

Regulations on Animal Experimentation at Kyoto University

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Article 1 (Purpose)

These regulations shall provide for necessary matters pertaining to the conduct of animal experiments, 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 5 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 permanently bred and housed or where an Animal Experiment is 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 Responsible for 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 department's facility, etc., 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 the person appointed to each Breeding and Housing Facility who manages Experimental Animals under the Manager of a Facility, etc. of the Breeding and Housing Facility.

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

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

(xii) 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 for Breeding and Housing of and Pain Alleviation for Experimental Animals (Ministry of the Environment, Notice No. 88 of 2006) and the Guidelines on the Method of Animal Disposal (Prime Minister's Office, Notice No. 40 of 1995).

(xiii) 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 (Control and Management)

(1) The President shall be responsible for control and management concerning the proper conduct of Animal Experiments at the University.

(2) The Executive Director for Research Standards (hereinafter referred to as "the Executive Director") shall assist the President in the duties described in the preceding paragraph.

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 of the department, and shall have control concerning the proper conduct of Animal Experiments in his or her Department.

Article 5 (Animal Experimentation Committee)

(1) The Animal Experimentation Committee (hereinafter referred to as "the Committee") shall be established at the University in order to deliberate the matters listed in the following items.

(i) Matters pertaining to the appropriateness of an experimental plan approved by a Department and the appropriateness of the method of implementation and the results of the experimental plan.

(ii) Matters pertaining to the appropriateness of a Facility, etc. approved by a Department and the appropriateness of the breeding and housing conditions of Experimental Animals.

(iii) Matters pertaining to education and training concerning the conduct of Animal Experiments.

(iv) Matters pertaining to self-examination assessment concerning the conduct of Animal Experiments.

(v) 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 by Article 9.

(3) The Committee shall report the outcome of deliberation to the Executive Director. In this case, the Committee may, when it finds any improper conduct with respect to an experimental plan, 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 of the professors and one of the associate professors of each Department that conducts an Animal Experiment.

(ii) Several professors and associate professors of 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 his or her predecessor. The committee members may be reappointed.

(4) The Committee described 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 knowledge.

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 all meetings of the Committee and preside over those meetings.

(4) The Vice-Chairperson shall assist the Chairperson and act for the Chairperson in his or her absence or incapacity.

Article 8

In addition to the matters prescribed in the preceding article, the Committee shall provide for necessary matters pertaining to the operation of the Committee.

Article 9 (Departmental Committee of Animal Experimentation)

(1) A Departmental Committee of Animal Experimentation (hereinafter referred to as a "Departmental Committee") shall be established at a Department that is to conduct an Animal Experiment in order to examine whether the conducting of the Animal Experiment and the establishment or change of a Facility, etc. (hereinafter referred to as "Establishment, etc.") at the Department should be approved.

(2) Necessary matters pertaining to the organization and operation of a Departmental Committee shall be provided for by the Department.

(3) Notwithstanding the provision set forth in the paragraph 1, Departments may, when they find it necessary, jointly establish 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 Responsible for the Animal Experiment shall, at the time of conducting an Animal Experiment, prepare an animal experiment plan in the prescribed form taking the matters listed in the following items into account and obtain approval from the head of the Department. The same shall apply to a case where an approved plan 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 Experiment

(b) The number of Experimental Animals that influences the precision and reproducibility of the results of an Animal Experiment

(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 that the requirements of the Animal Experiment can still be met.

(2) The head of a Department shall, where an application for approval set forth 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 Responsible for an Animal Experiment.

(3) The Person Responsible for an Animal Experiment may not conduct the Animal Experiment until an animal experiment plan is approved by the head of the Department.

(4) The head of a Department shall report an approved experiment plan to the Executive Director.

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

(6) The Person Responsible for 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

The Person Responsible for an Animal Experiment shall, at the time of conducting an Animal Experiment, observe the Guidelines, etc., and take into consideration the matters stated in an animal experiment plan and the matters listed in the following items.

