

The 174th joint meeting of Human Investigation Committee and Ethics Committee for Genome Research (Expedited review)

Date: March 26, 2010 (Friday), 10:00 - 12:15

Place C-211 (Hiroshima), 3rd fl. meeting room (Nagasaki) (teleconference)

< Genome research review >

	Department	Research project title	Review results	Summary
1	Genetics	Pilot study of trans-generational effects of atomic-bomb radiation using a high-density array system to detect copy number variants	Approved	◆The application document refers to, in section VI-4., as methods used for anonymization, “anonymization numbers created by ITD.” This phrase should be changed to read “anonymization numbers newly created by ITD.”

*The above Research Protocol was approved after confirmation that the relevant modifications were made properly.

< Epidemiological research review >

	Department	Research project title	Review results	Summary
2	Clinical Studies	Diagnosis of pathologic conditions and genetic basis of progressive cardiac conduction disturbance (FY2010 research plan to be funded by Health and Labour Sciences Research Grants)	Approved	◆The “Application for Ethical Review” should clearly state, in “I-8. Study methods,” that the proposed study does not include genome analysis or clinical electrophysiological tests. ◆The description in “I-17. Ethical issues to be considered in relation to the project” should be improved by including presence or absence of expected ethical issue(s) and the reason thereof and also by adding details concerning personal information protection.
3	Statistics	A Semi-parametric Survival Extrapolation Method: Model Validation using RERF Cohort	Approved	◆The type of data anonymization chosen in “I-14. Methods of personal information protection” of the “Application for Ethical Review” should be changed from “Linkable anonymization” to “Unlinkable anonymization.” The RP also should be modified to clearly state that data will be unlinkably anonymized. ◆The review application form says that information will not be released to other institutions in “VI-1. Will information (including samples and genetic information) be released to other institutions?”. It should be corrected to indicate that information will be released, and consequently the other items in this section should be filled in.

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