

**The 208th joint meeting of Human Investigation Committee and Ethics Committee for Genome Research**

Date: May 21, 2015 (Thursday), 9:00 - 13:00

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

**< Ethical review of genetic and epidemiological research >**

	Department	Research project title	Review results	Summary
1	RERF	"Epidemiological Study of Health Effects in Fukushima Emergency Workers" (This review concerns a preliminary study.)	Approved	<p>◆ With regard to the research protocol, the following items should be confirmed, revised, or added:</p> <p>1) "2. Framework of this study"</p> <ul style="list-style-type: none"> <li>• In "1) Study subjects and design": "Human Investigation Committee" should be deleted from "The fundamental part described in this research protocol will be approved by the institutional review board (Human Investigation Committee) of the Radiation Effects Research Foundation. Individual research plans to be mainly developed by collaborative investigators will each undergo the ethical review of the most appropriate research organization before implementation." Furthermore, it is necessary to notify collaborative investigators of the results of RERF's IRB review of the fundamental part; It is also necessary to confirm how collaborative investigators' respective institutions conducted ethical review of the fundamental part and report results of the confirmation to HIC/ECGR.</li> <li>• In "10) Reporting to the head of research organizations and periodical evaluation by external parties": Revisions should be made to indicate that IRB will conduct a review annually as well as on an as-needed basis.</li> </ul> <p>2) Revisions of wording and format should be made appropriately in accordance with comments expressed at the meeting.</p> <p>◆ Furthermore, for the purpose of personal information protection, publication should be based on grouped data in a manner that does not allow for personal identification.</p>
2	Biosample center	"Research Protocol for Collection and Transfer of Samples and Information by the Biosample Center at the Radiation Effects Research Foundation"	Approved	<p>◆ The following modifications need to be made to the Research Protocol.</p> <p>1) On "Abstract"</p> <ul style="list-style-type: none"> <li>• The expression related to "sample information" should be revised to clarify the meaning.</li> </ul> <p>2) On "Ethical considerations"</p> <ul style="list-style-type: none"> <li>• The Ethical Guidelines for Epidemiological Studies and the Ethical Guidelines for Clinical Studies should be deleted, and the Ethical Guidelines for Medical and Health Research Involving Human Subjects be added.</li> <li>• Risks involved in the study should be stated.</li> <li>• Handling of consultations requested by subjects should be stated.</li> <li>• It should be clearly stated that the linkably anonymized key tables of samples and information are not provided to outside organizations.</li> </ul> <p>3) "Possible conflicts of interest and relationships to organizations with which researchers are affiliated" should include the wording "as stipulated in the RERF Regulations Regarding Management of Conflict of Interest."</p>

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