – 16:15
Place	Auditorium (Hiroshima) and the 3rd Conference Room (Nagasaki)
Participants	IRB co-chairpersons: Dr. Tanabe and Ms. Shinohara IRB members: Dr. Yamada, Dr. Sugiyama and Ms. Ogawa

< Review of research involving human subjects >

	Dept.	Study title	Review result	Summary minutes
1	Clinical Studies	CR174 “Radiation Effects on the Incidence of Myocardial Infarction in Atomic Bomb Survivors” (Kurisu *et al.*)	Approved	1. Application form ・Check also “a) Not to be anonymized” in “7. Handling of personal information” (p. 3). ・Indicate “Study obtaining special care-required personal information” in “9. Type of research” (p. 4). ・Regarding the information to be obtained, complete ① Justification, ② Period, and indicate the type of information (p. 10). ・Check “No storage of information” in “At collaborative research-implementing entity” (p. 11). 2. Research Protocol (RP) ・State that the data to be used in the study are not provided outside. ・Explain how the documents to be used in diagnosis are kept. ・Regarding the results/data to be obtained in the study, state specifically how they are used, handled, and kept, and the period of storage. In particular, the policy on disclosure of the results/data to the study participants and the justification thereof need to be given. ・Give “Research schedule” by specifying the year and month of completion. 3. Information disclosure form ・Make the title of study consistent with that in the RP. ・Regarding “Samples/information items to be used or provided,” use only months and years to describe the dates of birth and death as instructed in the ethical review application form. Handle the exposure dose and others in the same manner. Delete the expression “data from certificate of death.” ・Add a column for the study period. ・Attach the Information Disclosure Document to the RP.

2	Epidemiology	Revisions to RP-A2-15 “A Proposal to Joint Pooled Analyses of Cohort Studies on Risk Factors for Cancer among Japanese Populations” (Utada *et al.*)	Approved	1. Application Form ・ Describe the revision of the content of the Information Disclosure Document and the switch to the Opt-out (Form 1-5-2). ・ Describe the changes to the composition of the research group. 2. Research Protocol (RP) ・ Provide details about “Expenses.” ・ Describe that informed consent will not be obtained, and instead the information disclosure will be done, and provide the reason. ・ Clearly indicate the number of cohorts and when the information was dated. ・ Clearly indicate a time limit (year and month) by which you will reconsider your continued participation in the study in the research schedule. ・ Describe the pseudonymization of personal information and other data. ・ Describe how you will keep a record of the information shared with other institutions. ・ Describe the nature and method of reporting to the head (Chairman) of our research institution. ・ Describe who will respond to inquiries from subjects and how such inquiries will be handled. ・ Describe in detail how the findings of this research will be publicized. 3. Information disclosure document ・ Switch to the Opt-out (Form 1-5-2). ・ Attach the Information Disclosure Document to the RP.

3	Statistics	Revisions to RP-S4-19 “Longitudinal Weight Fluctuation and Cancer and Cardiovascular Disease Mortality in Japanese Atomic Bomb Survivors” (Misumi *et al.*)	Approved	1. Application form ・Revisions made after the IRB review should be indicated. 2. Research Protocol (RP) ・ Ethical Considerations: the person responsible for management of the key table should be updated. State that personal information and other data will be pseudonymized. In addition, state that cancer registry data obtained from Hiroshima City/Prefecture and Nagasaki Prefecture through RP18-61 will be used. ・ Data storage and final disposition: Revise the wording of "secure PC" and provide specifics on how the data is stored. ・Consultation from the study participants: The sentence "As the study data will be anonymized and information will not be disclosed directly to the participants, consultation by participants regarding individual information will not be accepted." should be deleted. ・Duration: Specify the year and month of completion. ・Explain how the records of provision of samples and information to outside institutions will be kept. ・Indicate whether or not there are any conflicts of interest. ・State that there is little risk that individuals will be identified based on the data handled in this study. 3. Information disclosure form ・State how the information to be provided to other institutions was obtained. ・The information disclosure form should be attached to the RP.

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.