Summary minutes of the 12th Institutional Review Board Meeting in FY2021 (Full review)

Date & time	Monday, October 18, 2021, 10:00 - 12:50
Place	Auditorium & C-211 (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, Dr. Yoshiura, Dr. Hiyama, Mr. Matsuura, Dr. Hashizume, Dr. Yamada, Dr. Satoh, Dr. Sugiyama, Dr. Hida, Ms. Ogawa, Ms. Dodo, and Mr. Fuchi

< Review of ethical survey on ongoing research projects >

	Dept.	Study title	Review result	Summary minutes
1	Clinical Studies	RP5-15 “Ophthalmological study of A-bomb survivors using a new ophthalmic camera” (Hida *et al.*)	Approved	(No problem in particular)
2	Epidemiology	RP18-61 “Tumor Registry study in Hiroshima and Nagasaki” (Ozasa *et al.*)	Approved	(No problem in particular)

< Review of research involving human subjects >

	Dept.	Study title	Review result	Summary minutes
1	Biosample Research Center	Addendum to RP3-15 “Establishment of protocols for quality control of blood samples” (Tanabe *et al.*)	Approved	1. The number of study participants is stated as "a total of 60 people," but the estimated number of actual people, excluding the number of participants who participate in multiple times, should also be stated. 2. It should be stated in the research protocol (addendum to RP3-15) that a maximum of 36 mL of blood may be collected in this study, based on the health status of the study participants and the judgment of the physician, although RERF's “Guidelines for Volume of Blood Collected from Study Participants” allows only the minimum volume required that is not larger than 25 mL. Also, describe the measures to be taken in case any health problems occur. 3. If part of the work related to the study is to be outsourced to an external laboratory, the research protocol must be modified to include details about the laboratory. 4. "11. Disclosure of information on research " in the research protocol (Addendum to RP3-15) should be revised as “to be published in academic conferences, journals, and international databases.” The same revision should be made for "12. Disclosure of information on research" in Appendix 2. 5. In Attachment 1, the sentence "RERF has been preserving for many years..." in the second line should be placed at the beginning of the sentence.

				6. In "8. There will be no disadvantage even if you do not cooperate " of the explanatory notes, it would be better to also state that there will be no disadvantage in the workplace even if you do or do not cooperate. 7. Check with the Personnel Section about what to do when RERF employees who will be study participants draw blood during working hours. 8. In “10. Handling of Personal Information” of the explanatory notes, it should be stated that the key table will be handled in accordance with RERF's Regulations for Protection of Personal Information, and consent should be obtained from the study participants after explaining that the principal investigator will manage the information in accordance with the said regulations as the personal information manager. 9. In the second line of the questionnaire, delete "If you do not wish to answer a question, you do not have to" and replace it with "If you do not mind, please fill it in" in items 4, 5, and 9.

< 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.*)	Continued deliberation	The IRB meeting went well over its scheduled end time., it was decided to discuss the issue again at a later date.

* To prevent the spread of COVID-19, external IRB members joined the meeting by Zoom, and the committee members at RERF maintained sufficient distances from each other.