

TENTATIVE TRANSLATION

Kyoto University Regulations Regarding the Control of Pathogens, etc.

February 4, 2008

Established based on Notification No. 78

(Objective)

Article 1 These Regulations shall prescribe matters regarding the possession, use, and storage of pathogens, etc. in the possession of Kyoto University (hereinafter referred to as the “University”).

(Definitions of Terms)

Article 2 As used in these Regulations, each of the following terms shall be defined as set forth hereinbelow in addition to the definitions provided in Act on the Prevention of Infectious Diseases and Medical Care for Patients of Infectious Diseases (Act No. 114 of 1998; hereinafter referred to as the “Act”), the Ordinance for Enforcement of Act on the Prevention of Infectious Diseases and Medical Care for Patients of Infectious Diseases (Cabinet Order No. 420 of 1998), and the Enforcement Regulations of Act on the Prevention of Infectious Diseases and Medical Care for Patients of Infectious Diseases (Ordinance of the Ministry of Health and Welfare No. 99 of 1998; hereinafter referred to as the “Ministerial Ordinance”).

(1) “Pathogens, etc.” shall mean the pathogens and toxins of infectious diseases and shall include Class 1 pathogens, etc., Class 2 pathogens, etc., Class 3 pathogens, etc., and Class 4 pathogens, etc. as prescribed in Article 6, items (20) to (23) of the Act.

(2) “Toxin” shall mean a substance that is produced by the pathogen of an infectious disease and will cause a person to become sick or die if it enters his/her body (including artificially synthesized substances whose structural formula is the same as that of any toxin).

(3) “Sterilization, etc.” shall mean sterilizing or detoxifying pathogens, etc.

(4) “Facility handling pathogens, etc.” shall mean a facility that stores, uses, or otherwise sterilizes pathogens, etc.

(General Manager)

Article 3 The Executive Vice-President for Research Standards (hereinafter referred to as the “Executive Vice-President”) shall supervise the possession, handling, and control of pathogens, etc. in the University.

(Limitation on Possession of Class 1 Pathogens, etc.)

Article 4 Class 1 pathogens, etc. must not be possessed (including possession by import or transfer) or transferred to other parties, except when the provision of the proviso of Article 56-3, paragraph

(1), of the proviso of Article 56-4, or of the proviso of Article 56-5 of the Act applies.

(Permission for Possession of Class 2 Pathogens, etc.)

Article 5 In the event that a department intends to possess Class 2 pathogens, etc., the department must report it to the Executive Vice-President in advance and obtain the permission of the Minister of Health, Labour and Welfare as prescribed in the main clause of Article 56-6, paragraph (1) of the Act, except when the provision of the proviso of the same paragraph applies.

2 In the event that a party possessing Class 2 pathogens, etc. with the permission of the Minister of Health, Labour and Welfare as prescribed in the preceding paragraph intends to change the type of any of the permitted Class 2 pathogens, etc. (or the type and quantity of any toxin), the purpose and means of possession, or the location, structure, and equipment of a facility that stores, uses, and otherwise sterilizes Class 2 pathogens, etc. (hereinafter referred to as a “facility handling Class 2 pathogens, etc.”), the party must report it to the Executive Vice-President in advance and obtain the permission of the Minister of Health, Labour and Welfare as prescribed in the main clause of Article 56-11, paragraph (1) of the Act. However, in the event that the change concerned falls under a minor change as prescribed in the proviso of Article 56-11, paragraph (1) of the Act, the party must report it to the Executive Vice-President in advance and make a notification to the Minister of Health, Labour and Welfare as prescribed in paragraph (2) of the same article.

3 In the event that a party possessing pathogens, etc. with the permission of the Minister of Health, Labour and Welfare as prescribed in Paragraph 1 changed the personal name or entity name and address, the party must promptly report it to the Executive Vice-President and make a notification to the Minister of Health, Labour and Welfare as prescribed in Article 56-11, paragraph (3) of the Act.

4 The Executive Vice-President shall undertake the procedures for obtaining the permission of and making notifications to the Minister of Health, Labour and Welfare mentioned in the preceding three paragraphs of this Article.

5 The Executive Vice-President shall determine any and all matters regarding reporting mentioned in Paragraphs 1 to 3 of this Article.

