

## Regulations on Animal Experimentation at Kyoto University

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### Article 1 (Purpose)

These regulations shall provide for necessary matters regarding the implementation of animal experiments and the breeding and housing of experimental animals, the purpose of which is to ensure that animal experiments at Kyoto University (hereinafter referred to as the "University") are conducted properly.

### Article 2 (Definitions)

In these regulations, the meanings of the terms listed in the following items shall be as prescribed respectively in those items.

- (i) The term "Animal Experiment" as used in these regulations shall mean the scientific use of animals for education, research, testing, the production of biological preparations and so on.
- (ii) The term "Experimental Animal" as used in these regulations shall mean an animal belonging to Mammalia, Aves or Reptilia that is bred or housed in a Facility, etc. as prescribed in item (v) for use in an Animal Experiment.
- (iii) The term "Breeding and Housing Facility" as used in these regulations shall mean a facility where Experimental Animals are continuously bred and housed or where Animal Experiments are conducted.
- (iv) The term "Laboratory" as used in these regulations shall mean an animal laboratory where experimental operations are carried out on Experimental Animals (including cases where Experimental Animals are temporarily kept for experimental activities for no longer than 48 hours).
- (v) The term "Facility, etc." as used in these regulations shall mean a Breeding and Housing Facility and a Laboratory.
- (vi) The term "Animal Experimenter" as used in these regulations shall mean a person who

conducts an Animal Experiment.

(vii) The term "Person in Charge of an Animal Experiment" as used in these regulations shall mean one of the Animal Experimenters who controls activities concerning the conduct of the Animal Experiment.

(viii) The term "Manager of a Facility, etc." as used in these regulations shall mean a person who is responsible for the management of a Facility, etc. of the Department, under the Head of the Department, and who manages Experimental Animals in a Breeding and Housing Facility.

(ix) The term "Manager of Experimental Animals" as used in these regulations shall mean a person appointed to each Breeding and Housing Facility who has knowledge and experience regarding Experimental Animals, assists the Manager of a Facility, etc., and is in charge of managing Experimental Animals.

(x) The term "Caretaker" as used in these regulations shall mean a person who breeds and houses Experimental Animals under the Manager of Experimental Animals or Animal Experimenters.

(xi) The term "Animal Experimenter, etc." as used in these regulations shall mean the Animal Experimenter, the Manager of a Facility, etc., the Manager of Experimental Animals and the Caretaker.

(xii) The term "Law" as used in these regulations shall mean the Act on Welfare and Management of Animals (Act No. 105 of 1973).

(xiii) The term "Guidelines, etc." as used in these regulations shall mean the Fundamental Guidelines for Proper Conduct of Animal Experiment and Related Activities in Academic Research Institutions (Ministry of Education, Culture, Sports, Science and Technology, Notice No. 71 of 2006), the Standards relating to the Care and Keeping and Reducing Pain of Laboratory Animals (Ministry of the Environment, Notice No. 88 of 2006), the Guidelines on the Method of Animal Disposal (Prime Minister's Office, Notice No. 40 of 1995) and the Guidelines for Proper Conduct of Animal Experiments (Science Council of Japan dated June 1, 2006).

(xiv) The term "Department" as used in these regulations shall mean a graduate school, an institute, Kyoto University Hospital or a center (facilities, etc. as prescribed in Section 7,8,10 and 11 of Chapter 3 of the Regulations on the Organization of National University Corporation Kyoto University (Notice No. 1 of 2004)).

#### Article 3 (Responsibility of the President, etc.)

(1) The President, as a person with ultimate responsibility, shall manage overall of proper implementation of Animal Experiments and breeding and housing of Experimental Animals at the University.

(2) The President shall be responsible for approval of the Animal Experiment protocol, grasp of the status and results of implementation and improvement measures based on the results,

maintenance of Breeding and Housing Facilities, approval of Breeding and Housing Facilities and Laboratories, safety management regarding Animal Experiments, education and training, self-inspection and assessment, assessment and verification by external experts (hereinafter referred to as the "Assessment and Verification by a Third Party"), information disclosure and other measures necessary for proper implementation of Animal Experiments.

(3) The President shall organize the Animal Experimentation Committee (hereinafter referred to as the "Committee") at the University as prescribed in Article 5, as an organization that provides reports and advice in order to fulfill the responsibilities prescribed in the preceding paragraph.

