

## Rules of Animal Experiment in Kagawa University

Note: This document is a translation of the rules effective on April 1, 2021. This English translation does not guarantee uniqueness, provided for informational purposes only.

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(Purpose)

Article 1.

These Rules prescribe matters relating to the proper conduct of animal experiments at Kagawa University (hereinafter referred to as “the University”) based on the Guidelines for Proper Conduct of Animal Experiments (June 2006) (hereinafter referred to as “the Guidelines”) provided by the Science Council of Japan pursuant to the provisions of the Law for the Act on Welfare and Management of Animals (Law No. 105, 1973) (hereinafter referred to as “the Law”), the Standards relating to the Care and Keeping and Reducing Pain of Laboratory Animals (Notice No. 88 of the Ministry of Environment, 2006) (hereinafter referred to as “the Care and Management Standards”), and the Fundamental Guidelines for Proper Conduct of Animal Experiment and Related Activities in Academic Research Institutions under the jurisdiction of the Ministry of Education, Culture, Sports, Science and Technology (June 2006) (hereinafter referred to as “the Fundamental Guidelines”).

(Governing Law)

Article 2.

1. Experiment, care, and management of laboratory animals in the University shall conform to the provisions of the Law, Care and Management Standards, Fundamental Guidelines, Standards relating to the Methods of Destruction of Animals (Notice of the Prime Minister's Office), other related laws if any, and these Rules.
2. Animal experiments shall be properly conducted based on the animal experiment principles of “the Three Rs” (Replacement: use of alternative methods; Reduction: use of fewer animals; and Refinement: alleviation of pain).

(Definitions)

Article 3.

In these Rules, the following terms shall have the following meanings:

- (1) “Administrator” means a person who manages laboratory animals and facilities, etc. at the order of the president, and means the head of each dean or director of research center provided in Appendix 1;
- (2) “Animal experiments and other related activities” means utilization of animals for education (including practical training for students), testing, research and development,

manufacture of biological products, or other scientific purposes;

- (3) "Rearing and care facilities" means facilities in which animals are permanently reared and cared or in which animal experiments and related activities are conducted, under an integrated management system by administrator and care manager;
- (4) "Animal facilities" means facilities or equipment in which animals are constantly cared or maintained, and all animal facilities belong to the rearing and care facilities;
- (5) "Laboratory" means a laboratory where animal experiments and other related activities are performed (including cases where Laboratory Animals are temporarily cared for no longer than 48 hours);
- (6) "Facilities" means rearing and care facilities, animal facilities, and laboratories;
- (7) "Laboratory animals" means animals of mammalian, avian or reptilian species (including those in transport to animal facilities or laboratories), cared or maintained in animal facilities or laboratories for use in animal experiments and other related activities;
- (8) "Animal experiment protocol" means a protocol on conducting animal experiments and other related activities;
- (9) "Animal experiment researchers" means all individuals performing animal experiments and other related activities within the University;
- (10) "Principal investigator" means an animal experiment researcher who is responsible for all activities concerning the animal experiments and other related activities;
- (11) "Liaison investigator" means an animal experiment researcher who assists the principal investigator in consultation with the Animal Care and Use Committee for Kagawa University (hereinafter referred to as "the Committee") and plays a central role related to the implementation of animal experiments;
- (12) "Care manager" means an individual with adequate knowledge and experience of care who is responsible for managing laboratory animals, and for assisting the administrator with animal facilities in care and maintaining laboratory animals;
- (13) "Technician" means an individual who is engaged in the feeding and management of laboratory animals under the supervision of the care manager or animal experiment researchers;
- (14) "Guidelines" means the Fundamental Guidelines as well as the guidelines for animal experiments provided by government agencies.

In these Rules, unless the context requires otherwise, the singular includes the plural and vice versa.

(Scope of Application)

Article 4.

1. These Rules shall be applied to all animal experiments and other related activities conducted at the University which utilize living animals of mammalian, avian or reptilian species.
2. In the event that the principal investigator commissions animal experiments and other related

activities to an institute other than the University, he or she shall ensure that the animal experiments and other related activities are properly conducted at such institute pursuant to the Fundamental Guidelines and guidelines for animal experiments provided by other government agencies.

(The Animal Care and Use Committee)

Article 5.

