Summary minutes of the 18th Institutional Review Board Meeting in FY2021 (Expedited review)

Date & time: Thursday, March 24, 2022, 10:00 – 11:00

Place: Auditorium (Hiroshima) and the 3rd Conference Room (Nagasaki)

Participants: IRB co-chairpersons: Dr. Tanabe and Ms. Shinohara
IRB members: Dr. Sato and Ms. Dodo

< Review of research involving human subjects >

	Dept.	Study title	Review result	Summary minutes
1	Clinical Studies	Revisions to RP1-17 "Detection of the onset of hematological malignancy among atomic bomb survivors" (Miyazaki *et al.*)	Approved	**1. Application** ・Confirm the specifics such as the storing place and storing period of data after the completion of study. **2. RP** ・Replace "to be stored in a database equipped with a security system" with "to be stored in a server equipped with a security system." (Page 33) ・Keep the records of providing and receiving samples/information indefinitely (p. 33). ・Write down clearly the sample and data analyses to be conducted by the research organizations, names of outsourced parties, and flow of samples and data. Also write down the method to record the transfer of samples and data among institutions and the person in charge (p. 27). ・Note in the "Informed consent" section that Information Based on the Guidelines has been updated to include the post-IC changes such as the extension of study period and the data analysis at the University of Tokyo. ・Include the limitation on use of the data registered with a public database (p. 33). ・To comply with the Ethical Guidelines for Medical and Biological Research Involving Human Subjects (7: Matters to be in the research protocol), explain (11) Details and methods of reporting to the research institution's head, (12) Funding sources, (13) Methods of disclosing research-related information, (15) Procedures for providing consultation to the participants, and (23) Methods of supervising contractors. ・Correct the Japanese words argued by the IRB, such as *array, the most … 14, IRB,* and *concurrent appointment*. **3. Information Based on the Guidelines** ・Add an item of study period in Information Based on the Guidelines and include a specific month and year for completion. ・In the purpose and method of use of sample/information, state how the samples and information will be handled after the study is completed. ・In the samples and information to be provided, replace "date of diagnosis" and "date of death" with "year and month of diagnosis" and "year and month of death," respectively. ・Include the outsourced organizations.

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 distance from each other.