(Permission for Import of Class 2 Pathogens, etc.)

Article 6 The provisions of the preceding article (excluding the proviso of Paragraph 1) shall apply mutatis mutandis when importing Class 2 pathogens, etc. In this case, the term “possess” in Paragraph 1 shall be deemed to be replaced with “import,” the phrase “the main clause of Article 56-6, paragraph (1) of the Act” shall be deemed to be replaced with “Article 56-12, paragraph (1) of the Act,” the phrase “a party possessing” in Paragraph 2 shall be deemed to be replaced with “a party intending to import,” the phrase “the purpose and means of possession” shall be deemed to be

replaced with “the purpose of import,” the phrase “or the location, structure, and equipment of a facility that stores, uses, and otherwise sterilizes Class 2 pathogens, etc. (hereinafter referred to as a “facility handling Class 2 pathogens, etc.”)” shall be deemed to be replaced with “the personal name or entity name and address of the importer, the term of import, the means of transportation, or the name of the port of import,” the phrase “the main clause of Article 56-11, paragraph (1) of the Act” shall be deemed to be replaced with “the main clause of Article 56-11, paragraph (1) of the Act that applies mutatis mutandis according to the provision of Article 56-14 of the Act,” the phrase “the proviso of Article 56-11, paragraph (1) of the Act” shall be deemed to be replaced with “the proviso of Article 56-11, paragraph (1) of the Act that applies mutatis mutandis according to the provision of Article 56-14 of the Act,” the phrase “paragraph (2) of the same article” shall be deemed to be replaced with “Article 56-11, paragraph (2) of the Act that applies mutatis mutandis according to the provision of Article 56-14 of the Act,” the phrase “a party possessing” in Paragraph 3 shall be deemed to be replaced with “a party intending to import,” and the phrase “Article 56-11, paragraph (3) of the Act” shall be deemed to be replaced with “Article 56-11, paragraph (3) that applies mutatis mutandis according to the provision of Article 56-14 of the Act.”

(Restriction on Transfer and Takeover of Class 2 Pathogens, etc.)

Article 7 Class 2 pathogens, etc. must not be transferred or taken over, except in cases falling under any of the items of Article 56-15 of the Act.

(Notification of Possession of Class 3 Pathogens, etc.)

Article 8 In the event that a party intends to possess Class 3 pathogens, etc., the party must report it to the Executive Vice-President before the date of the start of possession of the Class 3 pathogens, etc. concerned and make a notification to the Minister of Health, Labour and Welfare according to the provision of the main clause of Article 56-16, paragraph (1) of the Act, except when the provision of the proviso of the same paragraph applies.

- 2 In the event that a party who made a notification to the Minister of Health, Labour and Welfare as prescribed in the preceding Paragraph and possesses Class 3 pathogens, etc. changes any of the matters of the notification and determines to discontinue the possession of the Class 3 pathogens, etc. concerned, the party must report it to the Executive Vice-President in advance and make a notification to the Minister of Health, Labour and Welfare according to the provision of Article 56-16, paragraph (2) of the Act.
- 3 The Executive Vice-President shall undertake the procedure for making notifications to the Minister of Health, Labour and Welfare mentioned in the preceding two paragraphs of this Article.
- 4 The Executive Vice-President shall determine any and all matters regarding reporting mentioned in Paragraphs 1 and 2 of this Article.

(Notification of Import of Class 3 Pathogens, etc.)

Article 9 The provisions of Article 8 (excluding the proviso of Paragraph 1 and Paragraph 2) shall apply mutatis mutandis when importing Class 3 pathogens, etc. In this case, the term “possess” in Paragraph 1 shall be deemed to be replaced with “import,” the phrase “the date of the start of possession” shall be deemed to be replaced with “the date of the start of transportation,” the phrase “the main clause of Article 56-16, paragraph (1) of the Act” shall be deemed to be replaced with “Article 56-17 of the Act,” the phrase “the preceding two paragraphs of this Article” in Paragraph 3 shall be deemed to be replaced with “Paragraph 1,” and the phrase “Paragraphs 1 and 2” in Paragraph 4 shall be deemed to be replaced with “Paragraph 1.”

