

Kyushu University Detailed Regulations for Safety Management of Research Microorganisms

Kyushu University Detailed Regulation No. 11 of 2004

Established: April 1, 2004

Last amended: June 29, 2018

(Kyushu University Detailed Regulation No. 4 of 2018)

(Purpose)

Article 1 These Detailed Regulations shall provide for necessary matters relevant to procedures, etc. for applications related to the handling of research microorganisms pursuant to the provisions of Articles 21 of the Kyushu University Regulations for Safety Management of Research Microorganisms (Kyushu University Regulation No. 83 of 2004; hereinafter referred to as the "Regulations").

(Levels of Research Microorganisms)

Article 2 (1) The levels of research microorganisms provided in Article 5 of the Regulations shall be as set forth in Appended Table 2 of the Notification Prescribing Certified Host-Vector Systems, etc. pursuant to the provisions of the Ministerial Ordinance Providing Containment Measures to Be Taken in Type 2 Use of Living Modified Organisms for Research and Development” (Notification of the Ministry of Education, Culture, Sports, Science and Technology No.7 on January 29, 2004; hereinafter referred to as the “Appended Table 2 of the Notification”). In this case, the references in the Appended Table 2 of the Notification to “1. Microorganisms designated by the Minister of Education, Culture, Sports, Science and Technology as listed in Table 1 of Article 3 of the Ministerial Ordinance” shall be read as “Level 1”; “2. Microorganisms designated by the Minister of Education, Culture, Sports, Science and Technology as listed in Table 2 of Article 3 of the Ministerial Ordinance” shall be read as “Level 2”; “3. Microorganisms designated by the Minister of Education, Culture, Sports, Science and Technology as listed in Table 3 of Article 3 of the Ministerial Ordinance” shall be read as “Level 3”; and “4. Microorganisms designated by the Minister of Education, Culture, Sports, Science and Technology as listed in Table 4 of Article 3 of the Ministerial Ordinance” shall be read as “Level 4.”

(2) Notwithstanding the preceding paragraph, research microorganisms that are not listed under “2. Microorganisms designated by the Minister of Education, Culture, Sports, Science and Technology as listed in Table 2 of Article 3 of the Ministerial Ordinance” or “3. Microorganisms designated by the

Minister of Education, Culture, Sports, Science and Technology as listed in Table 3 of Article 3 of the Ministerial Ordinance” in the Appended Table 2 of the Notification shall, from the perspective of pathogenicity to humans, be classified into Levels 1 to 3 according to their risk, and confirmation shall be obtained from the Microorganism Research Safety Management Committee (hereinafter referred to as the “Safety Committee”) using the prescribed form.

(Procedures for Handling Research Microorganisms)

Article 3 (1) The notification prescribed in the main clause of Article 10, paragraph (1) of the Regulations shall be submitted using the prescribed form.

(2) Applications relating to use or storage and applications relating to provision as prescribed in Article 10, paragraph (2) of the Regulations shall be made using the prescribed form.

(3) The notifications and applications set forth in the preceding two paragraphs shall, with the consent of the director of the affiliated division, be submitted to the chief administrator.

(Safety Facilities and Operational Standards)

Article 4 (1) Laboratories for Level 1, Level 2, and Level 3 shall be P1, P2, and P3 laboratories, respectively, that have been approved pursuant to Article 11 of the Kyushu University Regulations for Safety Management of Experiments involving genetic modification (Kyushu University Regulations No. 82 of 2004).

(2) Notwithstanding the preceding paragraph, where the chief administrator intends to establish or modify a laboratory or other handling facility for specified pathogens, etc. as prescribed in Article 2, item (ii) of the Regulations (hereinafter referred to as “specified pathogens, etc.”), the chief administrator shall develop such facilities in accordance with the standards prescribed in the Enforcement Regulations of the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Ministry of Health and Welfare Ordinance No. 99 of 1998), and shall apply to the President for approval using the prescribed form.

(3) When an application under the preceding paragraph has been submitted, the President shall have the Safety Committee examine the laboratory or other handling facility pertaining to the application, and based on its advice, shall grant approval or reject the application.

(4) Where the chief administrator abolishes a laboratory or other handling facility for specified pathogens, etc. that has been approved pursuant to preceding paragraph, the chief administrator shall

notify the President thereof using the prescribed form.

(Signage for Designated Laboratories)

Article 5 The signage prescribed in Article 14, paragraph (2) of the Regulations shall be affixed using the prescribed form.

(Records of Experiments)

Article 6 The handling manager shall, with respect to experiments conducted using Level 3 research microorganisms, record the details of the experiments using the prescribed form and retain such records.

(Education and Training)

Article 7 Any person who intends to conduct experiments using research microorganisms shall complete, among the education and training provided to Genetic Modification Experiment staff, the course entitled “Fundamentals for Handling Pathogenic Microorganisms.”

(Health Examinations)

Article 8 The health examinations prescribed in Article 19 of the Regulations may be replaced by the general periodic health examination prescribed in Article 12, paragraph (1), item (ii) of the National University Corporation Kyushu University Rules for Safety and Health Management for Employees (Kyushu University Employment Regulations No. 23 of 2004) for employees, and by the periodic health examination for students. However, for persons who intend to conduct experiments using research microorganisms that fall under Category II Pathogens as prescribed in Article 6, paragraph (21) of the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Act No. 114 of 1998), or Category III Pathogens as prescribed in paragraph (22) of the same Article, and whom the Safety Committee deems necessary, a blood test shall be conducted and the blood shall be preserved; the period of preservation shall be two years from the time the person ceases to engage in such experiments.

Supplementary Provisions

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

Supplementary Provisions (Kyushu University Detailed Regulation No. 43 of 2004)

These Detailed Regulations come into effect as of April 1, 2005.

Supplementary Provisions (Kyushu University Detailed Regulation No. 18 of 2008)

These Detailed Regulations come into effect as of April 1, 2009.

Supplementary Provisions (Kyushu University Detailed Regulation No. 21 of 2014)

These Detailed Regulations come into effect as of April 1, 2015.

Supplementary Provisions (Kyushu University Detailed Regulation No. 4 of 2018)

These Detailed Regulations come into effect as of July 1, 2018.