

The 186th joint meeting of Human Investigation Committee and Ethics Committee for Genome Research (Expedited review)

Date: November 16, 2011 (Wednesday), 9:00 - 10:00

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

< Genome research review >

	Department	Research project title	Review results	Summary
1	Radiobiology/ Molecular Epidemiology	Case-control study of the prevalence of genetic mutations in women with gynecologic cancer and the mutation effects on treatment outcome	Approved	<ul style="list-style-type: none"> ◆Methods of discarding information, etc., and methods of anonymization for storage: Handling by the National Cancer Center in Korea and by RERF each should be indicated. ◆Regarding the absence of a personal information manager at RERF, since the samples, etc., to be provided to RERF were anonymized in advance in an unlinkable manner and will not be linked with personal information, there is no need for a personal information manager.
2	Radiobiology/ Molecular Epidemiology	A pilot study: Evaluation of the existence and utility of the thymus autopsy specimens that are available from LSS subjects who dies at 70 or more years old in the RERF tissue archives and that are available from LSS subjects in Hiroshima University Hospital (addendum to RP-B-48-09)	Approved	<ul style="list-style-type: none"> ◆Since this study involves specimens of deceased persons, there is the view that the anonymized specimens cannot be used in a linkable manner without obtaining the consent of proxies. This study, however, aims to examine not genetic information but gene expression quantity, and therefore justification could be made for use of specimens anonymized in a linkable manner. However, if a study is newly initiated involving the specimens examined in the current study in the future, it would be necessary to reconsider handling of the specimens.
3	Clinical Studies	Modifications to “Consent to thyroid samples preservation for future studies including human genome/gene analysis” of “RP7-11: Preservation of fresh thyroid samples obtained from AHS participants (addendum to RP2-86)”	Approved	<ul style="list-style-type: none"> ◆“Informed consent form concerning thyroid sample preservation for future studies including human genome...” should be replaced with “Informed consent form concerning thyroid sample preservation/use for future studies including human genome...” In connection with this, the explanatory note to the informed consent form also should be modified. ◆The explanatory note to the informed consent form should include the effect that withdrawal of consent during the study will not impact in any way the contents or handling of health examinations at RERF in the future.

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