The 204th joint meeting of Human Investigation Committee and Ethics Committee for Genome Research

Date: December 11, 2014 (Wednesday), 9:05 - 12:40

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

＜Genome and epidemiological research review＞

Department		Research project title	Review results	Summary
1	RERF	"Epidemiological Study of Health Effects in Fukushima Emergency Workers" (This review concerns the acquisition of a list of subjects for preparation of the study.)	Approved	◆ To include words of appreciation. ◆ To explain how the personal information necessary for sending the letter was obtained. ◆ To indicate protection of personal information. ◆ To clarify the responsible party of the research. ◆ To state that this is a scientific study. ◆ To assure that the subjects can choose not to participate. ◆ To indicate the contact information.

＜Epidemiological research review＞

Department		Research project title	Review results	Summary
1	Clinical Studies	"CR109 Effects of ionizing radiation on impairments of glucose and lipid metabolism and impact on risks of arteriosclerotic diseases and cancers"	Approved	◆ To the subjects who have not provided informed consent, "Observational studies involving stored materials" in the Ethical Guidelines Concerning Epidemiological Studies (Ethical Guidelines) will be applicable. The authors therefore should modify the Application for Ethical Review pursuant to the Ethical Guidelines. ◆The following points in the RP should be modified. 1)The dose-relate phrasing in "Radiation dose" should be consistent. 2)The authors should clarify in "Expenses" that no additional costs will be necessary. 3)The authors should refer to the conflict of interests. ◆ A checklist for simplification/exemption of informed consent should be submitted.
2	Clinical Studies	"CR118 Taking images of lens using new ophthalmic camera among volunteers"	Approved	◆The following points in the RP should be modified. 1)Regarding item 4 in "Subjects and Methods," the authors should clarify the justification for the ophthalmologist to observe ocular angle and the requirement for applying mydriatic drops. 2）The authors should refer to whether or not there are side effects of miotic drug. ◆ The following points in the written consent should be modified. 1)Regarding the expression "We would like you to be a participant in our ophthalmological study," this expression may daunt the employees receiving this document and making free decision. The authors should modify it into a more appropriate expression. 2)The authors should refer to the requirement for applying mydriatic drops. 3)"Safe" is not exactly a wording for objective explanation of fact. The authors should modify it into a more appropriate expression. 4)The wording "protection of privacy" should be replaced with "protection of personal information." ◆ The title of research project should be consistent between the RP and written consent.
3	Clinical Studies	"CR112 The association between radiation and atrial fibrillation among atomic bomb survivors"	Approved	◆ When no informed consent is obtained, "Observational studies involving stored materials" in the Ethical Guidelines Concerning Epidemiological Studies (Ethical Guidelines) will be applicable. The authors therefore should modify the Application for Ethical Review pursuant to the Ethical Guidelines. ◆The authors should attach copies of the forms of explanatory document for obtained informed consent and written consent.

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