The 9th Institutional Review Board Meeting (FY2016) (Regular review)

Date: September 23, 2016 (Friday) 9:15 - 12:00

Place: Auditorium (Hiroshima) and 3rd fl. meeting room (Nagasaki) (teleconference)

＜Review concerning human genome/gene analysis research protocol＞

	Department	Research project title	Review results	Summary
1	Epidemiology	CR132 "A pilot study of genomic characterization of radiation-associated papillary thyroid cancer among the atomic-bomb survivors" (Ozasa, et al.)	Approved	◆ The results of ethical reviews conducted at other collaborating research institutes should be reported to the co-chairperson. ◆ Item I-4-2) Type of information -b) other type of information of the application form should refer to the use of LSS (Life Span Study) information, and other issues noted by IRB be modified. IRB has concluded that the Ethical Guidelines for Medical and Health Research Involving Human Subjects are applicable to the issue of LSS information.

*With regard to the aforementioned items, IRB approved by confirming revisions made properly.

＜Review concerning human subject research＞

	Department	Research project title	Review results	Summary
1	Epidemiology	RP-S2-16 "Evaluation of DNA/RNA library with repair of fragmented DNA/RNA for suitability for whole genome sequencing of thyroid cancer (pretest-2 of A pilot study of genomic characterization of radiation-associated papillary thyroid cancer among the atomic-bomb survivors)" (Ozasa, et al.) [Revision of RP]	Approved	◆ With regard to Procedure 13 of Methods, the RP should clarify that samples of liver and kidney cancers will not be sent to the NCI(National Cancer Institute).
2	Epidemiology	CR133 "A Proposal to Join the CONCORD 3 of Hiroshima Prefecture Cancer Registry" (Sugiyama, et al)	Approved	◆The Research Protocols should reflect the items 12-14 shown in the checklist.(12.Burden to be caused on the research subject and anticipated risks and benefits, including comprehensive assessment of such burden, risks and benefits as well as measures to minimize those burden and risks.13.Means for storage and disposal of specimens and information, including period of storage.14.Matters to be reported to the chief executive of the research implementing entity and procedures for such reports) ◆Since IRB confirmed that data would be published in the form of tabulated results and that it is impossible to identify individuals, IRB has concluded that information about the date of birth can be provided. ◆It is necessary to decide on the handling of data after publication of a paper and make appropriate changes to the application form (VI. Storage of Specimens/Information to be provided) and the RP.

*With regard to the aforementioned items, IRB approved by confirming revisions made properly.