

Summary minutes of the 12th Institutional Review Board Meeting in FY2023 (Review by internal members and expedited review)

Date & time Monday, October 30, 2023, 13:00 – 15:05

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

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

 IRB members: Dr. Satoh, Dr. Sugiyama, Dr. Hida, Ms. Ogawa, Ms. Dodo, and Mr. Fuchi

Review of “Ethical Survey on Ongoing Research Project”

	Dept.	Research title	Result	Summary
1	All	<ul style="list-style-type: none">Review of RPs with minimal risk	Approved	<ul style="list-style-type: none">For RPs requiring recommendations, a written opinion of the IRB will be prepared and delivered to the relevant representative investigators.A reminder will be sent requesting that the study period be changed and that compliance with the U.S. and Japanese laws and the guidelines be reviewed for modification.

Review of research involving human subjects

	Dept.	Research title	Result	Summary
2	Clinical Studies	Modification to RP A10-08 “The risk of disorders in subclinical thyroid dysfunction: An individual participant pooled analysis of large international cohort studies” (Imaizumi et al.)	Approved	<p>1. Research Protocol (RP)</p> <ul style="list-style-type: none">The statement “RERF researchers will not perform any analysis using the individual data” should be added under “6. Statistical Analysis” on page 11.A note should be added stating that the RERF representative investigator will serve as the point of contact for consultation and inquiries regarding research.For TSC-related RPs; TSC 1-21, TSC 2-21, and TSC 1-23, “2021/12” and “2023/9” listed in “Expected data usage deadline” column should be deleted and “Continued use” should be listed instead on page 19.

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.