1. The president of the University shall be responsible for overseeing proper conduct of Animal Experiments and Related Activities at the University, as well as proper feeding and management of Laboratory Animals.
2. The president of the University shall establish “the Committee” which will: approve animal experiment protocols, animal facilities and laboratories; assess the progress and results of each experiment, provision of education and training, self-inspection, evaluation, and information disclosure; deliberate other matters relating to the proper conduct of animal experiments; and other related activities.
3. Matters relating to the Committee shall be provided separately.

(Animal Experiment Protocol)

Article 6.

1. In the event that there is an animal experiment protocol, the principal investigator shall prepare and submit such protocol (hereinafter referred to as “a/the Protocol”) (attached Form 1) to the president of the University, based on the following items, to assure the reliability of data obtained from animal experiments and other related activities:
  - (1) Purpose, significance, and necessity of the research;
  - (2) Appropriate utilization of laboratory animals with a view to alternative methods;
  - (3) Consideration of the selection of animal species appropriate for the purpose of animal experiments and other related activities with a view to reducing the number of laboratory animals, the number of laboratory animals which may influence the accuracy and reproducibility of results of animal experiments, the genetic and microbiological quality, and the care conditions;
  - (4) Proper conduct of animal experiments and other related activities in consideration of alleviating pain;
  - (5) Study of the setting of a humane end-point (timing of ending the experiment to relieve the laboratory animals of severe pain) at the stage of planning animal experiments and other related activities which may involve a high degree of pain including, but not limited to, lethal toxicity testing, infection experiments and radiation experiments.
2. Upon receipt of a Protocol from the principal investigator, the president of the University shall request the Committee to review the Protocol, decide whether to approve or reject it based on the results of the review, and notify the principal investigator of the decision.
3. The principal investigator shall not be authorized to start animal experiments and other related

activities prior to receiving the president's approval of the Protocol.

4. In the event of amendments to the contents of an already approved Protocol, the principal investigator shall newly submit such amended Protocol to the president of the University for approval.

(Experimental Procedure)

Article 7.

In the event that animal experiment researchers conduct animal experiments and other related activities, they shall observe the following items in addition to the Law, the Care and Management Standards, and the Guidelines:

- (1) Conduct of animal experiments and other related activities in properly managed and maintained animal facilities or laboratories;
- (2) Observance of the following items in addition to the matters stated in the Protocol:
  - a. Use of appropriate anesthetics and analgesics
  - b. Timing of ending the experiment (including the humane end-point)
  - c. Proper postoperative management
  - d. Proper choice of euthanasia
- (3) Observance of applicable laws and regulations as well as related rules of the University governing the conduct of animal experiments and other related activities as may require special attention to safety management (i.e., those involving physically and chemically dangerous agents, pathogens, or genetically-modified animals);
- (4) Securement of appropriate safety facilities and equipment for conducting animal experiments and other related activities which may involve physically and chemically dangerous agents or pathogens;
- (5) Endeavors to master techniques necessary for experiments in advance;
- (6) Prudential large-scale invasive life-sustaining operations under the supervision of a person who has knowledge and experience in such field.

(Reporting)

Article 8.

After implementing planned animal experiments, the principal investigator shall report to the president of the University by using an animal experiment report form (attached Form 2) every academic year, regarding the number of animals used, any deviations from the original protocols, and the results of the experiments.

(Establishment of Animal Facilities)

Article 9.

1. In the event that animal facilities are established, the administrator shall submit an application for approval of establishing animal facilities (attached Form 3) to the president of the University in advance.

2. The president of the University shall request the Committee to investigate the facilities applied for in the preceding paragraph, and decide whether to approve or reject them based on the results of the investigation.
3. The administrator shall not be authorized to permit care and maintenance of laboratory animals or animal experiments in such facilities unless approved by the president of the University.
4. In the event of amendments to the contents of the already approved application for approval of establishing animal facilities, the administrator shall newly submit an application for approval of establishing animal facilities (attached Form 3) to the president of the University for approval.
5. In the event that animal facilities are established, the administrator shall appoint a care manager at each animal facility.

(Requirements of Animal Facilities)

Article 10.

Animal facilities shall meet the following requirements:

- (1) Structure capable of maintaining appropriate temperature, moisture, ventilation, and brightness according to experiment purposes and animal species;
- (2) Appropriate care equipment according to animal species and the numbers of animals maintained;
- (3) Floors and inner walls which are easy to clean and sterilize, and sanitary equipment for cleaning and sterilizing instruments and materials;
- (4) Structure and strength capable of preventing laboratory animals from escaping;
- (5) Measures taken against negative impacts of odor, noise, and wastes on the surrounding environment;
- (6) Appointment of a care manager.