(4) The Executive Vice-President for Research Regulations (hereinafter referred to as the "Executive Vice-President") shall assist the President in the duties prescribed in paragraph (1).

#### Article 4 (Responsibility of the Head of a Department)

The Head of a Department shall be responsible for the management of Experimental Animals and Facilities, etc. of the Department, and shall supervise the proper conduct of Animal Experiments in the Department.

#### Article 5 (Animal Experimentation Committee)

(1) The Committee shall deliberate the matters listed in the following items.

Matters regarding the appropriateness of an experimental protocol approved by the Department and the appropriateness of the status of implementation and results of the Animal Experiments.

- (i) Matters regarding the appropriateness of a Facility, etc. approved by the Department and the appropriateness of the breeding and housing conditions of Experimental Animals.
- (ii) Matters regarding education and training concerning the conduct of Animal Experiments.
- (iii) Matters regarding self-inspection and assessment concerning the conduct of Animal Experiments, the Assessment and Verification by a Third Party and information disclosure.
- (iv) Other matters necessary for the proper conduct of Animal Experiments.

(2) In addition to the matters prescribed in the preceding paragraph, the Committee may give necessary guidance or advice to a Departmental Committee as prescribed in Article 9.

(3) The Committee shall report the result of deliberation to the Executive Vice-President. In this case, the Committee may, when it finds any improper conduct concerning an experimental protocol, etc., offer opinions on necessary measures such as the suspension of an experiment.

#### Article 6

(1) The Committee shall consist of the committee members listed in the following items.

- (i) One professor or associate professor from each Department that conducts an Animal Experiment.
  - (ii) A few professors or associate professors from Departments other than the Department prescribed in the preceding item.
  - (iii) Some other persons if deemed necessary by the President.
- (2) The committee members are appointed by the President.
- (3) The term of office of the committee members shall be two years; provided, however, that the term of office of the committee members appointed to fill a vacancy shall be the remaining term of office of the predecessor. The committee members may be reappointed.
- (4) The Committee prescribed in paragraph (1) shall include at least one member who has excellent judgement regarding Animal Experiments, at least one member who has excellent judgement regarding Experimental Animals and at least one member who has other academic knowledges.

#### Article 7

- (1) The Committee shall have a Chairperson and a Vice-Chairperson.
- (2) The Chairperson shall be selected by the Committee from among its members, and the Vice-Chairperson shall be appointed by the Chairperson from among the committee members.
- (3) The Chairperson shall call meetings of the Committee and preside over these meetings.
- (4) The Vice-Chairperson shall assist the Chairperson and act for the Chairperson in absence or incapacity.

#### Article 7-2

The affairs of the Committee shall be handled by the Office of Research Acceleration.

#### Article 8

In addition to the matters prescribed in the preceding four Articles, the Committee shall provide for necessary matters regarding the operation of the Committee.

#### Article 9 (Departmental Committee of Animal Experimentation)

- (1) The Departmental Committee of Animal Experimentation (hereinafter referred to as the "Departmental Committee") shall be organized at the Department conducting Animal Experiments, in order to examine whether the conduct of the Animal Experiments and the establishment or change of a Facility, etc. (hereinafter referred to as the "Establishment, etc.") at the Department should be approved.
- (2) Necessary matters regarding the organization and operation of the Departmental Committee shall be provided for by the Department.
- (3) Notwithstanding the provision prescribed in paragraph (1), Departments may, when they

find it necessary, jointly organize a Departmental Committee. In this case, the term "the Department" in the preceding paragraph shall be deemed to be replaced with "the agreement between the Departments."

#### Article 10 (Approval, etc. of an Animal Experiment)

(1) The Person in Charge of an Animal Experiment shall, at the time of conducting an Animal Experiment, prepare an Animal Experiment protocol in the prescribed form taking the matters listed in the following items into account and obtain approval from the Head of a Department. The same shall apply to a case where the approved protocol is to be changed.

##### (i) The use of an alternative method

At the time of conducting an Animal Experiment, due consideration shall be given to making appropriate use of Experimental Animals by such ways as using alternative methods that can be substituted for methods involving the use of Experimental Animals wherever possible while still allowing the scientific purpose of the research to be achieved.

