

Kyushu University Detailed Regulations for Implementation of the Regulations for Joint Research

Kyushu University Detailed Regulation No. 19 of 2004

Effective date: April 1, 2004

Last amended: January 31, 2025

(Kyushu University Detailed Regulation No. 5 of 2024

(Purpose)

Article 1 These Detailed Regulations shall provide for necessary matters relevant to the application procedure and other matters concerning joint research pursuant to the provisions of Article 18 of the Kyushu University Regulations for Joint Research (Kyushu University Regulation No. 94 of 2004; hereinafter referred to as the "Regulations").

(Review Committees)

Article 2 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 the "Medical Campus Departments") shall establish Clinical Research Review Committees, Observational Research Ethics Review Committees, Clinical Trial Ethics Review Committees, and Ethics Review Committees for Clinical Studies (hereinafter referred to as the "Review Committees"). These Review Committees shall comprehensively deliberate on the validity, usefulness, safety, and other aspects of clinical joint research conducted within the Medical Campus Departments (meaning research conducted using pharmaceuticals and medical devices provided by private entities for the diagnosis, prevention, or treatment of patients, as well as research using unapproved or off-label pharmaceuticals, etc.; the same shall apply hereinafter).

(Application Form for Joint Research)

Article 3 An application provided in Article 4 of the Regulations shall be made by means of a form specified separately by the President. However, an application for clinical joint research based on the preceding Article to which Article 7, paragraph (10) applies shall be submitted using the form separately prescribed by the Director of the Hospital.

(Decision to Conduct Clinical Joint Research)

Article 4 The Director of the Hospital shall obtain prior deliberation of the Review Committees when making decisions regarding the implementation of clinical joint research based on the provisions of Article 5, paragraph (1) of the Regulations.

(Request for Agreement Procedure)

Article 5 A request for the agreement procedure to the President, etc. provided in Article 5, paragraph (3) of the Regulations (hereinafter referred to as the "President, etc.") shall be made by submitting a request form for agreement procedure with a copy of a notice of commencement of the agreement procedure to a private organization, etc. (meaning the private organization, etc. provided in Article 1 of the Regulations) and a copy of an application form for joint research referred to in Article 2.

(Joint Research Agreement)

Article 6 A joint research agreement provided in Article 6, paragraph (1) of the Regulations shall be concluded based on a standard joint research agreement specified separately by the President, etc. or an agreement or the like presented by a private organization, etc.

(Research Expenses, etc.)

Article 7 (1) The items of direct expenses as provided in Article 9, paragraph (2) of the Regulations (hereinafter referred to as "direct expenses") are as follows:

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

(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 as prescribed in Article 9, paragraph (2) of the Regulations (hereinafter referred to as "indirect expenses") shall be the sum of an amount equal to at least 30 percent of the direct expenses and the management expenses incurred when the Academic Research and Industrial Collaboration Management Office of Kyushu University conducts management.

(4) The details of the management conducted by the Academic Research and Industrial Collaboration Management Office of Kyushu University in the preceding paragraph, as well as the amount of management expenses, shall be prescribed separately.

(5) Notwithstanding the provisions of the preceding two paragraphs, in a case that falls under any of the following items, the faculty director of the principal researcher's

division may grant a private organization, etc. a reduction or exemption regarding indirect expenses based on its application and with the approval of the President, etc.:

(i) if the research expenses, etc. are arranged by means of project expenses or competitive research funds and other research funds from the government or an incorporated administrative agency, and the percentage of indirect expenses is fixed or no indirect expenses are arranged under the relevant project or program;

(ii) if the private organization, etc. is the government or a public service corporation, a corporation in the public interest or the like provided in Article 2, item (v) or item (vi) of the Corporation Tax Act (Act No. 34 of 1965) (in the case of a general incorporated association and 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;

(iii) beyond what is provided in the preceding two items, if joint research is implemented as a result of a researcher having applied for a joint research program, and the percentage of indirect expenses is fixed or no indirect expenses are arranged under the joint research program; or

(iv) if other unavoidable circumstances are found.