(Notification of Possession of Class 4 Pathogens, etc.)

Article 10 A party possessing Class 4 pathogens, etc. must report the possession of the Class 4 pathogens, etc. concerned to the Executive Vice-President within seven days from the date of possession. This provision shall also apply when the party changes any of the matters of the notification and discontinues the possession of the Class 4 pathogens, etc. covered by the notification.

- 2 The provision of the preceding paragraph shall not apply during the period from the possession of Class 4 pathogens, etc. by Kyoto University Hospital or a department that performs inspections of pathogens, etc. in connection with its operations until the sterilization or transfer (which means sterilizing or handing over pathogens, etc.; the same applies hereinafter) of Class 4 pathogens, etc. according to the Ministerial Ordinance.
- 3 The Executive Vice-President shall determine the form of the notification prescribed in Paragraph 1 of this Article and the matters that must be entered on the form.

(Establishment of Regulations for Prevention of Outbreaks of Infectious Diseases)

Article 11 The head of a department possessing Class 1 pathogens, etc. or Class 2 pathogens, etc. must establish Regulations for Prevention of Outbreaks of Infectious Diseases before the start of possession of the pathogens, etc. concerned in order to prevent the outbreak and spread of infectious diseases resulting from the pathogens, etc. concerned, and must make a notification of the Regulations to the Executive Vice-President.

- 2 The Executive Vice-President shall determine any and all matters to be included in the Regulations for Prevention of Outbreaks of Infectious Diseases mentioned in the preceding paragraph.
- 3 Whenever the Executive Vice-President receives a notification mentioned in Paragraph 1 of this Article, the Executive Vice-President shall undertake the procedure for making notifications to the Minister of Health, Labour and Welfare as prescribed in Article 56-18, paragraph (1) of the Act.

(Appointment of Chief Supervisor for Handling Pathogens, etc.)

Article 12 A chief supervisor for handling pathogens, etc. shall be appointed and stationed in each department possessing Class 1 pathogens, etc. (possessing Class 1 pathogens, etc. based on the provision of Article 56-3, paragraph (1), item (1) of the Act, of the proviso of Article 56-4 of the Act, or of Article 56-5, item (1) of the Act; the same applies hereinafter) and in each department possessing Class 2 pathogens, etc.

- 2 The head of the department concerned shall appoint a chief supervisor for handling pathogens, etc. from among those who have sufficient knowledge and experience in the handling of pathogens, etc. and who fulfill any of the requirements of the items of Article 31-22 of the Ministerial Ordinance.
- 3 Whenever the head of the department appoints a chief supervisor for handling pathogens, etc. according to the provision of the preceding paragraph or dismisses the chief supervisor, the head of the department concerned must make a notification of appointment or dismissal to the Executive Vice-President as prescribed by the Executive Vice-President.
- 4 Whenever the Executive Vice-President receives a notification mentioned in the preceding paragraph, the Executive Vice-President shall undertake the procedure for making notifications to the Minister of Health, Labour and Welfare as prescribed in Article 56-19, paragraph (2) of the Act.

(Responsibilities of Chief Supervisors for Handling Pathogens, etc.)

Article 13 Each chief supervisor for handling pathogens, etc. shall supervise the prevention of the outbreak and spread of infectious diseases resulting from pathogens, etc. within his/her department.

- 2 The head of a department possessing Class 1 pathogens, etc. or Class 2 pathogens, etc. must respect the views of the department's chief supervisor for handling pathogens, etc. regarding the prevention of the outbreak and spread of infectious diseases resulting from the pathogens, etc. concerned.
- 3 All personnel who enter a facility storing, using, and otherwise sterilizing Class 1 pathogens, etc. (hereinafter referred to as a "facility handling Class 1 pathogens, etc.") or a facility handling Class 2 pathogens, etc. must observe the instructions of the chief supervisor for handling pathogens, etc. regarding the prevention of the outbreak and spread of infectious diseases resulting from the pathogens, etc. concerned.