(Establishment of Laboratory)

Article 11.

1. In the event that a laboratory is established in addition to the animal facilities, the administrator shall submit an application for approval of establishing a laboratory (attached Form 4) in advance.
2. Upon receiving the application stated in the preceding paragraph, the president of the University shall request the Committee to investigate the laboratory, and decide whether to approve or reject it based on the results of the investigation.
3. The administrator shall not be authorized to permit animal experiments and other related activities (including temporary keeping of animals for less than 48 hours) in such laboratory unless approved by the president of the University.
4. In the event of amendments to the contents of the already approved application for approval of establishing a laboratory, the administrator shall newly submit an application for approval of establishing a laboratory (attached Form 4) to the president of the University for approval.

(Requirements of Laboratory)

Article 12.

The laboratory shall meet the following requirements:

- (1) Structure and strength capable of preventing laboratory animals from escaping, and laboratory environment where it is easy to catch animals in case they have escaped from their cages in the room.
- (2) Structure where it is easy to clean and sterilize parts contaminated by feces, blood, and so forth.
- (3) Maintenance of sanitary conditions, and measures taken against negative impacts of odor, noise, and wastes on the surrounding environment.

(Maintenance and Improvement of Animal Facilities and Laboratories)

Article 13.

1. The administrator shall ensure that animal facilities and laboratories are maintained, managed, and improved to properly manage laboratory animals and conduct animal experiments and other related activities.
2. The administrator must ensure that the appropriate environment for feeding and management is provided for Laboratory Animals that takes their species, habits, and other particulars into consideration.

(Abolishment of Animal Facilities and Laboratories)

Article 14.

1. In the event that animal facilities or a laboratory are abolished, the administrator shall submit a notification of abolishment of animal facilities or a laboratory (attached Form 5) to the president of the University in advance.
2. The administrator shall ensure that laboratory animals cared or maintained are transferred to other animal facilities in cooperation with the principal animal experiment researcher as and when necessary.

(Preparation and Familiarization of Manual - Standard Procedures)

Article 15.

Each care manager shall prepare a manual on care and management for each animal facility and familiarize all the animal experiment researchers and technicians with such manual.

(Introduction of Laboratory Animals)

Article 16.

1. The principal investigator shall introduce laboratory animals from organizations which are properly managed pursuant to applicable laws and guidelines.
2. The principal investigator shall conduct medical inspections and quarantine care of laboratory

animals to be introduced.

3. The principal investigator shall take necessary measures to acclimatize and adapt the laboratory animals introduced to the care environment.

(Feeding and Water)

Article 17.

Care managers, animal experiment researchers, and technicians shall properly feed and water laboratory animals according to their physiology, ecology, and habits.

(Health Management)

Article 18.

1. Care managers, animal experiment researchers, and technicians shall manage the health of laboratory animals to prevent injuries or diseases other than those for experiment purposes.
2. In the event that laboratory animals suffer an injury or disease other than those for experiment purposes, the care manager, animal experiment researchers, and technicians shall provide appropriate treatment for them.

(Care of Different Species or Strains)

Article 19.

In the event that different animal species or multiple animals are cared or maintained on the same premises of the animal facility, the care manager, animal experiment researchers, and technicians shall house them in consideration of their combination.

(Maintenance of Records)

Article 20.

The principal investigator shall maintain records of the sources of laboratory animals as well as their care and medical histories.

(Information Provision in Transfer)

Article 21.

In the event that laboratory animals are transferred to other animal facilities, the principal investigator shall provide the facilities with information on their traits, care and maintenance, infectious diseases, and others.

(Transport)

Article 22.

In the event that laboratory animals are transported, the principal investigator shall comply with the Care and Management Standards, and ensure that the health and safety of the laboratory animals is secured and measures are taken to prevent them from causing harm to humans.

(Protection of Harm)

Article 23.

