Summary minutes of the 17th Institutional Review Board Meeting in FY2021 (Expedited review)

Date & time	Monday, February 28, 2022, 9:30 – 12:40
Place	Auditorium (Hiroshima) and the 3rd Conference Room (Nagasaki)
Participants	IRB co-chairpersons: Dr. Tanabe and Ms. Shinohara IRB members: Dr. Yamada, Dr. Sato, 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	CR173 "A preliminary study to estimate solid cancer risk based on radiation-associated immunological changes in A-bomb survivors: Cancer incidence follow-up among Adult Health Study participants based on the relative number of naïve T cells and the diversity of T-cell receptor repertoire in peripheral blood CD4 T lymphocytes" (Kusunoki *et al.*)	Approved	On the condition that registration with a public database is not made, the application form, RP, and Information Based on the Guidelines will be revised, Form 1-6-1 will not be attached, and the following revisions will be made. 1. Application form • Fix the period of study by starting from the date of IRB approval or using other specific dates. 2. RP • Clarify "Age at the time of bombing (10)" in Table 1 and "ATB X dose" in Table 2 by adding notes (pages 23-24). • Replace 1998-1994 with 1988-1994 in Figure 3 (page 25). • In 1) Management of personal information, replace "safe storing place in the Department of Epidemiology" and "cancer registry room at RERF" with "ITD" and "the Department of Epidemiology," respectively. Also, clarify the data on cancer incidence by including the expression "cancer registry information obtained pursuant to RERF RP18-61 will be provided by the Department of Epidemiology for use in the study." (Page 30) • In "Explanation of the study and informed consent", delete the expression "limited to that unable to identify individuals," and explain that informed consent was orally obtained and in and after a specific year it was obtained as an examination item included in the AHS written informed consent (page 30). • Replace the information technology department and tumor registry room with ITD and Tumor Tissue Registry Office, respectively, and correct a letter of the Chairman's name (pages 30-31). • Regarding the datafiles after the study's completion, modify as follows: the datafiles will be submitted to the Scientific Reports Review Committee for approval and then submitted to ITD for storage (page 31). 3. Information Based on the Guidelines

				• Revise the expression “owing to recent cancer immunotherapy … it was clearly indicated that cancer cells could be eradicated” in “Objective and method of using samples/information” in the Information Based on Guidelines, which is too intense. • Regarding “approximately 800 persons examined from 1988 to 2011” in “Objective and method of using samples/information”, explain what study they were given explanation in, and that this pertains only to those examined in Hiroshima. • In “Samples/information items to be used or provided,” detail the results of RP3-87, 1-93, and 4-02. • Include Information Based on the Guidelines in the RP.

< Review of human genome/gene analysis research >

	Dept.	Study title	Review result	Summary minutes
1	Molecular Biosciences	CR172 “Preliminary study to determine the applicability for GWAS of DNA extractable blood smears and blood-infiltrated paper discs preserved in the past” (Hayashi *et al.*)	Approved	1. Application form • Revise the answer to “registration of the individual identification code in a database” into “Yes” and check “limited release” (page 1). • Revise the answer to “providing the specimens or information to overseas parties” into “Written IC will be/ has been obtained” (page 8). • On the preservation of information obtained, revise the answer to “Is the preservation period specified?” into “No” (page 11). • Regarding the collaborating research institutions, revise the answer into (information) “be preserved,” and include the name of recipient institution (page 11). Check the box appropriate for the status of anonymization in “3) The relevant information…” 2. RP • Revise the expressions “unique resources” (page 19) and “human subjects” (page 21). • Reword explanations on “call rate” and “agreement rate” in an understandable manner (page 20). • In the testing method, clarify where the samples and paper discs are provided to (page 24). State that the data will be provided to outside collaborative researchers (page 25, the same can be said for the explanatory note). Specify “the encrypted method for sending the samples/information in a state of ensured tight security” and the staff at RERF Dept. of Statistics to analyze genome data (page 25). • Rephrase “replication is important to assess the degree of repeatability of the study results” and “application to plates or chips” in an understandable manner (page 27).

				• In “Informed consent,” revise “Flow of the study” for the attachment into a new title (page 29). • In “Storage and disposal of samples/information,” delete “disposal of written consents.” (Page 29) • State that overseas researchers may share the samples/information based on the registration with public database, and delete the expression “before registration, a new individual number will be assigned to an anonymization number for research used in analysis.” (Page 30) • State the requirements for limited use. • Reword “Type and age of samples” and “sample age” properly; the same can be said for the application form. • Unify “ITD” and “Information Technology Department” into a consistent expression. 3. Attachments • Delete the sentence “Please fill in the consent form” to help the participants not to confuse comprehensive consent with the present study’s consent (page 34). • Delete the expression “personal information including that on health status is not collected” (page 36). • Regarding the storage and disposal of samples/information, clarify that the remaining samples and information obtained by measurement will be preserved, if consent to future research use is obtained (page 37). Delete the mention of disposal of written consents (page38). • Make the section under “Report of study results and publication of study results” easily understandable by rearranging sentences (page 38). • As for the registration with public database, state that the information may be shared by domestic and overseas researchers (page 38). In the Attachment 2, explain collaborative research with domestic organizations in ⑤ and add ⑥ to explain the possibility of sharing the information with domestic and overseas researchers based on the registration with a database (page 40). Rewrite page 42 and after that likewise. • Explain that genetic information will be obtained by assaying more than 670,000 genetic polymorphisms. Add explanation on genetic information (page 34).

				• Make “someone’s sample” and “sample of which person” into a consistent expression. • Make genetic polymorphism and SNP array into a consistent expression, or additionally explain SNP array. • Make the project title consistent. • Add explanation in Attachment 2 about the conflict of interest on the check item 13 in the consent form. • Include information as well as samples as those to be stored after analysis in item 2 of the written consent. Clarify in item 3 that, if the participant does not consent to registering with a public database, he/she will be excluded from the study subjects. State that effect also in the RP and the explanatory note (page 45). • Consult with the Department of Clinical Studies to determine how to send Attachment 1 to the participants.

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.