

When handling microorganisms (bacteria, fungi, viruses, parasites, and toxins) for research purposes, the mishandling of pathogens can cause a biohazard, not only to researchers themselves, but also to related personnel of the University and even to third parties. For this reason, researchers must strictly abide by the regulations given in the Infectious Diseases Act and other related laws, as well as University regulations, and ensure appropriate handling of microorganisms at all times.

The University regulations

[Rules on safe management of microorganisms for research](#)

[Regulations on safe management of microorganisms for research](#)

[Regulations on prevention of domestic animal infectious diseases](#)

Levels of microorganisms for research purposes

At the University, microorganisms for research are classified as shown below according to Appended Table 2 (hereinafter referred to as “ Appended Table 2 of the public notice on type 2 for research and development ”) of “ The Ministerial Ordinance Providing Containment Measures to Be Taken in Type 2 Use of Living Modified Organisms for Research and Development ” (Public Notice of the Ministry of Education, Culture, Sports, Science and Technology No.7 on January 29, 2004). (Regulations on safe management of microorganisms for research Article 2)

- **Equivalent to Level 1 (No pathogenicity for mammals)**

Microorganisms equivalent to Level 1 which is not mentioned in the Appended Table 2 of the public notice on type 2 for research and development.

- **Level 2 (Low pathogenicity for mammals)**

“ 2. Microorganisms defined by the Minister of Education, Culture, Sports, Science and Technology on Article 3 Chart No.2 ” of Appended Table 2 of the public notice on type 2 for research and development.

- **Level 3 (High pathogenicity for mammals and low contagiousness)**

“ 3. Microorganisms defined by the Minister of Education, Culture, Sports, Science and Technology in Article 3 Chart No.3 ” in the Appended Table 2 of the public notice on type 2 for research and development.

- **Level 4 (High pathogenicity for mammals and high contagiousness)**

“ 4. Microorganisms defined by the Minister of Education, Culture, Sports, Science and Technology in Article 3 Chart No.4 ” in the Appended Table 2 of the public notice on type 2 for research and development.

Education and training

Before using or storing microorganisms for experiments, educational training needs to be taken.

You cannot use or store microorganisms for experiments without having taken the necessary educational training.

University procedures

When initiating the use or storage of microorganisms for research purposes, the following procedures are required depending on the type of microorganism to be used in research. In addition, applications to experiment and registration must be updated each academic year, and if the use of microorganisms is discontinued, researchers will be required to submit completion confirmation documents.

- **Equivalent to Level 1 (No pathogenicity for mammals)**

A notification on handling microorganisms for research purposes (Form No.1) needs to be submitted to the head of the department (chief administrator) who manages the facility where microorganisms for research purposes are handled.

- **Level 2 (Low pathogenicity for mammals)**

A notification on handling microorganisms for research purposes (Form No.2) needs to be submitted to the head of the department (chief administrator) who manages the facility where the microorganisms are handled.

- **Level 3 (High pathogenicity for mammals and low contagiousness)**

An application for handling microorganisms for research purposes (Form No.3) needs to be submitted to the president through the head of the department (chief administrator) who manages the facility where the microorganisms are handled to get approval.

- **Level 4 (High pathogenicity for mammals and high contagiousness)**

It cannot be used at the University.

Electronic Application System for Genetic Modification Experiments

**Notification of Microorganisms Handling
(for Research Use, Level 1 and 2)**

**Microorganism Handler
Microorganism Handling Manager
(*)**

(1) Notification
of Microorganisms Handling

Chief Administrator

(2) Report of acceptance
of notification

**President
Microorganism Research
Safety Management Committee
(Environmental Safety Management Division)**

(* indicates the handler has completed the required education and training)

**Application for Handling of Microorganisms
(Level 3, for research purposes)**

**Microorganism Handler
Safety Manager**

- * When handling Level 2 and Level 3 microorganisms for research purposes, you need to use laboratories approved for experiments involving genetic modification according to article 11 of the Rules on safety management of experiments involving genetic modification.
- * When handling Level 3 microorganisms, a laboratory needs to have a designated area as a designated laboratory and each laboratory needs to have a person who is in charge of preventing hazards.

At Kyushu University, applications and notifications for research microorganisms are accepted through the electronic application system, so please complete the procedures through the system.

Major system which requires another application when using or storing microorganisms for experiments.

- 1. When possessing specific pathogens
 - When possessing specific pathogens defined in the “ Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (the Infectious Diseases Control Law) ” . permission by The Minister of Health, Labor and Welfare or notification to The Minister of Health, Labor and Welfare is required.
 - Class 1 pathogen ... it cannot be possessed in principle.
 - Class 2 pathogen ... permission by The Minister of Health, Labor and Welfare is required to possess it.
 - Class 3 pathogen ... notification to the Minister of Health, Labor and Welfare is required within 7 days of possession.
 - Class 4 pathogen ... permission or notification to the Minister of Health, Labor and Welfare is not required.
 - When handling or storing specific pathogens (class 2 to 4), the facility needs to be approved by the president.
- 2. When possessing pathogens of monitored infectious diseases
 - When possessing pathogens of monitored infectious diseases stipulated in the “ Act on Domestic Animal Infectious Diseases Control ” and the “ enforcement regulations of the Act on Domestic Animal Infectious Diseases Control ” . permission by The Minister of Agriculture, Forestry and Fisheries or notification to The Minister of Agriculture, Forestry and Fisheries is required.
 - Pathogens of monitored infectious diseases ... permission by the Minister of Agriculture, Forestry and Fisheries is required to possess.
 - Pathogens of notifiable infectious diseases ... notification to the Minister of Agriculture, Forestry and Fisheries is required within 7 days of possession.

Donation of microorganisms for research purposes

An application for a donation of microorganisms for research purposes (Form No.4) needs to be submitted to the president for approval.

Procedures for experiments involving genetic modification and approval for the relevant facilities

• Electronic application system for experiments involving genetic modification [University-exclusive]

<https://revisp.jimu.kyushu-u.ac.jp/>

Want to know more

• Experiments involving genetic modification at Kyushu University <https://airimaq.kyushu-u.ac.jp/dna/> • Public notification Type 2 of research and development (Reference material for the levels of microorganisms for research purposes) https://www.mext.go.jp/content/20250311-mxt_life-000035572_2.pdf • Control of specific pathogens in accordance with the Infectious Diseases Act, Ministry of Health, Labor and Welfare https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/kekkaku-kansenshou17/03.html • The Ministry of Agriculture, Forestry and Fisheries - possession of pathogens https://www.maff.go.jp/j/syouan/douei/eisei/e_koutei/kaisei_kadenhou/pathogen.html

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