

# Regulations for Animal Experiments in Kumamoto University

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## Supplementary Provisions

### Chapter 1 General Rules

#### (Purpose and Basic Principle)

#### Article 1.

1. From the perspective of science, animal welfare, environmental preservation, and safety of faculty or students conducting Animal experiments and related activities, these rules shall provide the necessary guidelines pertaining to the conduct of animal experiments and related activities (Establishment of the Animal experiment Committee, Procedure of the Animal experiment Protocol, etc.), the purpose of which is to ensure that animal experiments and related activities at Kumamoto University (hereinafter referred to as “the University”) are conducted properly.

2. Animal experiments and related activities at the University shall be conducted pursuant to the provisions of the Law for the Humane Treatment and Management of Animals (Law No. 105, 1973) (hereinafter referred to as “the Law”), the Standards Relating to the Care and Management of Laboratory Animals and Relief of Pain (Ministry of Environment, Notice No.88 of 2006) (hereinafter referred to as “the Care and Management Standards”), 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) (hereinafter referred to as “the Fundamental Guidelines”), the Guidelines on the Method of Animal Disposal (Prime Minister’s Office, Notice No. 40 of 1995), and other related laws and regulations.

3. Animal experiments shall be properly conducted based on the animal experiment principles of “the Three Rs” (Replacement, Reduction, and Refinement), pursuant to the Law, the Care and Management Standards

(1) Replacement (use of alternative methods; *ie.*, substituting animals with non-animal research methods, while still allowing achievement of the scientific objective)

(2) Reduction (use of fewer animals; *ie.*, minimizing the number of animals used, while still allowing achievement of the scientific objective)

(3) Refinement (alleviation of pain; *ie.*, techniques to reduce pain and distress to animals used in experiments, while still allowing achievement of the scientific objective)

(Definitions)

## Article 2

The following terms used in the Rules are defined below:

(1) Animal experiments and related activities

Utilization of animals for education, testing, research and development, manufacture of biological products, or other scientific purposes.

(2) Animal facilities

Facilities where laboratory animals are permanently bred and maintained or animal experiments are conducted.

(3) Laboratory

Animal laboratory where experimental operations are carried out on laboratory animals (including cases where laboratory animals are temporarily kept for experiments for less than 48 hours), other than the Animal facilities mentioned above (2).

(4) Facility, etc.

Animal facilities and Laboratory.

(5) Laboratory animals

Animals of mammalian, avian or reptilian species (including those in transport to animal facilities or laboratories), bred or maintained in animal facilities or laboratories, for use in animal experiments and related activities.

(6) Animal experiment protocol

Protocol for conduct of animal experiments or related activities.

(7) Animal experiment researcher

Individual performing the animal experiment or related activities.

(8) Principal investigator

The animal experiment researcher who is responsible for all activities concerning the animal experiment and related activities.

(9) Manager

Chief of the Department managing laboratory animals and facilities, etc. by order of the President of the University.

(10) Care manager

Individual with adequate knowledge and experience of laboratory animals, who is responsible for managing the laboratory animals and assisting the Manager.

(11) Breeder

Individual who breeds and maintains the laboratory animals under the Manager and an animal experiment researcher.

(12) Managers, etc.

The President of the University, the Manager, the Care manager, Animal experiment researchers, and Breeders.

(13) Care and Management Standards, etc.

The Law, the Care and Management Standards, and the Fundamental Guidelines.

## Chapter 2 Scope of Application

### Article 3

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.
- 3 Animal experiments and related activities, conducted by faculty or students of the University at research institutes other than the University, shall be conducted pursuant to the internal rules of said institutes.

In such a case, animal experiment protocol pertaining to animal experiments and related activities shall be approved pursuant to the provision of Article 11 of these rules.

## Chapter 3 Animal Experiment Committee

(Establishment of the Animal Experiment Committee)

### Article 4

The President of the University shall establish an Animal Experiment Committee for Kumamoto University (hereinafter referred to as “the Committee”) which will: approve animal experiment protocols, animal facilities and laboratories; assess the progress and results of each experiment, provide education and training, self-inspection, evaluation, and information disclosure; deliver

reports or give advice on other matters relating to the proper conduct of animal experiments; and other related activities.

(Roles of the Committee)

#### Article 5

The Committee shall deliberate or investigate the matters listed in the following items, and report the results or give advice to the President of the University.