1. The administrator shall establish procedures for catching escaped laboratory animals in advance.
2. In the event that laboratory animals which may cause harm to humans have escaped from the animal facilities or laboratory, the administrator shall immediately contact the authorities concerned.
3. The administrator shall take necessary measures to prevent and deal with infectious diseases or bite wounds of experiment animal origin which may involve the care manager, animal experiment researchers, and technicians.
4. In the event that toxic animals such as poisonous snakes are cared or managed, the administrator shall separately prescribe necessary matters pursuant to the Care and Management Standards to prevent harm to humans.
5. The administrator shall make every effort to take appropriate measures that is technologically possible such as attaching tags, leg bands, microchips, or other identifying devices to laboratory animals, when they may inflict harm on people.
6. The administrator shall take necessary measures to ensure that no one except those involved in care or conducting animal experiments and other related activities is allowed to contact laboratory animals.

(Emergency Protocol)

Article 24.

1. The administrator shall prepare an emergency protocol for earthquakes, fire, and others in advance, and familiarize those concerned with such protocol.
2. In the event that an emergency arises, the principal investigator shall ensure that laboratory animals are secured and measures are taken to prevent harm caused by escaped laboratory animals.

(Prevention and Handling of Zoonoses)

Article 25.

1. Animal experiment researchers, care managers, and technicians must endeavor to thoroughly acquire knowledge about zoonoses and to gather information about zoonoses that are transmissible between humans and animals.
2. Administrators, care managers, and animal experiment researchers must endeavor to maintain a contact system with public health institutions and similar organizations so that in the event an outbreak of a zoonosis occurs, the necessary responses may be taken swiftly.

(Education and Training)

Article 26.

1. Before applying for the Protocol, care managers, animal experiment researchers, and



technicians shall receive education and training organized by the Committee on the following matters:

- (1) Applicable laws, guidelines, and rules established by the University;
  - (2) Basic matters related to animal experiment procedures and others;
  - (3) Basic matters related to care and maintenance of laboratory animals;
  - (4) Matters related to the security and safety management;
  - (5) Other matters related to the proper conduct of animal experiments and other related activities.
2. The Committee shall keep records of the date of the training, the content of the education, the names of the instructors and participants.

(Self-inspection and Evaluation)

Article 27.

1. Upon request of the Committee, the administrator, care managers, principal investigator, animal experiment researchers, and technicians shall submit information for self-inspection and evaluation to the Committee.
2. The president of the University shall endeavor to conduct an external evaluation of the self-inspections and evaluation results.

(Public Information Disclosure)

Article 28.

Information on animal experiments and other related activities conducted at the University (including rules for animal experiments and other related activities, care and maintenance conditions of laboratory animals, results of self-inspection and evaluation, and composition of the Committee, etc.) shall be made public.

(Application Mutatis Mutandis)

Article 29.

Animal experiments and other related activities in which animals other than those defined in Paragraph 5 of Article 3 are used shall be conducted in line with the Care and Management Guidelines.

(Exclusion of Application)

Article 30.

1. These Rules shall not be applied to the care or maintenance of experimental animals (which are limited to animals generally considered to be industrial livestock) for the purpose of care management education, testing and research, or breed improvement in stockbreeding. Neither shall these rules be applied to the care and maintenance of experimental animals for the purpose of ecological observation.
2. The provisions of the preceding paragraph notwithstanding, when research includes surgical

procedures, or if the research involves pharmacological experiments, or when Laboratory Animals will be provided for education and hands-on training into basic sciences such as anatomy, physiology, or pathology, or if any other such circumstances are present, these Regulations will apply.

3. The rearing and care of livestock animals must comply with the Standards Relating to the Care and Keeping of Industrial Animals (Notice No. 85 of Ministry of the Environment, 2013), and the rearing and care of Laboratory Animals for the purpose of performing ecological observation must comply with the Standards Relating to the Care and Keeping of Animals at home, etc. (Notice No. 104 of Ministry of the Environment, 2007).

(Penalties)

Article 31.

1. The president of the University can immediately suspend the animal experiment of a person who violates this rule and prohibit the conduct of the animal experiment for a fixed period.
2. The President of the University can seek advice from the committee on the application of penalties.

(Miscellaneous Provision)

Article 32.

In addition to these Rules, the president of the University shall separately prescribe other matters as may be necessary.

(Supplementary Provisions)

1. These Rules shall be enforced on February 1, 2007.
2. The Animal Experiment Guidelines of Kagawa University (enacted on April 1, 2004) shall be abolished by the enforcement of these Rules.

Appendix 1 (related to Article 3)

Faculties, Life Science Research Center
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