

Summary minutes of the 5th Institutional Review Board Meeting in FY2021 (Expedited review)

Date & time Wednesday, June 16, 2021, 14:00 - 15:10
 (Hiroshima) Auditorium
 Place (Nagasaki) The 3rd Conference Room [teleconference]
 Participants IRB co-chairpersons: Dr. Tanabe, Ms. Shinohara
 IRB members: Dr. Sugiyama, Ms. Ogawa

< Review of research involving human subjects >

	Dept.	Study title	Review result	Summary minutes
1	Clinical Studies	RP-A10-08 “The association between subclinical thyroid dysfunction and cardiovascular diseases and mortality: an individual participant pooled analysis of large international cohort studies” (Dr. Imaizumi <i>et al.</i>)	Approved	<ul style="list-style-type: none"> ① In addition to the four RPs (RP-A4-13, A5-13, A3-14, and A2-16), RP-S2-12, A7-12, and A3-13 (a total of seven RPs) should be integrated into this RP, and the Application for Revisions and the annex should be modified accordingly. ② For active research plans, the name of the projects and the co-investigators, both old and new, should be listed on the first or second page of the RP. ③ The list of the “TSC-related research protocols” should be modified. (Should be prepared in Japanese; period of data use should be added; approval date for A3-14 should be changed; “Approved / Status as of 2020” and “Status in 2021” should be clarified.) ④ The abbreviation, such as “CHD” and “CHF” in “4. Variables for pooled meta-analysis of large prospective cohorts” and “HF” in “6. Statistical analysis” should be reworded in an easy-to-understand manner. ⑤ The effective date of amendment of the Ethical Guidelines for Medical and Health Research Involving Human Subjects should be changed to May 30, 2017. ⑥ The date of approval should be included.

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

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