August 10, 2017 Ver. 1.0

June 30, 2021 Ver. 2.0

# Standard Operating Procedure for the Secretariat of the Kyushu University Certified Institutional Review Board for Clinical Trials

(Purpose)

Article 1 This manual establishes the operating procedures to be followed by the Secretariat of the Kyushu University Institutional Review Board for Clinical Trials (hereafter, "the Secretariat") with regard to entrustment of ethical review to the Kyushu University Institutional Review Board for Clinical Trials (hereafter, "the Board").

(Scope of This Manual)

Article 2 This manual applies to the following types of ethical review handled by the Board.

(1) Central comprehensive review associated with multi-institutional joint research for which someone belonging to Kyushu University serves as the research representative. Hereafter, in cases of multi-institutional joint research, the term "research representative" can be used as an equivalent term for "principal investigator."

(2) Ethical review of research conducted by another institution with which no one belonging to Kyushu University is involved and for which sufficient reason is deemed to exist for entrusting said review to the Board.

(Necessary Documents for Review Entrustment)

Article 3 The Secretariat will request the principal investigator to submit the separately established "Request for Ethical Review" form and, for each institution involved in the research, the "Institution Requirements Confirmation" form.

2 At the time of ethical review entrustment, the Secretariat shall request the principal investigator to submit a "Resume" form, specified separately, and documentation in a format of his/her choosing, such as a "Certificate of Participation in Education and Training," which establishes that the principal investigator has sufficient education and training to appropriately carry out the research in question. However, this is not necessary in cases which correspond to Paragraph 1 of the preceding article.

3 The Secretariat shall use the documents stipulated in Paragraph 1 and Paragraph 2 to confirm that the institution entrusting the ethical review has an appropriate research implementation system in place.

(Submission of Review Documents)

Article 4 In the case of a new application from a principal investigator, the Secretariat shall request submission of review documents as per the items enumerated below.

(1) The Secretariat shall request submission of the following documents from the relevant principal investigator. With regard to the explanatory document and consent form used in the research participant institutions which are part of the multi-institutional joint research in question, the Secretariat shall request the principal investigator to submit documents that are based on the explanatory document and consent form approved by the Board.

i. Request for Ethical Review
ii. Research Implementation Plan
iii. Explanatory Document
iv. Consent Form
v. Self-Check Sheet
vi. Conflict of interest-related documentation
vii. Copy of the clinical research insurance contract or estimate
viii. Other essential documents

(2) In the case of altered or revised applications, the Secretariat shall request submission of the following review document from the principal investigator.

i. Request for Ethical Review
ii. List of Revisions
iii. Revised documents (research implementation plan, explanatory document, consent form, etc.)
iv. Other essential documents

(3) After receiving the review document stipulated in Paragraph 1 and Paragraph 2, the Secretariat shall carry out the procedures for obtaining the opinion of the Board. These procedures shall be carried out in conjunction with the duties stipulated in Article 8.

(Electronic Application System)

Article 5 The Secretariat shall not prevent use of the electronic application system for the review materials stipulated in the preceding article. In such cases, as well, compliance with all relevant information management-related laws, regulations, guidelines, etc., is required.

2 The Secretariat may use a tablet terminal to deliver the review documents, and the Board may use a tablet terminal to review them.

3 The Secretariat shall not prevent the storage of documents relating to entrustment of ethical review (including contracts) from being stored in a format which guarantees confidentiality on prescribed servers within Kyushu University Hospital. As a rule, appropriate access authority will apply to document management in such cases.

(Pre-review Handling by the Secretariat)

Article 6 In the case of a new application for which Kyushu University is the main research institution, the Secretariat shall coordinate as necessary with the Kyushu University Hospital ARO Next-Generation Medical Center. The Center may conduct a pre-review, based on the documents stipulated in Article 3, to provide advice from a scientific and ethical standpoint and to confirm any conflicts of interest. This shall be carried out in conjunction with operations dictated by the separately prescribed "Standard Operating Procedures for Managing Clinical Research Conflicts of Interest."

(Board and Secretariat Handling of Review Opinion Duties)

Article 7 The Board and Secretariat shall adhere to the separately established "Kyushu University Ethical Review Board (Observational/ Intervention) Standard Operating Procedures" (hereafter, "Kyushu University Observational/Intervention Procedure Manual") with regard to deliberations, voting, decision adoption, etc.

2 When performing a review, as per the stipulations of the preceding paragraph, if it is especially difficult to perform said review in-person, it shall be permissible to perform it via video conference (i.e., via means enabling smooth, two-way communication) or in writing.

(Board and Secretariat Handling of Ethical Review Results Reporting)

Article 8 For the cases stipulated in Article 2, Paragraph 1 and Paragraph 2, the Board chairperson shall use the separately provided "Review Results Notification" form to report the review results to the research representative in question. These duties shall be performed by the Secretariat. The research representative in question must submit an "Implementation Authorization Request to Conduct Medical and Biological Research Involving Human Subjects" along with any other necessary documentation requested by the head of the relevant research institution, to receive authorization to carry out the planned research.

(Board and Secretariat Handling of Implementation Status Report)

Article 9 The institution entrusting the ethical review must submit a "Research Implementation Status Report" at least once a year to the Secretariat in accordance with the prescribed format. When necessary, the Board shall review the content of these reports and notify the relevant research representative about whether it approves of the research being continued or if it has necessary recommendations. The same shall apply to reports about research discontinuation or conclusion.

(Board and Secretariat Handling of Expedited Reviews)

Article 10 Following Board review approval of research implementation, it is possible to conduct expedited review as stipulated in the Kyushu University Observational/Intervention Procedure Manual.

(Board and Secretariat Handling of Severe Adverse Event Reporting)

Article 11 In the event of a severe adverse event occurring in research which was reviewed by the Board, the institution entrusting the ethical review shall make a report to the Secretariat using the "Severe Adverse Event Report" form. The Secretariat shall issue a "Request for Ethical Review" addressed to the Board chairperson from the research representative conducting the research in question and shall carry out the procedures for referring the matter to the Board. This response shall be carried out in conjunction with the procedures stipulated in Article 8. After receiving and reviewing the "Severe

Adverse Event Report," the Board shall make a decision on whether or not the research should be continued.

2 The Board chairperson shall use the "Review Results Notification" form to report the results of the review conducted as per the preceding paragraph to the research representative in question. These duties shall be performed by the Secretariat. The research representative must then make a report to the head of the relevant research institution.

(Secretariat Handling of Inappropriate Case Reports)

Article 12 As a rule, when an inappropriate case occurs or is discovered with regard to research reviewed by the Board, an investigation and necessary response shall be undertaken by the institution where the case occurred or was discovered, after which a report shall be made to the Secretariat using the separately prescribed "Research Implementation Status Report." The Board shall review the content of the inappropriate case and the response to it and shall provide notification of the review results to the institution where the case occurred or was discovered.

(Maintenance of Records)

Article 13 Documents (including electromagnetic records and other media) to be preserved which relate to ethical review boards shall be kept for ten years by the Secretariat. The principal record keeper for said records shall be the head of the relevant section.

(Other)

Article 14 If, in the context of appropriately executing duties relating to the entrustment of ethical review, a case arises which requires special arrangements, the relevant sections shall coordinate together as needed to handle the matter.

Supplementary Provision: This manual shall come into effect from August 10, 2017.

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