Summary minutes of the 13th Institutional Review Board Meeting in FY2021 (Expedited review)

Date & time	Monday, December 6, 2021, 14.00 – 17.05
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	—	CR166 "Does the FLASH effect change the effective dosimetry of the life span study of atomic bomb survivors?" (Dutil *et al.*)	Approved*	1. Application Form for Ethical Review ・The handling of personal information should be considered as anonymized (processed or managed so that it is not immediately identifiable), and the application form should be reviewed entirely based on the revisions made by the IRB. ・As for "VI. Informed consent at the time of providing the specimens or information to overseas parties," item 1 should be unchecked and left blank. 2. Checklist (Form 2-2-1) ・Check "yes" for the item 14 "Matters to be reported to the chief executive of the research implementing entity" and describe the contents and methods in the research proposal. 3. Research proposal ・Correct any Japanese translation that does not match the original English or any descriptions that are unclear. "National Officer for Radiation Protection in Quebec," "radiation risks" (p.19), use a consistent word for "delayed" and "late" (p. 20), deletion of colons and semicolons (p.20), etc. ・In "Anticipated Results", "research notes" should be revised to be more specific, such as "research reports for publication". ・In "Impact Statement," the sentence "Understanding the long-term health effects of ionizing radiation exposure is a fundamental research question pursued by many scientists around the world" should be changed to "Scientifically important research issues that have a strong impact on public health." ・The research period should be set either from the date of IRB approval or defined by a specific date. ・In "Consultation from the Subjects," delete "As the study data are anonymized and information is not disclosed to the subjects, consultation of individual information by the subjects will not be accepted. General inquiries about the study may be accepted." Provide only the name and email address of the Dr. Grant for inquiries.

				・For the figure on page 24, delete the English explanation. Also, delete the word “Figure2”, and replace the first description with the second description. 4. Information disclosure documents ・Use Form 1-5-2 and make it a part of the research proposal. ・To correct “mortality data" to “cause of death.” ・The name of the country should be included in the affiliation of the principal investigator. Delete “Same as Mortality Report 14”. Use easy-to-understand wordings for the general public.

< Review of human genome/gene analysis research >

	Dept.	Study title	Review result	Summary minutes
1	Molecular Biosciences	Revision to RP-P1-19 “Preliminary study to determine the applicability of Wright-stained blood smear samples in GWAS” (Hayashi *et al.*)	Approved*	1. The planned research period should be specified as the period from the date of IRB approval or as a specific date. 2. Reflect any additions and corrections made by Dr. Hayashi himself during the IRB review.
2	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	1. Research proposal ・The research period should be specified as the period from the date of IRB approval or as a specific date. ・The storage period of samples and information should be set from an identifiable date, such as the date of approval by the IRB or the date of completion of research, or from a specific date. ・Add an explanation on data deposit to a public database. ・In the case of a participant with cognitive function problems, state that the participant is not eligible for the study. ・Revise “cancer and diseases other than non-cancer diseases” to “cancer and diseases other than cancer (p.19). ・“In addition to” in English should be changed to Japanese (p. 23). ・“Randomly selected” should be put before “6 persons” (p. 24). ・The sentence that starts with “After the blood is drawn...” in the “Experimental Methods 1” should be changed to “After the blood is drawn, a research number unrelated to the RERF SysID will be randomly assigned to the specimen by ITD” so that it will be easier to read (P.24). ・Specifically explain “the state in which security is ensured” (P.25) and “with all possible security measures” (P.29). ・Clarify the data to be provided to external collaborators to obtain advice (P.25). ・Use a consistent word for “call rate” (P.26). ・Be specific about what the paper data refers to.

				・ Describe from which department each sample will be provided and how the samples and records of information will be kept. ・ Include the contents of items 15 (funding sources), 17 (response to consultation), 23 (availability of compensation), and 30 (genetic counseling) of the checklist (Form 2-2-1) in the research proposal. ・ The content of item 2 (Matters to be reported to the chief executive of the research implementing entity and approval of the IRB) in the checklist (Form 2-1-1) should be described in the explanatory note to written consent. 2. Explanatory note to written consent and consent form ・ It is easier for the subject to understand if word “leak” as a loanword from English be changed to a Japanese native word meaning “leakage” (p. 33). ・ “Those who do not wish to receive the results of genetic analysis” should be added to the “subjects of the survey” (P34). ・ The phrase "entrusted to a company capable of measurement" should be changed to "entrusted to a domestic company capable of measurement.” (P35). ・ State what “cannot be discarded even if it has been made public” (P35). ・ Add the explanation of data deposit to a database. ・ The explanatory note should be easy for the participants to understand. A solution may be to add a brief explanation to the check items 1 to 13 of the consent form. ・ After preparation of the consent form, it should be sent to Dr. Ohishi, and the opinions of the staff members of the Contacting Unit and Nursing Unit, who are responsible for the health checkup of AHS participants, should be sought for better cooperation.

*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.