Summary minutes of the 8th Institutional Review Board Meeting in FY2022 (Full review)

Date & time　Monday, November 28, 2022, 10:00 – 12:30

Place　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, and Mr. Fuchi (Absentees: Ms. Ogawa and Ms. Dodo)

< Review of research involving human subjects >

	Dept.	Study title	Review result	Summary minutes
1	Molecular Biosciences	CR175 "Study of the association between parental radiation exposure and occurrence of *de novo* germline mutations in their offspring" (Uchimura *et al.*)	Continued deliberation	1. Application for Ethical Review ・State the proportion of the participants from whom blood will be newly collected and the risks involved in blood drawing. (The same applies to the RP and the explanatory document.) ・"Informed consent includes participant's preference for disclosure of such a result" should be changed to be consistent with the content of the RP. ・Regarding the use of the SHIROKANE, state the methods of supervision by RERF, such as the security management including personal information protection based on a contract, and also state a person responsible for the management at the University of Tokyo. (The same applies to the RP.) ・A person with the relevant qualification should provide genetic counseling and this should be stated. (The same applies to the RP and the explanatory document.) ・As for the guarantee of opportunity to refuse, it should be stated that the information will be made public on the website and that the participants are assured that they can withdraw their consent at any time. ・"As for an incidental finding, only if deemed that the participant will benefit from disclosure of such information, the IRB will be consulted as to whether the finding should be disclosed or not." should be changed to be consistent with the RP (page 23). 2. Research Protocol ・State that the association between genome information and health information will be analyzed. (The same applies to the Application for Ethical Review.) ・An "atomic bomb" should not be included in "nuclear accidents." "detrimental effects on health" and "future WGS analysis" should be changed to appropriate expressions. (pages 1 and 3) "F1 master list" should be changed to easier-to-understand expression (page 7).

				・As for “… according to the guideline (pages 10)” and “Following RERF guidelines (page 20),” the titles of these guidelines should be specifically stated. ・Regarding “Advantages and disadvantages for the study subject,” check the extent of the coverage of RERF’s liability insurance policy, and explain “… for the purpose of confirming secondary findings” means to confirm an incidental finding not for the purpose of research (page 20) (The same applies to the Application for Ethical Review.) ・In the "Informed Consent" section, the title of Attachment 1 should be corrected and necessary corrections should be made to the sentence (page 21). ・Under “Protection and anonymization of personal information,” “… VPN connection to prevent unauthorized access by a third party …” should be changed to “… VPN connection that guarantees no tampering or eavesdropping of communication contents by a third party.” (page 22) (The same applies to the Application for Ethical Review.) ・State the reason for not using VPN connection with the RIKEN, and mention the use of authentication keys in addition to the registration of IDs and passwords as a security measure. Confirm whether having only one port will not give rise to any problem. (page 22) (The same applies to the Application for Ethical Review.) ・Under “Storge and disposal of samples and data,” clearly state the storage locations and disposal methods separately for samples and genome data. State how genome data of approximately 600 trio families will be stored and whether such data will be disposed of. (page 22) ・Regarding cancer registry information, decide and state whether information in and after 2016 will be used (page 22) (The same applies to the Application for Ethical Review.) Maintain consistency with the explanatory document for the informed consent. ・Under “Submission to a public database,” state that the overseas provision is limited to countries stipulated in the Enforcement Regulations of the Act on the Protection of Personal Information: currently the UK and EU only. (page 23) (The same applies to the explanatory document.) 3. Explanatory and other documents ・As for the descriptions in the explanatory document of the informed consent, solicit opinions from those engaged in obtaining informed consent (staff in the Department of Clinical Studies) and reflect them on the document. Use unified terms as much as possible (e.g., “human genome analysis,” “human genome/gene

				analysis research," and "whole genome/gene analysis research" as well as "genome" and "DNA") ・Change "… those whose parents were not exposed to an atomic bomb" to "those with low dose."(page 35) ・Under "Individuals to be investigated," state the number of the stored samples and the number of the subjects to be studied in this RP. (page 36) ・State at the beginning that some participants will be requested to donate blood. Also under "Study method," state that the stored blood samples will be used but in some cases blood may be newly collected. (page 37) (The same applies to the Application for Ethical Review.) ・Under "What we ask you to provide," state the amount of blood to be drawn. (page38) ・Under "Protection of personal information and the handling of managed samples," state the storage locations separately for samples and information, whether discarded or not, and storage methods of genome information. (page 38) ・Under "Registration of genome data in public genome databases," state that the data will not be registered if so wished by the participant. (page 38) ・Under "Policy on disclosure of information to individual," change the sentence to "…there are effective ways to treat the disease, … upon the decision by the IRB, …after reconfirming your preference." (page 39) ・Under "Benefits and disadvantages of cooperating in the survey," "… provide a correct explanation to society" should be changed to more scientific expression. State detrimental events involving blood drawing and the extent of compensation. (page 39) ・On page 42 of the RP, "Regarding the genome analysis of parents and children using the blood provided earlier," the title should correspond to that of the RP. This document is intended only for the parents, so some corrective measures are needed. State the process in which if a mutation is suspected, upon the decision by the IRB, participants' preference on the disclosure will be confirmed. State that some participants may be requested to donate blood and that analysis results will not be reported to the participants. ・In the informed consent form, the 16th consent item, "If the data is used …," should be also stated in the explanatory document. Make necessary changes so that the participants can easily understand that they are asked about incidental findings when they read the question, "Do you wish to have your genome data returned?" (page 44)

				4. Information Disclosure Form ・”SNP information” should be changed to something like “single nucleotide polymorphism” so that it will be easier for the general public to understand. ・Information Disclosure Form should be part of the RP.