(Education and Training)

Article 14 A department possessing Class 1 pathogens, etc. or Class 2 pathogens, etc. must instill, as prescribed in Article 31-24, paragraph (1) of the Ministerial Ordinance, the Regulations for Prevention of Outbreaks of Infectious Diseases in all personnel who enter a facility handling Class 1 pathogens, etc. or a facility handling Class 2 pathogens, etc., and also provide these personnel with education and training necessary for the prevention of the outbreak and spread of infectious

diseases resulting from the pathogens, etc. concerned.

(Sterilization, etc.)

Article 15 In the event that a department possessing Class 1 pathogens, etc. or Class 2 pathogens, etc. no longer needs to possess the pathogens, etc. concerned or falls under any of the items of Article 56-22, paragraph (1) of the Act, the department must sterilize and transfer the Class 1 pathogens, etc. or Class 2 pathogens, etc. in its possession.

2 When the department sterilizes and transfers the pathogens, etc. in its possession, the department must promptly report it to the Executive Vice-President as prescribed by the Executive Vice-President.

3 Whenever the Executive Vice-President receives a report as mentioned in the preceding paragraph, the Executive Vice-President shall undertake the procedure for making notifications to the Minister of Health, Labour and Welfare as prescribed in Article 56-22, paragraph (2) of the Act.

(Duty of Keeping Records)

Article 16 A department possessing Class 1 pathogens, etc., Class 2 pathogens, etc., or Class 3 pathogens, etc. must keep the books prescribed in Article 56-23 of the Act and record matters regarding the storage, use, sterilization, etc. of the pathogens, etc. concerned and other necessary matters regarding the prevention of the outbreak and spread of infectious diseases resulting from the pathogens, etc. concerned.

2 The Executive Vice-President shall determine the forms of the books mentioned in the preceding paragraph and the matters that must be entered in these books.

(Standards for Facilities)

Article 17 A department possessing pathogens, etc. must maintain its facility handling pathogens, etc. based on the provision of Article 56-24 of the Act in such a way that the location, structure, and equipment of the facility concerned comply with the technical standards specified by the Ministerial Ordinance.

2 The Executive Vice-President shall determine the necessary matters regarding compliance with the technical standards and maintenance mentioned in the preceding paragraph.

(Standards for Storage, etc.)

Article 18 When a department possessing pathogens, etc. stores, uses, transports (excluding transportation by vessels or aircraft; the same applies hereinafter except for Paragraph 5 of Article 19 below), or otherwise sterilizes the pathogens, etc., the department must take necessary measures based on the provision of Article 56-25 of the Act to prevent the outbreak and spread of infectious

diseases resulting from the pathogens, etc. concerned according to the technical standards specified by the Ministerial Ordinance.

- 2 The Executive Vice-President shall determine the necessary matters regarding measures to be taken to prevent the outbreak of infectious diseases, etc. mentioned in the preceding paragraph.

(Exclusion from Application)

Article 19 The provisions of Articles 11 to 14 of these Regulations shall not apply when Class 1 pathogens, etc. are possessed according to the provisions of Article 56-3, paragraph (1), items (2) to (4) of the Act and when Class 2 pathogens, etc. are possessed according to the provision of the proviso of Article 56-6, paragraph (1) of the Act.

- 2 The provisions of the said four articles shall not apply when pathogens, etc. are possessed according to Article 56-3, paragraph (1), items (2) and (4) of the Act, Article 56-6, paragraph (1), items (1) and (3) of the Act, or Article 56-16, paragraph (1), items (1) and (3) of the Act.
- 3 The provisions of Articles 16 and 17 of these Regulations shall not apply when pathogens, etc. are possessed according to the provision of Article 56-3, paragraph (1), item (3) of the Act, of Article 56-6, paragraph (1), item (2) of the Act, or of Article 56-16, paragraph (1), item (2) of the Act.
- 4 The provisions of the said two articles shall not apply when Kyoto University Hospital or a department that performs inspections of pathogens, etc. comes to possess Class 4 pathogens, etc. in connection with its operation during the period until the sterilization and transfer of the Class 4 pathogens, etc. concerned as prescribed in Article 56-26, paragraph (3) of the Act or when a party other than parties possessing Class 4 pathogens, etc. possesses the Class 4 pathogens, etc. for the purpose of its operations.
- 5 The provisions of Article 17 shall not apply when a party undertaking transportation entrusted by a party possessing Class 4 pathogens, etc. possesses the entrusted Class 4 pathogens for the purpose of transportation thereof.