(6) An application by the faculty director of the principal researcher's division for the approval of the President, etc. provided in the preceding paragraph shall be made by means of an application form for reduction/exemption regarding indirect expenses specified separately by the President, etc.

(7) Payment of research expenses, etc. may be made in installments.

(8) In principle, research expenses, etc. paid to the University shall not be returned; provided, however, that if there is any amount that has become unnecessary at the time the joint research is completed or discontinued, and the private organization, etc. claims refund of the amount, all or part of the amount shall be returned after negotiation between the parties.

(9) The University shall have the private organization, etc. pay research expenses, etc. by the date designated by the University which is prior to the date of commencement of joint research (in the case of payment in installments, by the date designated by the University which is prior to the first day of each installment period set in advance), using an invoice issued by the University; provided, however, that in a case that falls under all of the following items, the University may set the due date for payment of research expenses, etc. as the date of commencement of joint research or any subsequent date:

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

(10) Notwithstanding the preceding paragraph, if it is necessary to stipulate the payment of research expenses, etc. based on the achievements after the completion of the research objectives of the clinical joint research, the deadline for payment of research expenses, etc. may be set within the period from the date of conclusion of the clinical joint research agreement to the end date.

(Research Collaborator)

Article 8 If the University has a person other than the members of a researcher provided in Article 3, item (ii) of the Regulations collaborate in joint research as a research collaborator provided in Article 3, item (iv) of the Regulations, it shall have the research collaborator submit a written consent specified separately.

(Change of the Research Period)

Article 9 (1) An application for change in joint research provided in Article 10, paragraph (2) of the Regulations shall be made by means of an application form for change in joint research specified separately by the President, etc.

(2) A notice to the President, etc. provided in Article 10, paragraph (3) of the Regulations shall be given by submitting a written notice with a copy of an application form for change in joint research referred to in the preceding paragraph.

(Suspension, etc. of Clinical Joint Research)

Article 10 When suspending or extending Clinical Joint Research pursuant to Article 10, paragraph (2) of the Regulations, the Director of the Hospital shall obtain prior deliberation by the Review Committees.

(Management of Provided Pharmaceuticals and Medical Devices)

Article 11 (1) A researcher shall properly manage the pharmaceuticals and medical devices provided by private organization, etc., including by recording their receipt and disbursement.

(2) When the clinical joint research is completed or suspended, a researcher shall return any unused pharmaceuticals and medical devices to the provider.

Supplementary Provisions

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

Supplementary Provisions (Kyushu University Detailed Regulation No. 21 of 2005)

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

Supplementary Provisions (Kyushu University Detailed Regulation No. 13 of 2006)

These Detailed Regulations come into effect as of March 1, 2007.

Supplementary Provisions (Kyushu University Detailed Regulation No. 6 of 2012)

1. These Detailed Regulations come into effect as of September 25, 2012.

2. The provisions of Article 5, paragraph (1) of the Kyushu University Detailed Regulations for Implementation of the Regulations for Joint Research as amended by these Detailed Regulations apply to joint research for which acceptance is decided on or after the date on which these Detailed Regulations come into effect; and the provisions of paragraphs (3) and (4) of the same Article as amended apply to joint research for which acceptance is decided on or after October 1, 2012.

Supplementary Provisions (Kyushu University Detailed Regulation No. 24 of 2012)

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

Supplementary Provisions (Kyushu University Detailed Regulation No. 12 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 joint research that falls under either of the following:

(i) joint research to be commenced by March 31, 2018; or

(ii) joint research that is not subject to management, coordination, etc. by the Academic Research and Industrial Collaboration Management Office of Kyushu University and that is commenced by March 31, 2019 (excluding the case where the principal researcher notifies the University of the intention to implement joint research pursuant to the Kyushu University Detailed Regulations for Implementation of the Regulations for Joint Research as amended by these Detailed Regulations).

Supplementary Provisions (Kyushu University Detailed Regulation No. 35 of 2018)

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

Supplementary Provisions (Kyushu University Detailed Regulation No. 9 of 2020)  
These Detailed Regulations come into effect as of December 10, 2020.