- (1) Matters pertaining to whether the Animal experiment protocol complies with the Care and Management Standards, etc. and these rules or not.
  - (2) Matters pertaining to the method of implementation and the results of animal experiments performed according to animal experiment protocol.
  - (3) Matters pertaining to the facilities, etc. and the breeding and maintaining conditions of laboratory animals
  - (4) Matters pertaining to the proper implementation of the animal experiments and related activities and the proper treatment of laboratory animals, and the contents and implementation mechanism of education and training concerning related laws and regulations.
  - (5) Matters pertaining to self-inspection and evaluation.
  - (6) Other matters necessary for the proper conduct of animal experiments and related activities.
- 2 In the event that the President receives a request to review animal experiment protocol from other research institutes with no organization equivalent to the Committee of the University, the President shall consult the Committee on this matter.

(Membership of the Committee)

#### Article 6

The Committee shall consist of the committee members listed below.

- (1) Institution of Resource Development and Analysis, Director
- (2) Institute of Resource Development and Analysis (Center for Animal Resources & Development), Department Manager

- (3) Institute of Resource Development and Analysis (Center for Animal Resources & Development), Department Vice-Manager
- (4) Associate Professor or Lecturer at the Graduate School of Medical Sciences, 1 person
- (5) Associate Professor or Lecturer at the Graduate School of Pharmaceutical Sciences, 1 person
- (6) Associate Professor Lecturer at the University Hospital, 1 person
- (7) Associate Professor or Lecturer at the Institute of Molecular Embryology and Genetics or Center for AIDS Research, 1 person
- (8) Associate Professor or Lecturer at the Faculty of Education, 1 person
- (9) Associate Professor or Lecturer at the Graduate School of Science and Technology (Department of Technology), 1 person
- (10) Associate Professor or Lecturer of Graduate School of Science and Technology (Department of Science), 1 person
- (11) An expert (in a field other than that of animal experiments and related activities, or laboratory animals) designated by the President, 1 person
- (12) Research Promotion and International Affairs Division, Director(13) Some other persons if deemed necessary by the President.

2 Committee members described in Item 4 through 11 and 13 of the previous Paragraph shall be commissioned by the President.

3 The term of office of the Committee members described in Item 4 through 11 and 13 of the previous Paragraph shall be 2 years, and can be reappointed.

4 In the event of the absence of a Committee member described in Item 4 through 11 and 13 of the previous Paragraph, the term of office of the substitute members shall, notwithstanding the provision of the previous Paragraph, be the remaining period of the predecessor's.

(Chairperson, etc.)

## Article 7

1. The Committee shall have a Chairperson, selected from among its members.

2. The Committee shall have a Vice-Chairperson, who 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 on behalf of the Chairperson in his or her absence or incapacity.

(Committee Meetings)

#### Article 8

- 1 The Committee shall not conduct Committee meetings without more than half of the members in attendance.
- 2 The Committee shall only approve decisions that receive the majority vote of those in attendance. The Chairperson will make the decision in the case of a tied vote.
- 3 The Committee members shall not participate in meetings discussing animal experiment protocol submitted by themselves as Principal Investigator.

(Confidentiality)

#### Article 9

The Committee members shall not disclose confidential information, even after resigning from their position.

(Matters related to the Committee)

#### Article 10

Matters related to the Committee shall be treated by the Research Cooperation Section, Research Promotion and International Affairs Division and Administrative Office for Life Sciences.

Chapter 4 Implementation of animal experiments and related activities

(Preparation, review, and procedure of the animal experiment protocol)

#### Article 11

1. The Principal Investigator shall prepare and submit the Animal Experiment Protocol to the President of the University every academic year, 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 consideration of alternative methods;
  - (3) Consideration of the selection of animal species appropriate for the purpose of animal experiments and other related activities with the aim to reduce 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 the Animal Experiment Protocol from the Principal Investigator, the President of the University shall request that the Committee review the Animal Experiment 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 Animal Experiment Protocol.
  - 4 In the event of amendment to the contents of an already approved Animal Experiment Protocol, the Principal Investigator shall be pursuant to the previous three Paragraphs (1 to 3).

