Minutes of the 7th Institutional Review Board Meeting in FY2022 (Expedited Review)

Date: Monday, October 3, 2022, 14:00-17:10

Place: [Hiroshima] Auditorium
[Nagasaki] The 3rd conference room

Participants: *IRB co-chairpersons*: Dr. Tanabe and Ms. Shinohara *IRB members*: Drs. Yamada, Satoh, Sugiyama, Hida, Mses. Ogawa, Dodo, and Mr. Fuchi

[Review of research involving human subjects]

	Department	Study title	Review result	Summary minutes
1	Department of Molecular Biosciences	CR154: Evaluation of radiation-associated clonal hematopoiesis among atomic-bomb survivors (Yoshida *et al.*)	Approved	1. Application Form for Ethical Review ・ The description should be such that it is clear that personal information is not sent to Kyoto University, which is a collaborative research institute (P.1). ・ It should be stated that the “server not connected to any external network” described in “(3) Safety control” is not connected to any internal network (P.3). (The same statement also appears on the research protocol.) ・ In “VII.-1 Storage of specimens to be obtained,” under “(1) Will the specimens be stored?”, state that all residual samples will be returned to RERF (P.13). 2. Research Proposal ・ State that if it cannot be confirmed that the proxy meets the selection policy, he/she will not be selected as a proxy. ・ State that only cancer registry information up to the point of blood collection will be used. (P.28). ・ It should be stated in the "Ethical Considerations" section that this research protocol is subject to ethical review by Nagasaki University and the University of Tokyo, which are the collaborative research institutions. (P.37). ・ Regardless of whether or not the study participants wish to have the results explained to them, if the results are found to be life-threatening, they must be reported to the Institutional Review Board (IRB), and it must be stated in the “Handling of Result Obtained through Research” that the IRB will discuss how to deal with the situation. (The same statement also appears on the application form.) 3. Consent Explanatory Note ・ In Attachment 1, “not diagnosed with cancer at the time of blood collection” should be revised to “not diagnosed with solid cancer at the time of blood collection” (P.46).

				・ Delete “Please indicate on the consent form whether or not you would like to receive the information concerning genetic mutation that could cause significant effects”, and it should be stated that the IRB will deliberate on its handling (P.48). ・ The phrase “personal information including genetic analysis data” should be changed to simply “genetic analysis data.” In addition, “in compliance with Japanese laws and guidelines” should be specifically stated in such a way as “in compliance with Japanese laws and regulations such as the Act on the Protection of Personal Information and Research Ethics Guidelines.” (P.49). ・ The source of funding for the research should be included in In Attachment 1. ・ Delete “3. In this study, I or my blood relatives...” from Attachment 2 (P.51). ・ The disagreement form in Attachment 4 should be written in such a way that it is clear whose sample or information is involved. In addition, the phrase “by mail by the end of the following month” should be written on a separate sheet. The title of the "disagreement form" should be revised to something like "refusal or withdrawal of consent." 4. Information Disclosure Document ・ In the "Samples/information items to be used or provided" section, the name, address, and date of birth should be listed in (b), and cancer registries should be listed in "Provision of samples/information to external institution(s). In addition, in (b), correct "Smoking history (collected through mail survey)" to “Smoking history (collected through RERF’s mail survey).” ・ The sample and information should be described in such a way that it is clear which samples and information will be provided and which will not be provided. ・ Information Disclosure Form should be attached to the research protocol.
2	Department of Clinical Studies	Revisions to RP2-11: “Study of Arteriosclerosis in the Adult Health Study Population (Part 2. Analysis of the Cytokine Network Regulating Differentiation of Mesenchymal Stem Cells in Artery” (Nakamizo et al.)	Approved	1. Check List ・ Blood collection is considered a minor invasion, and items 22 and 23 should be checked “Yes” (P.3). 2. Research Protocol ・ In “Research design,” the period required for sample collection and analysis should be stated as 4 years (P.7). ・ In “Accuracy control of the above cytokine assay,” the newly added sentence "Serum and other ..." should be listed at the end of “blood samples” statement. In addition, “control group samples” and “blinded standard samples” should be revised to “control

				samples” (PP. 9-10). ・ Under “Ethical Considerations,” revise the name of the ethical guideline to the new name. In "Informed Consent," state that consent for this study was obtained as part of the consent for the AHS health examinations, and that separate consent was obtained for volunteers as seen in the attachment (P.14). ・ In “Handling of Personal Information,” do not delete the sentence "The results of this study...data only will be reported.” Also, delete “Anonymization will be performed by the Information Technology Department” and state that the system ID will be used as the personal number for the study (P.15). In addition, the method of storing the data of the medical questionnaire used for volunteers and the method of assigning anonymizing numbers should also be described. ・ In the “Disclosure of information and consultation” section, the change of responder should be clearly indicated. The official name of the Contacting Section should also be written (P.15). ・ The “Handling of research results” should be a separate item, and the policy of not disclosing the results to study participants should be described (P. 16).

Approved by confirming that the aforementioned revisions have duly been made

[Review of ethical survey on ongoing research projects]

	Department	Study title	Review result	Summary minutes
1	All	Review of research projects below minimum risk	Approved	・ For research proposals (RPs) for which the research period has expired, we request that the researcher submit a termination report or an application for extension. ・ For all RPs, including platform RPs, for which no research term has been set, and for which a certain period of time has passed since the last application for modification, we request that the researcher review whether the research conforms to the current ethical guidelines and make modifications as appropriate.

To prevent the spread of COVID-19, the IRB members at the meeting maintained sufficient distances from each other.