Supplementary Provisions (Kyushu University Detailed Regulation No. 22 of 2020)  
1. These Detailed Regulations come into effect as of April 1, 2021.  
2. The provisions of Article 5 and the appended table of the Kyushu University Detailed Regulations for Implementation of the Regulations for Joint Research as amended by these Detailed Regulations apply to an application filed with the University or an offer made by the University on or after April 1, 2021; and prior provisions continue to govern joint research for which an agreement is concluded or agreement details are modified based on an application filed on or before March 31, 2021.

Supplementary Provisions (Kyushu University Detailed Regulation No. 20 of 2021)  
These Detailed Regulations come into effect as of October 1, 2021.

Supplementary Provisions (Kyushu University Detailed Regulation No. 32 of 2021)  
These Detailed Regulations come into effect as of April 1, 2022.

Supplementary Provisions

1. These Detailed Regulations come into effect as of July 1, 2022.  
2. The provisions of Article 5, paragraphs (3) and (4) of the Kyushu University Detailed Regulations for Implementation of the Regulations for Joint Research as amended by these Detailed Regulations apply to an application filed with the University or an offer made by the University on or after July 1, 2022; and prior provisions continue to govern joint research for which an agreement is concluded or agreement details are modified based on an application filed on or before June 30, 2022.  
3. With regard to joint research through comprehensive collaboration, these Detailed Regulations start to apply based on a consensus of the Collaboration Council for the joint research.

Supplementary Provisions (Kyushu University Detailed Regulation No. 13 of 2022)  
These Detailed Regulations come into effect as of April 1, 2023.

Supplementary Provisions (Kyushu University Detailed Regulation No. 16 of 2023)  
These Detailed Regulations come into effect as of April 1, 2024.

Supplementary Provisions (Kyushu University Detailed Regulation No. 3 of 2024)

1. These Detailed Regulations come into effect as of May 1, 2024.
2. The provisions of Article 7, paragraphs (3) and (4) of the Kyushu University Detailed Regulations for Implementation of the Regulations for Joint Research as amended by these Detailed Regulations apply to an application filed with the University or an offer made by the University on or after May 1, 2024; and prior provisions continue to govern joint research for which an agreement is concluded or agreement details are modified based on an application filed on or before April 30, 2024, the previous provisions shall continue to apply only for the duration of the relevant contract period.

Supplementary Provisions (Kyushu University Detailed Regulation No. 5 of 2024)

1. These Detailed Regulations come into effect as of April 1, 2025(hereinafter referred to as the “Effective Date”).
2. At the time of enforcement of these detailed rules, any joint research agreement (hereinafter simply referred to as “agreement”) that was concluded between the President, etc. and the head of private organization, etc. based on Article 6 of the Kyushu University Detailed Regulations for Implementation of the Regulations for Joint Research prior to amendment whose contractual research period commenced on or before the last day of March 2025, and which continue to conduct joint research after the effective date, may be deemed to have been concluded based on the contract documents presented by the President, etc., pursuant to the provisions of the Kyushu University Detailed Regulations for Implementation of the Regulations for Joint Research, as of the effective date. However, this shall be limited to cases where the head of the private organization, etc., has given approval.

Appended Table (Re: Article 7)

Item of expenses	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
	Student in a doctoral program (excluding a first two-year master's program of a doctoral program, and the part equivalent to a master's program in an integrated doctoral program) employed under the doctoral students joint research program for enrollment/ career support provided in Article 17-2 of the Kyushu University Regulations for Joint Research (Kyushu University Regulation No. 94 of 2004)	Amount of allowance provided in Kyushu University Rules for Doctoral Students Joint Research Program for Enrollment/Career Support (Kyushu University Rule No. 78 of 2017)
	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 expenses	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 the Center of Advanced Instrumental Analysis (Kyushu University Rule No. 56 of 2006) and other related regulations, etc.
	Communication and transportation expenses	Equivalent amount of the actual costs
	Others	Same as above
(6) Expenses for visiting joint researchers	Amount specified below according to the period of acceptance of one visiting joint researcher 1 year: 360,000 yen 6 months: 180,000 yen 1 month: 30,000 yen	