Summary minutes of the 5th Institutional Review Board Meeting in FY2023 (Full review)

Date & time	Monday, June 5, 2023, 13:30–15:30
Place	Auditorium (Hiroshima), the 3rd Conference Room (Nagasaki), and respective offices of external members (remote meeting by Zoom)
Participants	IRB co-chairpersons: Dr. Tanabe and Ms. Shinohara IRB members: Dr. Matsui, Ms. Okuda, Dr. Hiyama, 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
1	Clinical Studies	CR178: Thyroid diseases in Hiroshima and Nagasaki atomic bomb survivors (renewal of RP 2-99) (Imaizumi et al.)	Continuing Deliberation	There will be a continuing deliberation for this review. After considering the details below, please reapply and resubmit the research protocol (RP). **1. Application Form** ・ Select “Yes” for “Is collective review desired?” under I-2 “Collaborative research by multiple entities” (p.1). ・ Add more details to I-7-(3) “Safeguarding” on page 3: You might quote the Addendum to RP 18-61 and RP 29-60. For example, you might mention that “names and addresses are removed to protect anonymity before using the data at RERF in research.” For provisions to outside institutions, you might quote page 66 and indicate that RERF “will use encrypted storage media (such as USB flash drives) and traceable delivery methods when sharing data with project implementation offices.” ・ Under “(2) Intervention” in “9. Type of research,” select “research with intervention” (p.3). ・ Uncheck “IC-5: No consent will be obtained” in “1. Will informed consent be obtained from research scientists?” and do the same for II. 2. (p.4). ・ Regarding the receipt of cancer registry information in V-2, include the

				following details from the Addendum: (1) For informed consent (IC), state that “we will not obtain consent, but we will make the information public on the RERF website and give the subjects the option to refuse”: (2) for the name of the providing entity, indicate “the project implementation offices of the national and local cancer registries”; and (3) indicate that the process of obtaining samples and information is based on “the Health Promotion Act, the Cancer Control Act, and the Cancer Registry Promotion Act” (p.9). ・ VII-2.1.(2): In the "Justification" section, if the information is stored, add “However, cancer registry information will only be used to reproduce and verify research results” (p.13). ・ VII-2-2: In “(1) Will the information be stored?" under "2. A collaborating research-implementing entity”, “the provision of cancer registry information...” should be deleted (p.13). ・ VIII-3: In response to the question, “When obtaining IC from the proxy or the like of a living research subject, will informed assent be obtained from the research subject?” show that you will obtain assent and add that you will verbally explain the content to subjects in an understandable way to obtain assent even if you gain IC from their proxies (p.14). (This also applies to p.40 of RP.) **2. Research Protocol** ・ Consider adding a document for participants to clarify the potential disadvantages and risks for those who are referred to medical facilities based on the results of thyroid ultrasound examinations (p.32 and p.41). ・ For the reason why IC will not be obtained, add that IC will not be obtained due to difficulties in contacting participants both technically and humanly (p.40). ・ Due to the unclear status of obtaining IC for the research use of medical

				information sent to RERF by outside medical institutions regarding subjects referred by RERF in the past, add an opt-out provision to the information disclosure document (p.40). ・ Provide specific details about how cancer registry information will be obtained and used: According to page 68, the Addendum, “The study does not require subjects’ consent, but subjects will be given the opportunity to refuse because the information will be made public on the website.” Also, according to page 67, the Addendum, “Names and addresses will be removed and anonymized before being used in the study." (p.40 and p.41). ・ Consider how to transfer information to/from medical facilities in a way that can be tracked (p.41). ・ Regarding the role of external collaborating researchers, delete “they also conduct detailed examinations including aspiration biopsies when necessary.” (p.43). **3. Information Disclosure Document** ・ In the “Samples/information items to be used or provided” section, add that the procedures for using cancer registry information should be based on the procedures described in RP 18-61 and RP 29-60 (p.52). **4. Reference Documents** ・ In “Flow of information and IC,” add revisions to indicate that cancer registry information is anonymized for analyses (p.57).

*Approved by confirming that the aforementioned revisions have been duly made.

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