(Experimental Procedure)

#### Article 12

1. In the event that animal experiment researchers conduct animal experiments and related activities, they shall observe the following items in addition to the Law, the Care and Management Standards, and the Fundamental Guidelines:
  - (1) Animal experiments and related activities shall be conducted in a properly managed and maintained animal facility or laboratory;



- (2) Observance of the following items in addition to the matters stated in the Animal Experiment Protocol:
    - a. Use of appropriate anesthetics and analgesics
    - b. Consideration of the timing of the end of the experiment (including a 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 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) Securing appropriate safety facilities and equipment for conducting animal experiments and related activities which may involve physically and chemically dangerous agents and pathogens;
  - (5) Endeavors to master techniques necessary for experiments in advance;
  - (6) Conducting large-scale invasive life-sustaining operations under the supervision of a person who has knowledge and experience in such a field.
2. After implementing or in the event of discontinuation of planned animal experiments, the Principal Investigator shall report to the President of the University by submitting an animal experiment implementation/discontinuation report form.

Chapter 5 Facility, etc.

(Establishment of Animal Facilities)

#### Article 13

1. In the event that animal facilities are established (including the event of amendment of their specifications), the Manager shall submit an application for approval of establishing animal facilities to the President of the University and obtain his or her approval in advance.
2. The President of the University shall request that the Committee 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 Manager of the animal facility shall not be authorized to permit breeding or maintenance of laboratory animals or animal experiments in such facilities unless approved by the President of the University.

(Requirements of Animal Facilities)

#### Article 14

1. Animal facilities shall meet the following requirements:

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

(Establishment of a Laboratory)

#### Article 15

1. In the event that experiment facilities are established (including any changes) in addition to the existing animal experiment facilities, the Manager shall submit an application for approval of establishing a laboratory to the President of the University and obtain his or her approval in advance.
2. The President of the University shall request that the Committee investigate the laboratory applied for in the preceding paragraph, and decide whether to approve or reject it based on the results of the investigation.
3. The Manager shall not be authorized to permit animal experiments or related activities (including the temporary housing of animals for less than 48 hours) in such laboratory unless approved by the President of the University.

(Laboratory Requirements)

Article 16

1. The Laboratory shall meet the following requirements:

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

(Maintenance and Improvement of Facility, etc.)

Article 17

The Manager shall ensure that the Animal Facilities and Laboratory are maintained, managed, and improved to properly manage laboratory animals and conduct animal experiments and related activities.

(Discontinuation of a Facility, etc.)

Article 18

1. In the event that a facility, etc. is discontinued, the Manager shall submit a notification of discontinuation of a facility, etc. to the President of the University in advance.
2. In the event of the previous paragraph, the Manager shall ensure that laboratory animals bred or maintained there are transferred to other animal facilities in cooperation with the Principal Investigator as and when necessary.

Chapter 6 Breeding and Maintaining of Laboratory Animals

(Preparation and Dissemination of the Standard Protocol Manual)

Article 19

The Manager and the Care manager shall decide upon a standard operational procedure of care and management of laboratory animals and make sure all animal experiment researchers and breeders are aware of the procedure.

(Health and Safety Maintenance of Laboratory animals)

#### Article 20

The Care manager, animal experiment researchers, and breeders shall endeavor to maintain the health and safety of laboratory animals pursuant to the Care and Management Standards.

(Introduction of Laboratory Animals to Animal Facilities)

#### Article 21

1. The Manager shall introduce laboratory animals from organizations which are properly managed pursuant to the Care and Management Standards etc.
2. The Care manager shall conduct medical inspections and quarantine care of laboratory animals to be introduced.
3. The Care manager shall take the necessary measures to acclimatize and adapt the laboratory animals introduced into the care environment.

(Introduction of Laboratory Animals to Laboratory)

#### Article 22

1. The Principal Investigator shall introduce laboratory animals from organizations which are properly managed pursuant to the Care and Management Standards etc.
2. The Principal Investigator shall conduct medical inspections and quarantine care of laboratory animals to be introduced from other organizations.

(Feeding and Providing Water)

#### Article 23

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

(Health Management)

#### Article 24

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

(Care of Different Species or Strains)

Article 25

In the event that different animal species or multiple animals are cared for and maintained on the same premises of the animal facilities, the Care managers, animal experiment researchers, and breeders shall house them in consideration of the appropriate combinations.

(Preservation of Records)

Article 26

The Manager etc. shall organize records of the sources of Laboratory animals as well as their breeding and medical histories and retain for five years.

(Information Provision in Transfer)

Article 27

In the event that laboratory animals are transferred to other animal facilities, the Manager etc. shall provide the facility with information on their traits, care and maintenance methods, infectious diseases, etc.

