Summary minutes of the 13th Institutional Review Board Meeting in FY2023 (Expedited Review)

Date & time	Tuesday, December 5, 2023, 9:30-11:20
Place	Auditorium (Hiroshima) and the 3rd Conference Room (Nagasaki)
Participants	IRB co-chairpersons: Dr. Tanabe and Ms. Shinohara IRB members: Dr. Satoh, Dr. Sugiyama, and Mr. Fuchi

< Review of research involving human subjects >

	Dept.	Study title	Review result	Summary minutes
1	Department of Molecular Biosciences	Modification to RP 3-23 “Study of the association between parental radiation exposure and occurrence of *de novo* germline mutations in their offspring” (Uchimura et al.)	Continued deliberation	1. Research Protocol ・On page 7, under ”f. Design and Methods,” it says, “In this study, a preliminary study will first be conducted …”. It should be clearly stated that the association with radiation dose will not be analyzed using the samples from the four families in the preliminary study but will be analyzed in the full-scale study (the same applies to the application for revisions.). ・On page 18, under “Informed Consent” in “g. Bioethical Considerations,” it says, “… acquisition efforts will continue until consent from all trios is obtained.” It should be changed to read, “… efforts will continue to obtain IC with the goal of obtaining consent from all trio participants.” ・On page 20, in “Linking Genome Analysis Results with Individual Health Information and Cancer Incidence Information,” it says, “… individual genomic information with past AHS and FOCS health information.” The word “past” should be deleted. “Information from non-AHS and non-FOCS participants to be obtained at the time of IC acquisition” should be reconsidered, and the questions to be answered by study participants, including the format if a questionnaire is used, should be clearly stated. Also, it should be clearly stated that health examination data and health information obtained at the time of health examinations of non-AHS and non-FOCS participants will be used for the study (the same applies to the application for revisions.). ・On page 21, “the RERF mortality follow-up study (RP1-75 and RP4-75)" should be more clearly stated as “the RERF mortality follow-up studies (study of lifespan of A-bomb survivors, RP1-75, and mortality study of children of A-bomb survivors, RP4-75)”. ・In Attachment 1 on page 32, the researchers of the RIKEN and the University of Tokyo, who newly joined the study, should be included in [Outside Collaborators]. As for the investigators of the NCI, it should be stated that only the representative investigator is listed.

				・In Attachment 1 on page 32, under [Duration], “7 years” should be changed to read “7 years (until June 2030).” ・In Attachment 1 on page 33, under [Individuals Who Act As a Proxy], “If it is deemed that a subject will have difficulty understanding the explanation of this study and giving consent (e.g., a person with cognitive decline due to aging and other reasons as determined by a physician, family members, or others, or a deceased person)” should be changed to read “If it is deemed that a subject will have difficulty understanding the explanation of this study and giving consent (e.g., a person with cognitive decline due to aging and other reasons as determined by a physician, family members, or others), or a person is already deceased.” ・In Attachment 1 on page 34, under [Handling of Samples Containing DNA and the Analysis of the Obtained Genomic Data], “RIKEN and NCI … by accessing the cloud computer at the Institute of Medical Science, University of Tokyo” should be changed to “The researchers of RIKEN, NCI and the University of Tokyo … by accessing the cloud computer at the Institute of Medical Science, University of Tokyo” ・In Attachment 1 on page 34, under [Correlating Family Health Information with the Results of this Genome Analysis], it says “The health information of parents and children includes records of health examinations you have undergone at RERF, findings of RERF lifespan studies, …”. “lifespan studies” should be changed to “lifespan studies of A-bomb survivors and their children” (the same applies to the column "Samples/ Information Items to be Used or Provided" of the Information Disclosure Form on page 47). ・In Attachment 1 on page 36, under [Use of Samples for Other Studies], “… to retain your samples for other future studies” should be changed to read “for other future genetic effect studies.” 2. Information Disclosure Form ・In the column, “Provision of Samples/Information to External Institution(s)”, "the Department of Genetic Medicine of Nagasaki University" should be corrected to "the Clinical Genome Center of Nagasaki University Hospital". 3 Records of Provided Specimens/Information ・Regarding “Other Items to be Included in RP” on page 53 and 55 (Form 1-6-1), in the column “Method for the Party to be Provided to Confirm the Detail of IC of the Party to Provide,” “Confirmed by viewing the IC explanatory note and IC form of the RP” should be corrected to “Confirmed by viewing the IC explanatory note and IC form of the RP as well as the Information Disclosure Form.”

				・In the “How Specimens/Information were Obtained” column under “Obligations for Preparing and Keeping Record of Provided Specimens/Information” in Form 1-6-1 on page 56, “based on this RP” should be corrected to “based on this RP and RP5-85.”
2	Department of Molecular Biosciences	Modification to RP-P2-22 “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. Research Protocol ・On page 9, “How to treat DNA” should be explained using Japanese terms as much as possible. ・For the "Informed Consent" section on page 14, a sentence such as “The informed consents were obtained by MM/YY and there are no plans to obtain reconsent” should be added (the same applies to the application for revisions).

*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.