

Kyushu University Detailed Regulations for Implementation of Sponsored Research

Kyushu University Detailed Regulation No. 18 of 2004

Effective date: April 1, 2004

Last amended: January 31, 2025

(Kyushu University Detailed Regulation No. 6 of 2024)

(Purpose)

Article 1 These Detailed Regulations shall provide for necessary matters relevant to the implementation of sponsored research pursuant to the provisions of Article 16 of the Kyushu University Regulations for Sponsored Research (Kyushu University Regulation No. 95 of 2004; hereinafter referred to as the "Regulations").

(Institutional Review Boards)

Article 2 (1) A Certified Institutional Review Board for Clinical Trials, Institutional Review Board for Clinical Research, Institutional Review Board for Clinical Trials, and Institutional Review Board for Clinical Trials for Approval of Drugs/Equipment (hereinafter referred to as "Institutional Review Boards") shall be established at the Hospital, the Faculty of Medical Sciences, the Faculty of Dental Science, the Faculty of Pharmaceutical Sciences, and the Medical Institute of Bioregulation (hereinafter referred to as "Kyushu University's Medical Institutions") to comprehensively deliberate on the appropriateness, usefulness, safety, and other matters of sponsored clinical research (meaning research conducted using pharmaceuticals and tools and instruments as entrusted by a party outside Kyushu University and research conducted using unapproved and off-label pharmaceuticals, etc. or research conducted with funds provided by a pharmaceutical company, etc., for the purpose of diagnosis, prevention or treatment of illness of patients; the same applies hereinafter).

(2) Notwithstanding the provisions of paragraph (1), director of Kyushu University Hospital may request review by an external institutional review board established pursuant to the provisions of Article 27, paragraph (1) of the Ministerial Ordinance on Good Clinical Practice for Drugs (Ordinance of the Ministry of Health and Welfare No. 28 of March 27, 1997) if director of Kyushu University Hospital finds it necessary.

(Method of Making Application for Entrustment)

Article 3 An application provided in Article 3 of the Regulations shall be made by means of a form specified separately by the President; provided, however, that an application relating to sponsored clinical research under the preceding Article to which Article 6, paragraph (3) applies shall be made by means of a form specified separately by director of Kyushu University Hospital.

(Decision to Accept Sponsored Clinical Research)

Article 4 To make a decision to accept sponsored clinical research pursuant to the provisions of Article 4, paragraph (1) of the Regulations, the director of Kyushu University Hospital shall go through deliberations at the Institutional Review Board in advance.

(Notice of Decision to Accept)

Article 5 (1) A notice of the decision to accept to be given to the President, etc. as provided in Article 4, paragraph (2) of the Regulations shall be given by attaching a copy of an application form for sponsored research referred to in Article 3 to a written notice of the decision to accept.

(2) Notwithstanding the provisions of the preceding paragraph, a notice of the decision to accept to be given to the President, etc. in the case set forth in Article 3, paragraph (2) of the Regulations shall be

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given by attaching a copy of a notice of adoption in response to a call for proposals or any other similar document to a written notice of the decision to accept. In this case, the division director must ensure that the conclusion of a sponsored research agreement would not be impeded, by taking measures such as attaching a document prepared by using a form specified separately by the President, etc. and filling it with information necessary for concluding a sponsored research agreement.

(Payment of Research Expenses, etc.)

Article 6 (1) The Kyushu University (hereinafter referred to as the "University") shall have the sponsor pay research expenses, etc. referred to in Article 8, paragraph (1) of the Regulations by the day designated by the University using an invoice issued by the University.

(2) A case provided in Article 8, paragraph (2) of the Regulations where research expenses, etc. may be paid on or after the date of commencement of the relevant sponsored research is a case that falls under all of the following items:

- (i) if there are circumstances due to which sponsored research needs to be commenced without waiting for payment of research expenses, etc.;
- (ii) if the sponsor has promised to pay research expenses, etc. certainly under the sponsored research agreement; and
- (iii) if it has been confirmed that the sponsor is in sound financial condition.

