Summary minutes of the 4th Institutional Review Board Meeting in FY2022 (Full review)

Date & time: Friday, August 5, 2022, 13:10 – 16:15

Place: Auditorium (Hiroshima), the 3rd Conference Room (Nagasaki), and external IRB members from their respective places [by Zoom meeting]

Participants: IRB co-chairpersons: Dr. Tanabe and Ms. Shinohara
IRB members: Dr. Matsui, Ms. Okuda, Dr. Yoshiura, Dr. Hiyama, Dr. Yamada, Dr. Satoh, 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	CR154 “Evaluation of radiation-associated clonal hematopoiesis among atomic-bomb survivors” (Yoshida *et al.*)	Continued deliberation	1. Application Form ・ The University of Tokyo should also be listed as a collaborating institution (P.1). ・ In “7. Handling of Personal Information,” check the “(a) Personal Information” box (P.3). ・ For security control, provide details of physical and technical security control measures for the transfer, use, and storage of genome information at RERF and collaborating institutions (P.3) (the same applies to the RP). ・ For institutions that "(b) have a system in place that meets the standards set forth in the Enforcement Regulations of the Act on the Protection of Personal Information", the overseas destinations to which the information is provided should be listed (P.11). 2. Research Protocol (RP) ・ Consider whether or not the results obtained from this study are disclosed to study participants and state the policy and reasons for that. ・ Indicate whether or not fresh samples are used (P.31). ・ Indicate the analysis will be performed also by an outside laboratory (P.31). ・ Clarify the standards for selecting the participants based on the past informed consent to blood sample storage and use (P.39). ・ Be specific about the requirements to be a proxy for the informed consent and provide a clear explanation of “to be mailed at the appropriate time” (P. 39). ・ Include in the “Protection of Personal Information” section how the information is transferred as well as the transfer to the University of Tokyo (P.40). ・ State that when using information from cancer registries, information from the Hiroshima City and Hiroshima Prefecture Cancer Registries will be obtained according to RP18-61 and RP29-60. ・ State that the samples and information will also be provided to the University of

				Tokyo in Attachments 2 and 3. ・ State that the research number is different from RERF's Sys ID, and also describe the numbering method and how the key table is managed. ・ It should be stated that a new RP will be prepared when a longitudinal study is conducted after this study. ・ In the revised Act on the Protection of Personal Information and revised guidelines, a provision was added to the effect that when samples or information are provided to a person overseas, information regarding the recipient must be provided to the study participant at the time consent is obtained. The explanatory note should be modified by referring to the description in the NBDC Human Database Security Guidelines, and its contents should also be included in the RP. ・ Japanese should be used for figures and tables. 3. Information Disclosure Form ・ Describe how the samples and information to be provided to other institutions were obtained by RERF. ・ Consider whether "Samples/information items to be used or provided" section should include diagnosis of blood cancers in the cancer registry information. (The same applies to RP). ・ State that the data may be made available to foreign researchers if registered in the NBDC human database.
2	Clinical Studies	CR169 "A pilot study: feasibility of applying high throughput targeted sequencing technology to DNA and RNA extracted from stored FFPE samples of CML cases" (Yoshida *et al.*)	Approved*	1. Application Form ・ The research period should be described in detail so that the end date can be known (The same applies to the RP and Information Disclosure Form). ・ In "9. Type of research," check the box for "Research obtaining special care-required personal information" (P. 4). ・ Uncheck "(a) All of the relevant samples/information fall into one of the following categories" and "(b) The information used in the research is pseudonymized information" (P.6). ・ State that the research ID is different from RERF's Sys ID (P.12). 2. Research Protocol (RP) ・ State that the results of the genetic analysis will not be disclosed even if there are inquiries. ・ State that the data will be deleted so that it will not remain on the equipment used for analysis at Hiroshima University.

				・ The means of transferring the genetic analysis data should be considered, and physical and technical safety control measures should be described (see also P.3 and P.16 of the application form). ・ Indicate that the cloud data service server is located in Japan (P.30). ・ Japanese should be used for the figures and tables. ・ Describe in detail on the use policy, handling, and storage method/period of the results and data obtained from this research. In particular, describe the physical and technical safety control measures for genetic analysis data (the same applies to P.3 and P.16 of the application form). ・ Describe how the data will be stored after the completion of the research. ・ The "Chief Personal Information Manager" should be changed to "General Personal Information Privacy Protection Officer." Also, "Only the applicant may enter" should be changed to "people who are authorized to enter are restricted" (P.32). ・ The role of Dr. Sugiyama should be changed to "provides guidance in the preparation of pathology specimens" (P.35). 3. Information Disclosure Form ・ In "Samples/information items to be used or provided" section, add the results of targeted gene sequencing analysis using pathology samples as information to be used, and delete "Method of obtaining samples/information to be provided."

*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.