##### (ii) The selection of Experimental Animals

At the time of conducting an Animal Experiment, due consideration shall be given to making appropriate use of Experimental Animals by such ways as reducing as far as possible the number of Experimental Animals used for research purposes while still allowing the scientific purpose of the research to be achieved, taking the matters listed below into account.

(a) The selection of a species of Experimental Animals suited to the aim of the Animal Experiments

(b) The number of Experimental Animals that ensures the precision and reproducibility of the results of Animal Experiments

(c) The genetic and microbiological quality and the breeding conditions of Experimental Animals

##### (iii) The alleviation of pain

At the time of conducting an Animal Experiment, a method that causes as little pain as possible to Experimental Animals shall be adopted to the extent necessary for scientific purposes.

(2) The Head of a Department shall, where an application for approval prescribed in the preceding paragraph has been filed, decide to approve or reject it after the deliberation of the Departmental Committee and shall notify the Person in Charge of an Animal Experiment.

(3) The Person in Charge of an Animal Experiment may not conduct the Animal Experiment until the Animal Experiment protocol is approved by the Head of the Department.

(4) The Head of a Department shall report the approved experiment protocols to the Executive Vice-President.

(5) The Executive Vice-President may, where an opinion has been offered by the Committee as prescribed in paragraph (3) of Article 5, order the Head of the Department to suspend the experiment or to take any other measures.

(6) The Person in Charge of an Animal Experiment shall, where the Animal Experiment is entrusted to an organization outside the University, confirm that the Animal Experiment will be properly conducted at the organization based on the Guidelines, etc.

#### Article 11 (Implementation of an Animal Experiment)

The Person in Charge of an Animal Experiment shall, at the time of conducting an Animal Experiment, observe the Law, the Guidelines, etc. and take into consideration the matters stated in an Animal Experiment protocol and in particular the matters listed in the following items.

(i) Animal Experiments shall be conducted in a Facility, etc. that has been approved pursuant to the provision of paragraph (2) of Article 13.

(ii) Experiments involving physically or chemically hazardous materials, narcotics, psychotropics, pathogens, radioactive isotopes, radiation, or genetically modified organisms, etc. shall be governed by relevant laws and regulations and relevant regulations, etc. of the University.

(iii) The major, highly invasive operation on a living animal shall be performed under supervision of a person of experience, etc.

(iv) When conducting Animal Experiments with a high degree of suffering (lethal toxicity tests, infection experiments, radiation irradiation experiments, etc.), a humane endpoint (timing to terminate the experiment to relieve Experimental Animals from severe suffering) shall be considered and the Animal Experiments shall be terminated.

(v) When destroying animals, euthanasia shall be carried out using an internationally accepted and appropriate method.

#### Article 12 (Post-experimental Report)

The Person in Charge of an Animal Experiment shall, after conducting the Animal Experiments, report the number of used Experimental Animals, any changes to the protocol and other details to the Executive Vice-President via the Head of the Department using the prescribed form.

#### Article 13 (Approval of a Facility, etc.)

(1) The Manager of a Facility, etc. shall, where a Facility, etc. are to be established, submit an application in the prescribed form to the Head of a Department and obtain the approval.

(2) The Head of a Department shall, when the application prescribed in the preceding paragraph has been submitted, decide to approve or reject it after the deliberation of the Departmental Committee and shall notify the Manager of a Facility, etc.

(3) The Manager of a Facility, etc. may not give permission to breed and house Experimental Animals and to conduct Animal Experiments at the Facility, etc. until the establishment of the Facility, etc. is approved by the Head of the Department.

(4) The Head of a Department shall report the outline, etc. of the approved Facility, etc. to the Executive Vice-President.

Article 14 (Requirements of a Facility, etc.)

(1) The requirements regarding the Establishment, etc. of a Breeding and Housing Facility shall be as prescribed respectively in the following items:

(i) That it has a Manager of Experimental Animals.

(ii) That it has equipment that can maintain appropriate temperature, humidity, ventilation and lighting.

(iii) That it has breeding equipment suitable for the species, physiology, ecology, habits, etc. of Experimental Animals and the number of Experimental Animals to be bred or housed, etc.

(iv) That its floors and inner walls, etc. are easy to clean or sterilize, etc. and it has sanitary equipment for the washing and sterilizing of apparatus.

(v) That it has a design and sufficient strength to prevent Experimental Animals from escaping.