(3) Beyond the case provided in the preceding paragraph, if the private organization, etc. needs to promise to pay research expenses, etc. depending on the achievement made after accomplishing the research targets of sponsored clinical research, the deadline for payment of research expenses, etc. may be set as a day within the period from the date of conclusion of the sponsored clinical research agreement until the date of termination.

(Research Expenses, etc.)

Article 7 (1) The items of direct expenses provided in Article 8, paragraph (1) of the Regulations (hereinafter referred to as "direct expenses") are as follows:

- (i) personnel expenses;
- (ii) travel expenses;
- (iii) equipment expense;
- (iv) consumables expenses; and
- (v) others (utilities expenses, facility use fees, equipment use fees, communication and transportation expenses, and other expenses).

(2) The amounts referred to in the items of the preceding paragraph shall be calculated based on the appended table.

(3) The amount of indirect expenses provided in Article 8, paragraph (1) of the Regulations (hereinafter referred to as "indirect expenses") is an amount equivalent to 30% of the amount of direct expenses and Academic Facilitate Fee provided in Article 8, Article 1 of the Regulations.

(4) Notwithstanding the provisions of the preceding paragraph, in a case that falls under any of the following items, a reduction or exemption may be granted for indirect expenses:

- (i) if the sponsor is the national government or an incorporated administrative agency, and the percentage of indirect expenses is fixed or no indirect expenses are arranged under the program of the relevant sponsored research;
- (ii) if it is clear that the sponsor that has been entrusted with research from the national government or an incorporated administrative agency will further entrust research to a division of the University, and the percentage of indirect expenses is fixed or no indirect expenses are arranged under the program of the relevant sponsored research;
- (iii) if the sponsor is a public service corporation or corporation in the public interest, etc. provided in Article 2, item (v) or item (vi) of the Corporation Tax Act (Act No. 34 of 1965) (in the case of a

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general incorporated association and a general incorporated foundation, limited to those engaging in a business for public interest purposes provided in Article 2, item (iv) of the Act on Authorization of Public Interest Incorporated Associations and Public Interest Incorporated Foundations (Act No. 49 of 2006)), and no indirect expenses can be arranged due to financial circumstances;

- (iv) if the sponsor entrusts research to a division of the University using competitive funds, and the percentage of indirect expenses is fixed or no indirect expenses are arranged under the program of the relevant competitive funds;
- (v) beyond what is provided in the preceding four items, if research is entrusted to a division of the University as a result of an application or proposal by a researcher, and the percentage of indirect expenses is fixed or no indirect expenses are arranged under the program of the relevant sponsored research; or
- (vi) if other unavoidable circumstances are found.

(Consent of Patients)

Article 8 (1) To implement sponsored clinical research, a researcher must, in advance, provide patients or persons having legitimate authority over patients, such as persons having parental authority or guardians, with sufficient explanation in writing concerning the purpose of the research, the expected effects, and other matters, including risks, and obtain their consent in writing.

(2) Beyond what is provided in the preceding paragraph, a researcher must sufficiently examine the content of basic study, clinical study, etc. submitted by the sponsor and give due consideration to measures to ensure the safety of patients.

(Discontinuance of Sponsored Clinical Research)

Article 9 To discontinue or extend sponsored clinical research pursuant to the provisions of Article 9, paragraph (2) of the Regulations, the director of Kyushu University Hospital shall go through deliberations at the Institutional Review Board in advance.

(Management of Submitted Pharmaceuticals and Tools and Instruments)

Article 10 (1) A researcher shall properly manage pharmaceuticals and tools and instruments submitted by the sponsor by taking measures such as recording the status of payment and receipt of these.

(2) When sponsored clinical research is completed or discontinued, a researcher shall return unused pharmaceuticals and tools and instruments to the sponsor.

Supplementary Provisions

These Detailed Regulations come into effect as of April 1, 2004.

Supplementary Provisions (Kyushu University Detailed Regulation No. 23 of 2005)

These Detailed Regulations come into effect as of April 1, 2006.

Supplementary Provisions (Kyushu University Detailed Regulation No. 20 of 2009)

These Detailed Regulations come into effect as of April 1, 2010.

