

Summary minutes of the 14th Institutional Review Board Meeting in FY2023 (Expedited review)

Date & time Friday, Jan 12, 2024, 14:00 – 14:40

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

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

 IRB members: Dr. Satoh, Ms. Dodo

< Review of research involving human subjects >

	Dept.	Study title	Review result	Summary minutes
1	Clinical Studies	RP1-17 Modification to RP 1-17 “Detection of the onset of hematological malignancy among atomic bomb survivors” (Miyazaki et al.)	Approved	1. Research Protocol (RP) • P. 23: In item 7, add an explanation stating that the RERF researcher provides the study participant’s personal information, such as their name and date of birth, to other medical institutions and the Atomic Bomb Disease Institute (ABDI), Nagasaki University, through the researcher at Nagasaki University Hospital (make the same revision to Figure 2 on page 22, and to item (E) in the section “Samples/data to be used or provided” of the Information Disclosure Document). • P. 24: Regarding the phrase “electronic data transfer and sharing in a secure environment is possible,” add the explanation: “Data transfer and cloud-based storage are implemented in an encrypted manner.” Concerning the statement “The information will be stored together with related documents in ITD in a confidential manner,” specify the scope of data concerned and storage period. • P. 28: In the section "(8) Records of the Transfer of Samples and Information," add an explanation that ITD also stores the records. • P. 29: In the section " <i>Regarding Informed Consent</i> ," add the following information: From how many persons was written informed consent (IC) obtained, and when was the obtaining of written IC completed? • Change the word “anonymization” to “pseudonymization.” • P. 31: In the section " <i>Submission to a Public Database</i> ," change the phrase “anonymous numbers for research” to “research numbers for pseudonymization.” • Add a section on the handling of research results, and explain that the results obtained in this research will not be disclosed to study participants, along with the reason for this policy.

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.