(Notification of Transportation)

Article 20 When a party possessing Class 1 pathogens, etc., Class 2 pathogens, etc., and Class 3 pathogens, etc. intends to transport the pathogens, etc. concerned outside its place of business (excluding transportation by vessels or aircraft), the party must make a notification to the Prefectural Public Safety Commission as prescribed in Article 56-27, paragraph (1) of the Act and have a document certifying notification (hereinafter referred to as a "Transportation Certificate") issued by the Prefectural Public Safety Commission.

- 2 When the party undertaking transportation has a Transportation Certificate issued as prescribed in the preceding paragraph, the party must carry the Transportation Certificate concerned with it and transport the pathogens, etc. according to the instructions of the Transportation Certificate

concerned.

(Notification of Accidents, etc.)

Article 21 In the event that any of the pathogens, etc. in the possession of a department is stolen, goes missing, or another accident occurs to it, the department must report the accident to the Executive Vice-President without delay.

2 Whenever the Executive Vice-President receives a report as mentioned in the preceding paragraph, the Executive Vice-President shall undertake the procedure for making notifications to competent organizations as prescribed in Article 56-28 of the Act.

(Emergency Measures, etc. in Case of Disaster)

Article 22 In the event that the pathogens, etc. in the possession of a department are damaged by an earthquake, fire, or other disaster and an infectious disaster breaks out or spreads or may break out or spread due to the damaged pathogens, etc. concerned, the department must promptly take the emergency measures of the following items based on the provision of Article 56-29 of the Act and the Ministerial Ordinance.

(1) In the event that a fire may occur to or spread to a facility handling pathogens, etc. or pathogens, etc. stored in containers (hereinafter referred to as “pathogenic packages”), the facility shall make efforts to put out the fire or prevent its spread and, at the same time, promptly report it to the nearest fire station.

(2) A warning shall be given to the personnel inside a facility handling pathogens, etc., the personnel involved in the transportation of pathogenic packages, or the personnel close to these pathogenic packages if it is necessary to prevent the outbreak or spread of infectious diseases resulting from the pathogens, etc.

(3) Pathogens, etc. shall be relocated to a safe place as needed, and access by personnel, except for personnel involved, to the place where the pathogens, etc. are stored shall be prevented by placing ropes around the place or displaying signs, etc. and posting a guard there.

(4) Other necessary measures shall be taken to prevent the outbreak or spread of infectious diseases resulting from pathogens, etc.

2 Personnel who perform the emergency measures of the items prescribed in the preceding paragraph shall wear protective equipment, reduce the time of exposure to pathogens, etc., or take other measures to minimize exposure to the pathogens, etc.

3 In case of a situation as mentioned in Paragraph 1, the head of the department concerned or the person who found the situation must report the situation to the Executive Vice-President as prescribed by the Executive Vice-President.

4 Whenever the Executive Vice-President receives a report as mentioned in the preceding paragraph,

the Executive Vice-President shall undertake the procedure for making notifications, etc. to the competent organizations according to the provision of Article 56-29, paragraph (2) or (3) of the Act.

(Administrative Affairs)

Article 23 Administrative affairs regarding the control of pathogens, etc. shall be conducted by the Research Promotion Department.

(Others)

Article 24 In addition to the provisions of these Regulations, the Executive Vice-President shall determine any and all necessary matters regarding the control of pathogens, etc.

Supplementary Provisions

- 1 These Regulations shall come into effect on February 4, 2008.
- 2 Personnel who have already notified the Minister of Health, Labour and Welfare in connection with the possession of Class 3 pathogens, etc. as prescribed in Article 56-16, paragraph (1) of the Act at the time of enforcement of these Regulations shall be deemed to have given notification as prescribed in the main clause of Paragraph 1 of Article 8 of these Regulations.
- 3 Personnel who already possess Class 4 pathogens, etc. at the time of enforcement of these Regulations shall be deemed to have given notification as prescribed in the first sentence of Paragraph 1 of Article 10 of these Regulations.

Supplementary Provision

These Regulations shall come into effect on October 1, 2020.