Supplementary Provisions (Kyushu University Detailed Regulation No. 12 of 2011)

These Detailed Regulations come into effect as of April 1, 2012.

Supplementary Provisions (Kyushu University Detailed Regulation No. 16 of 2012)

These Detailed Regulations come into effect as of April 1, 2013.

Supplementary Provisions (Kyushu University Detailed Regulation No. 10 of 2013)

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These Detailed Regulations come into effect as of November 22, 2013.

Supplementary Provisions (Kyushu University Detailed Regulation No. 13 of 2017)

1. These Detailed Regulations come into effect as of February 1, 2018.
2. Notwithstanding the provisions of the preceding paragraph, prior provisions continue to govern sponsored research that falls under either of the following:
 - (i) sponsored research to be commenced by March 31, 2018; or
 - (ii) sponsored research that is not subject to management, coordination, etc. by the Academic Research and Industrial Collaboration Management Office and that is commenced by March 31, 2018 (excluding the case where the principal researcher notifies the University of the intention to implement sponsored research pursuant to the Kyushu University Detailed Regulations for Implementation of Sponsored Research as amended by these Detailed Regulations).

Supplementary Provisions (Kyushu University Detailed Regulation No. 36 of 2018)

These Detailed Regulations come into effect as of March 1, 2019.

Supplementary Provisions (Kyushu University Detailed Regulation No. 24 of 2019)

These Detailed Regulations come into effect as of April 1, 2020.

Supplementary Provisions (Kyushu University Detailed Regulation No. 10 of 2020)

These Detailed Regulations come into effect as of December 10, 2020.

Supplementary Provisions (Kyushu University Detailed Regulation No. 23 of 2020)

These Detailed Regulations come into effect as of April 1, 2021.

Supplementary Provisions (Kyushu University Detailed Regulation No. 21 of 2021)

These Detailed Regulations come into effect as of October 1, 2021.

Supplementary Provisions (Kyushu University Detailed Regulation No. 14 of 2022)

These Detailed Regulations come into effect as of April 1, 2023.

Supplementary Provisions (Kyushu University Detailed Regulation No. of 2024)

1. These Detailed Regulations come into effect (hereinafter referred to as the "effective date") as of April 1, 2025.
2. The sponsored research agreements that have been concluded between the President and the private organization, etc. provided in the Article 5 of the Kyushu University Detailed Regulations for Implementation of Sponsored Research prior to amendment and which actually exist at the time these Detailed Regulations come into effect, and which start date of the research period specified in the agreement is March 31, 2025 or earlier, and additionally, continued to conduct after the effective date may be deemed to have been concluded based on the contract presented by the president in accordance with the provisions of the Detailed Regulations for the Implementation of the Kyushu University Regulations for Commissioned Research after the amendments in accordance with these detailed regulations, effective from the date of the effective date. However, in this case, this shall be limited to cases where the head of the private organization, etc. has given approval.

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Appended Table (Re: Article 7)

Item of expense	Method and basis of calculation	
(1) Personnel expenses	Employee provided in Article 2 of the National University Corporation Kyushu University General Regulations of Employment (Kyushu University Employment Regulation No. 1 of 2004)	Amount of compensation provided in the regulations of the University
	Person employed for a fixed term, not pursuant to the provisions set forth above	Amount of compensation specified separately
(2) Travel expenses	National University Corporation Kyushu University Rules for Travel Expenses (Kyushu University Employment Regulation No. 57 of 2004) National University Corporation Kyushu University Detailed Regulations for Handling Travel Expenses (Kyushu University Detailed Regulation No. 45 of 2004)	
(3) Equipment expense	Amount based on an estimate or the like that indicates the price	
(4) Consumables expenses	Same as above	
(5) Others	Facility use fees	Kyushu University Rules for Use Fees for University-Wide Rental Spaces (Kyushu University Rule No. 56 of 2021) and other related rules and regulations
	Utilities expenses	Equivalent amount of the actual costs
	Equipment use fees	Kyushu University Rules for the Use of Center of Advanced Instrumental Analysis (Kyushu University Rule No. 56 of 2006) and other related regulations
	Communication and transportation expenses	Equivalent amount of the actual costs
	Others	Same as above

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