(vi) That measures are taken to prevent negative impacts on the surrounding environment due to odor, noise and waste, etc.

(2) The requirements regarding the Establishment, etc. of a Laboratory shall be as prescribed respectively in the following items:

(i) That it has a design that facilitates the cleaning or sterilizing of places polluted by feces, urine, and blood, etc.

(ii) That it has a design and sufficient strength to prevent Experimental Animals from escaping, and it maintains an indoor environment where Experimental Animals, should they escape, are easy to capture.

(iii) That measures are taken to prevent negative impacts on the surrounding environment due to odor, noise and waste, etc.

Article 15 (Maintenance and Management of a Facility, etc.)

(1) The Manager of a Facility, etc. shall endeavor to maintain and improve the approved Facility, etc.

(2) The Manager of Experimental Animals shall ensure an environment for breeding and housing of Experimental Animals by taking into consideration the species, physiology, ecology, habits, etc. and properly manage Experimental Animals.

Article 16 (Abolition of a Facility, etc.)

(1) The Manager of a Facility, etc. shall, when the Facility, etc. is abolished, submit a notification of abolition in the prescribed form to the Head of the Department.

(2) When receiving the notification of abolition mentioned in the preceding paragraph, the

Head of the Department shall approve the abolition after investigation of the Facility, etc. by the Departmental Committee and report to the Executive Vice-President.

(3) The Manager of a Facility, etc. shall, where the Breeding and Housing Facility is abolished, endeavor to transfer Experimental Animals that have been bred and housed to another Breeding and Housing Facility, cooperating with the Person in Charge of the Animal Experiment as the need arises.

#### Article 17 (Breeding and Housing of Experimental Animals)

(1) Necessary matters regarding the breeding and housing of Experimental Animals, such as their introduction, microbial monitoring, and other health care matters, etc., shall be determined and made well known to Animal Experimenters by the Head of a Department.

(2) The Animal Experimenter, etc. shall comply with basic principles of animal welfare, such as the "Five Freedoms" (freedom from hunger and thirst, freedom from physical discomfort and pain, freedom from injury and disease, freedom from fear and mental suffering, and freedom to express normal behavior), when breeding and housing of Experimental Animals.

(3) The Animal Experimenter, etc. shall house Experimental Animals in consideration of combinations when breeding and housing different species or multiple Experimental Animals in the same Facility.

(4) The Animal Experimenter, etc. shall feed and water the Experimental Animals appropriately according to the species, physiology, ecology, habits, etc.

(5) The Manager of Experimental Animals shall ensure that the number and condition of Experimental Animals being bred or housed are confirmed through daily management, maintenance and inspection of the Breeding and Housing Facility, as well as periodic patrols.

#### Article 17-2 (Introduction of Experimental Animals)

(1) The Head of a Department shall introduce Experimental Animals from an institute which properly manages them in accordance with relevant laws and regulations.

(2) When introducing Experimental Animals, the Manager of Experimental Animals shall properly conduct quarantine, isolation, etc.

(3) The Manager of Experimental Animals shall take the necessary measures to ensure that Experimental Animals can acclimate and adapt to the new breeding environment.

#### Article 18 (Health and Safety Maintenance of Experimental Animals)

The Animal Experimenter, etc. shall observe matters determined by the Head of a Department pursuant to Article 17 and endeavor to maintain the health and safety of Experimental Animals.



#### Article 19 (Preservation and Report of Records)

- (1) The Person Responsible for an Animal Experiment shall organize and retain records on suppliers, breeding histories and medical histories, etc. of Experimental Animals.
- (2) Every fiscal year, the Head of a Department shall report, in the prescribed form, the species and the number, etc., of Experimental Animals that are bred and housed to the Executive Vice-President.

#### Article 20 (Transfer)

The Person in Charge of an Animal Experiment shall, when Experimental Animals are transferred, provide the recipient with necessary information.

#### Article 20-2 (Transport)

The Person Responsible for an Animal Experiment, when Experimental Animals are transported, shall take the necessary measures to maintain the health and safety of the Experimental Animals, and to prevent the occurrence of harm to humans.