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

(ii) An experiment involving physically or chemically hazardous materials, 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) A major, highly invasive operation on a living animal shall be performed under supervision of a person of experience, etc.

Article 12 (Post-experimental Report)

The Person Responsible for the Animal Experiment shall, after conducting the Experiment, report the number of Experimental Animals used, any changes to the plan, and other details to the Executive Director 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 the Department and obtain his or her approval.
- (2) The head of a Department shall, when an application as set forth 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 or house Experimental Animals or to conduct an Animal Experiment 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 an approved facility to the Executive Director.

Article 14 (Requirements of a Facility, etc.)

1 The requirements pertaining to 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 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 pertaining to 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, etc. 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 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 notice of the abolition in the prescribed form to the head of the Department.

(2) After receiving the notice of abolition mentioned in the preceding paragraph, the head of the Department must report it to the Executive Director.

(3) The Manager of a Facility, etc. shall, where a 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 Responsible for an Experiment as the need arises.

Article 17 (Breeding and Housing of Experimental Animals)

Necessary matters pertaining to 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.

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)

An 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 Director.

Article 20 (Transfer)

The Person Responsible for an Animal Experiment shall, where Experimental Animals are transferred, provide the transfer 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 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 (Response to Infectious Diseases that Can Spread between Humans and Animals)

(1) Animal Experimenters must work to acquire thorough knowledge and collect information about infectious diseases that can spread between humans and animals.

(2) The head of a Department must establish a communication system with public health authorities to be able to quickly take necessary action in the event of an outbreak of an infectious disease that can spread between humans and animals.

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 Breeders concerning the matters listed in the following items.

- (i) Relevant rules and regulations, Guidelines, etc. and regulations, etc. of the University.
- (ii) Basic matters pertaining to the method of animal experimentation.
- (iii) Basic matters pertaining to the breeding and housing of Experimental Animals.
- (iv) Matters pertaining to the assurance and management of safety.
- (v) Other matters pertaining to the proper conduct of Animal Experiments.

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

Article 24 (Self-Examination Assessment)

(1) The head of a Department shall conduct a self-examination assessment concerning the compliance to these regulations and report the results to the Executive Director.

(2) The Executive Director shall report the results of the self-examination assessment described in the preceding paragraph to the President.

(3) The President shall receive a verification by an external person (hereinafter referred to as "External Verification") on the results of self-examination assessment described in the preceding paragraph.

Article 25 (Information Disclosure)

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

(2) The results of the self-examination assessment shall be disclosed after the conducting of an External Verification as prescribed in paragraph 3 of Article 24.

Article 26 (Exemptions)

These regulations shall not apply to Experimental Animals bred or housed for the purpose of education, research or testing related to animal husbandry or for the purpose of improving breeding related to animal husbandry (in these cases, Experimental Animals are limited to kinds of animals deemed to be industrial livestock) and shall not apply to the breeding and housing of Experimental Animals for the purpose of observation only. However, even if it is for the above purposes, these regulations shall apply in cases of research on Experimental Animals through carrying out a surgical procedure, research through conducting pharmacological experiments, or the use of Experimental Animals for education and training in basic sciences, including anatomy, physiology, and pathology, applied veterinary medicine, and clinical veterinary medicine.

Article 27 (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 Director 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 28

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

(2) The Executive Director will 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.

Supplementary Provisions

1. These regulations shall come into force on April 1, 2007.

2. Notwithstanding of the provisions of paragraph 3 of Article 6, the term of the first Committee members appointed after these regulations become effective shall be until September 30, 2008.

3. The Kyoto University Regulations for the Animal Experiment Committee (determined by the President on June 28, 1988) shall be abolished.

(Interim supplementary provisions are omitted)

Supplementary Provisions (Order No. 62, 2019)

These regulations shall come into force on October 1, 2019.

Supplementary Provisions

These regulations shall come into force on April 1, 2020.

Supplementary Provisions

These regulations shall come into force on October 1, 2020