**Summary minutes of the 10th Institutional Review Board Meeting in FY2022 (Expedited review)**

Date & time Friday, March 10, 2023, 14:00 – 16:05

Place (Hiroshima) Auditorium (Nagasaki) Zoom

Participants IRB co-chairpersons: Dr. Tanabe and Ms. Shinohara
IRB members: 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 |
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| 1 | Molecular Biosciences | Carried over from the previous meeting: CR175<br>"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 Form<br>• Information to be stored in the collaborative research institutions: Uncheck the boxes of "(a) Personal Information" and "(b) Pseudonymized Information" (P.15).<br><br>2. Research Protocol<br>• "Subject and sample selection": Change "only fathers" and "only mothers" to "fathers" and "mothers" (P.29).<br>• "Bio-sample usage": Include a statement that the volunteer providers of the blood samples that are stored cannot be identified, and genomic analysis of those samples will not be performed. If genomic analysis is to be performed, obtain consent (or allow opt-out) (P.32).<br>• "Advantages and disadvantages for the study subjects": Include a statement that even if a study participant refuses blood sampling for result confirmation, their request for result to be returned will be respected (the same applies to the Informed Consent Document on P.56 and P.59). Additionally, include a statement indicating that the purpose of the blood collection (2 mL) is for confirmation testing in cases where pathogenic mutations are suspected. (P.39).<br>• "Informed consent": If planning to recommend medical examination to those who are not participating in AHS or FOCS and intending to use their data for research purposes, clearly state this and obtain their consent (P.39) (the same applies to the Informed Consent Document).<br>• "Protection and anonymization of personal information": Change |

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| | | | | "Those involved in genome sequencing will not have any contact with personal information." to "… contact with the above-mentioned personal information." or "… contact with information that can easily identify individuals." (P.39) (the same applies to Application Form on P.3).<br>• Include a statement that by entering into a contract with the collaborative research institutions, the genomic information of SHIROKANE will not be used for purposes other than this research, will not be provided to third parties, and will not be downloaded to the collaborative research institutions. Also, mention that data management will be carried out in accordance with the "Information security policy" based on the agreement with the administrator of SHIROKANE. (P.40) (The same applies to Application Form on P.4).<br>• "Storage and disposal of samples and data": Provide details about data storage, methods, duration, and disposal procedures at the collaborative research institutions and SHIROKANE. (P.40) (The same applies to Informed Consent Document on P.55).<br>• "Linking genomic analysis results with individual health information and cancer incidence information": Specify that "future analysis" refers to the analysis conducted within the scope of this research project, rather than other studies. (P.41) (The same applies to the Informed Consent Document on P.53 and the Information Disclosure Document on P.72)<br>• "Reporting and publishing research results": It should be stated in the following order: "The results will be published within the presentation data." And then "The results might be registered in public databases." In addition, mention that a "list of mutations" is a list of individual-specific mutations. (P.41) (The same applies to a list of genomic alterations on P.55)<br>• "Submission to a public database": Mention that consent will be obtained separately for providing data domestically and internationally. Additionally, describe the measures to be taken if consent for data provision to overseas countries cannot be obtained. (P. 41) (The same applies to the explanatory document on P.55)<br>• In Figure 6, consider the necessity of including "RIKEN" and "NCI" |

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| | | | | on the left side. (P. 45)<br>• If samples are provided by the Biosample Research Center, consider the need to add the responsible personnel from the Center to the list of researchers.<br>• Update the affiliation of Dr. Berrington, a collaborator.<br><br>3. Informed Consent Document:<br>• "Development of new treatment methods": Please either specify treatment methods for what is being developed or remove the statement (P.52).<br>• Clearly state that NCI can access SHIROKANE at the Institute of Medical Science, the University of Tokyo, but not RERF's server (P.54-①).<br>• Ensure consistent terminology by unifying the wording for "Cancer Registry Information" (P.54-②).<br>• Remove the phrase "not related to radiation exposure." Add "irrespective of the wishes at the time of consent form creation" just before "based on the judgment of the IRB" (P.56).<br>• Add an item regarding the potential future use of samples in other research (P.58).<br>• As for 1) of "2. Regarding Genomic Data," state that a decision to return data will be made based on the judgment of the IRB (P.59).<br>• Clearly explain that if individuals are not subjects of the LSS or F1 studies, their addresses will be provided to the National Cancer Registry to obtain their cancer registry information (P. 59).<br>• Ensure the Withdrawal of Consent Form allows for selecting specific items to be withdrawn and clearly explains the possibility of partial withdrawal (P.61).<br>• Include information about the funding source for the study.<br><br>4. Items to be included in the research protocol (Forms 1-6-1 and 1-6-2)<br>• Delete "Clinical and epidemiological information" from "Items of |

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| | | | | sample/information” (P.77)<br>• These appendices should be made a part of the research protocol. |

To prevent the spread of COVID-19, the IRB members at the meeting maintained sufficient distances from each other.