#### Article 21 (Risk Prevention)

- (1) The Head of a Department shall determine in advance the capture method, etc. of escaped Experimental Animals.
- (2) The Head of a Department shall, where Experimental Animals that are potentially harmful to humans have escaped from a Facility, etc., promptly notify related organizations.
- (3) The Head of a Department shall take necessary measures in advance to prevent infectious diseases derived from Experimental Animals, bites by and allergies from Experimental Animals, etc., and to deal with such infectious diseases, etc. when they occur.
- (4) The Head of a Department shall, where poisonous Experimental Animals are bred and housed, determine in advance necessary matters to prevent the occurrence of harm to humans.
- (5) The Animal Experimenter, etc. shall endeavor to provide each other with the information to prevent the occurrence of harm due to Experimental Animals.
- (6) The Head of a Department shall take necessary measures in advance to prevent anyone who has no official role in the breeding and housing of Experimental Animals or the conduct of an Animal Experiment from coming into contact with Experimental Animals.

#### Article 22 (Emergency Measures)

- (1) The Head of a Department shall prepare a plan for emergency measures in times of crisis such as an earthquake or fire and endeavor to make sure the persons concerned fully understand its content.
- (2) The Head of a Department shall, in times of crisis, promptly take necessary measures to

protect Experimental Animals and to prevent the occurrence of harm to humans due to escaped Experimental Animals, threats to environmental protection and soon.

Article 22-2 (Measures for Infectious Diseases that Can Spread between Humans and Animals)

(1) Animal Experimenters shall work to acquire thorough knowledge and collect information about infectious diseases that can spread between humans and animals (hereinafter referred to as the "Zoonoses").

(2) The Head of a Department shall establish a communication system with public health authorities to be able to quickly take necessary action when the Zoonoses occur.

Article 23 (Education and Training)

(1) The Head of a Department must provide education and training for the Managers of Experimental Animals, Animal Experimenters and Caretakers concerning the matters listed in the following items.

(i) Relevant rules and regulations, Guidelines, etc. and regulations, etc. of the University.

(ii) Basic matters regarding the method of Animal Experiments.

(iii) Basic matters regarding the breeding and housing of Experimental Animals.

(iv) Matters regarding the assurance and management of safety.

(v) Matters regarding the Zoonoses

(vi) Other matters regarding the proper conduct of Animal Experiments.

(2) The Head of a Department shall endeavor to ensure that the necessary education and training is provided to the Managers of Experimental Animals, Animal Experimenters and Caretakers.

(3) In addition to the matters prescribed in paragraph (1), necessary matters regarding the implementation of education and training shall be provided for by the Committee.

Article 24 (Self-inspection and Assessment)

(1) The Head of a Department shall conduct a self-inspection and assessment concerning the compliance to these regulations and report the results to the Executive Vice-President.

(2) The Executive Vice-President shall report the results of the self-inspection and assessment prescribed in the preceding paragraph to the President.

(3) The President shall receive the Assessment and Verification by a Third Party on the results of self-inspection and assessment prescribed in the preceding paragraph.

Article 25 (Information Disclosure)

(1) The information concerning the self-inspection and assessment of Animal Experiments at the University shall be disclosed once a year or so.

(2) The results of the Assessment and Verification by a Third Party as prescribed in paragraph (3) of preceding Article shall be disclosed.

#### Article 26 (Enforcement Provision)

Upon receiving reports etc. as defined in paragraph (3) of Article 5, paragraph (4) of Article 10, Article 12, paragraph (4) of Article 13, paragraph (2) of Article 16 and paragraph (2) of Article 19, the Executive Vice-President shall report all necessary matters to the President. Any orders issued to suspend experiments, etc., as described in paragraph (5) of Article 10 will be decided in consultation with the President.

#### Article 27

(1) All matters necessary for the implementation of these regulations, including their provisions, shall be determined by the Executive Vice-President.

(2) The Executive Vice-President shall decide the necessary matters mentioned in the preceding paragraph in consultation with the President.

#### Supplementary Provisions

(1) These regulations shall come into force as from April 1, 2007.

(2) The term of office of the committee members who are appointed first after the enforcement of these regulations shall, notwithstanding the provision of paragraph (3) of Article 6, be until September 30, 2008.

(3) The Kyoto University Animal Experimentation Committee Guidelines (approved by the President on June 28, 1988) are abolished.

(Interim supplementary provisions are omitted)

Supplementary Provisions (Order No. 85, 2024)

These regulations shall come into force on January 1, 2025.