(Transport)

Article 28

In the event that laboratory animals are transported, the Manager etc. 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.

Chapter 7 Safety Management

(Hazard Prevention)

Article 29

1. The Manager shall establish procedures for catching escaped laboratory animals in advance.
2. In the event that a laboratory animal which may cause harm to humans has escaped from the animal facilities or laboratory, the Manager shall immediately contact the authorities concerned.
3. The Manager shall take necessary measures to prevent and deal with infectious diseases or bite wounds of laboratory animal origin which may involve the Care manager, animal experiment researchers, and breeders.

4. In the event that toxic animals such as poisonous snakes are bred or managed, the Manager shall prescribe special necessary measures to prevent harm to humans pursuant to the Care and Management Standards.
5. The Manager shall take necessary measures to ensure that no one except those involved in the care or conducting of animal experiments and related activities is allowed contact with laboratory animals.

(Emergency Protocol)

#### Article 30

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

#### Chapter 8 Education and Training

#### Article 31

1. The committee shall conduct education and training for the animal experiment researchers and breeders.
2. The animal experiment researchers and breeders shall receive education and training on the following matters:
  - (1) Applicable laws, the Care and Management Standards etc., and the rules established by the University;
  - (2) Basic matters related to animal experiment and related activity procedures ;
  - (3) Basic matters related to the care and maintenance of laboratory animals;
  - (4) Matters related to security and safety management;
  - (5) Other matters related to properly conducting animal experiments and related activities.
3. The Committee shall organize the records pertaining to the following matters, and retain them for five years: the date of implementation, the contents of education and training, the name of the trainers and trainees.

#### Chapter 9 Self-Inspection, Evaluation and Review

## Article 32

1. The Committee shall conduct the self-inspection and evaluation pertaining to the procedures of animal experiments and related activities, and report the results to the President of the University.
2. The Committee may request that the Manager, animal experiment researchers, Principal Investigator, and breeders submit information for self-inspection and evaluation
3. The President of the University shall endeavor to receive a review of the results of the self-inspection and evaluation by persons outside the University.

## Chapter 10 Public Information Disclosure

## Article 33

Information on animal experiments and related activities conducted at the University shall be made public once a year.

## Chapter 11 Miscellaneous Provision

(Application Mutatis Mutandis)

## Article 34

Animal experiments and related activities in which animals other than laboratory animals are used shall be conducted in line with the Care and Management Standards.

(Exclusion of Application)

## Article 35

These rules shall not be applied to the care or maintenance of laboratory 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 of these rules shall be applied to the care or maintenance of laboratory animals for the purpose of ecological observation.

(Miscellaneous Provision)

## Article 36

In addition to these Rules, the President of the University shall prescribe separately any other necessary items related to animal experiments or related activities or laboratory animals.

## Supplementary Provisions

1. These Rules shall be enforced on January 25, 2007.
2. The term of office of the committee members (stipulated in Item 1 to 4, 11, and 13 of the Paragraph 1 of Article 6) who are appointed first, after the enforcement of this rule shall, notwithstanding the provision of paragraph 3 of the Article 6, be until March 31, 2009.
- 3 After the enforcement of this rule, notwithstanding the provision of the Article 6, until the Committee members are commissioned to take office in accordance with the said Article, the provisional committee consisting of the Experiment Committee members at the Kurokami Campus and Honjo and Oe Campuses shall act for the Committee.
- 4 In the provision of the previous Paragraph, the Head of the Experiment Committee of the Honjo and Oe Campuses shall serve as the Committee Head of the provisional committee.
- 5 Animal experiments and related activities according to the Animal Experiment Protocol pursuant to Article 9 of the former Guidelines shall be conducted according to the said Guidelines only during FY 2006.
6. The following Rules and Guidelines shall be abolished:
  - (1) Animal Experiment Committee Rule of Kumamoto University (Kurokami District)  
(established on April 1, 2004)
  - (2) Animal Experiment Committee Rule of Kumamoto University (Honjo and Oe District)  
(established on April 1, 2004)
  - (3) Animal Experiment Guidelines of Kumamoto University (established on April 1, 2004)  
Supplementary Provisions (Rule No.163 of March 30, 2007)

This rule shall come into force as of April 1, 2007.

Supplementary Provisions (Rule No.98 of March 26, 2009)

This rule shall come into force as of April 1, 2009.