

Regulations for the Management of Laboratory Animals at Fujita Health University

April 1, 2007

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(Preface)

Conducting life science research that involves animal experiments at the University is required not only for the development and deployment of improved health, welfare, and advanced medicine, but also for the advancement of the research area and the enhancement of the health of animals. These regulations of Fujita Health University (hereinafter the University) to govern the conduct of animal experiments are based on the “Act on Welfare and Management of Animals” (Act No. 105 of October 1, 1973, up to the revisions of Act No. 68 of 2005, effective date June 1, 2006; hereinafter the Act), “Standards Relating to the Care and Management of Laboratory Animals and Relief of Pain” (Notice No. 88 of the Ministry of Environment dated April 28, 2006; hereinafter Standards Relating), “Fundamental Guidelines for Proper Conduct of Animal Experiments and Related Activities in Academic Research Institutions under the Jurisdiction of the Ministry of Education, Culture, Sports, Science, and Technology” (the Ministry of Education, Culture, Sports, Science, and Technology dated June 1, 2006; hereinafter Fundamental Guidelines), “Basic Policies for the Conduct of Animal Experiments in Research Institutions under the Jurisdiction of the Ministry of Health, Labor, and Welfare” (the Ministry of Health, Labor, and Welfare dated June 1, 2006; hereinafter Basic Policies), “Guidelines on Methods of Euthanizing Animals” (Notice No. 40 of the Prime Minister’s Office, July 4, 1995), and “Guidelines for Proper Conduct of Animal Experiments” (Science Council of Japan, June 1, 2006; hereinafter the Guidelines).

Chapter 1 General Rules

(Goals and basic principles)

Article 1

- 1) This regulation shall define requirements for appropriate conduct of animal experiments in the University from the perspectives of science, animal welfare, and environmental preservation and with the goal of maintaining the safety of staff and students.
- 2) Animal experiments shall be properly conducted according to the “Three R’s (Replacement, Reduction, and Refinement) in the internationally accepted 3R principles of animal experiments”, pursuant to the Act, Standards Relating, Fundamental Guidelines, Basic Policies, and Guidelines.

(Definitions)

Article 2

In this regulation, the terms used are defined as follows:

- 1) Animal Experiments
Use of animals for education, testing, research, manufacture of biological products, or other scientific purposes.
- 2) Facility
The building(s) with accommodations and equipments used for breeding, maintenance, and experiments (hereinafter the Facility).
- 3) Animal Room
The housing compartment in which live animals are kept for more than 24 hours to perform experiments.
- 4) Laboratory
The room in which live animals are kept for less than 24 hours to perform experiments.
- 5) Laboratory Animals
Mammalian, avian, or reptilian species of animals used for experiments.

- 6) Animal Experiment Protocol
The official document of plans and procedures drafted beforehand for the conduct of an animal experiment.
- 7) Director
The person with overall responsibility in the Facility for breeding and maintenance of animals and the proper and safe conduct of experiments under the authority of the President of the University.
- 8) Laboratory Animal Manager
The person who assists the director and is in charge of management of the laboratory animals.
- 9) Principal Investigator
The person who is responsible for and in charge of all duties and procedures of an experiment conducted under an animal experiment protocol.
- 10) Investigator
The person who carries out an experiment under an animal experiment protocol.
- 11) Animal Technician
The person in charge of care and management of laboratory animals under the authority of the Laboratory Animal Manager or/and Investigator.

(Application)

Article 3

- 1) This regulation shall be applied to all experiments using animals of mammalian, avian, or reptilian species.
- 2) The Principal Investigator shall strive to proceed in accordance with the intentions of these regulations when using animals not belonging to mammalian, avian, or reptilian species.
- 3) The Principal Investigator shall determine whether all animal experiments (even experiments entrusted to other organizations and animal experiments performed jointly with other organizations) are carried out correctly in accordance with the Act, Standards Relating, Fundamental Guidelines, Basic Policies, and Guidelines.

(Organization)

Article 4

The President shall establish an Institutional Animal Care and Use Committee (IACUC) as an advisory board in the University to discuss animal experiment protocols; comprehend the conditions and results of experiments; implement education and training related to experiments and procedures; perform self-inspections and self-assessments; and disclose information. Details of the IACUC are provided in Chapter 2.

Chapter 2 Institutional Animal Care and Use Committee (IACUC)

(Roles of IACUC)

Article 5

The IACUC shall discuss, investigate, and make reports with recommendations to the President on the points listed below. An IACUC member who is the Principal Investigator for a certain experiment should not participate in the review of the corresponding animal experiment protocol.

- (1) The animal experiment protocol with respect to the Guidelines and this regulation.
- (2) Implementation and results of the experiment protocol.
- (3) Maintenance of the Facility and care/management of breeding, maintenance, and housing of laboratory animals.
- (4) Education regarding animal experiments, handling of laboratory animals, control of breeding, and housing of laboratory animals with awareness of the laws and regulations.
- (5) Other matters pertaining to animal experiments.

(Composition of the IACUC)

Article 6

- 1) The members of the IACUC are appointed by the President of the University. The Chairperson is chosen by the IACUC members, approved by the President, and requested by the Chairman of the Board of Trustees.
- 2) The IACUC shall comprise persons with sufficient knowledge and/or experience in the following fields:
 - (1) Animal experiments (1-5 individuals)
 - (2) Laboratory animals (1-5 individuals)
 - (3) Animal welfare (1-5 individuals)
 - (4) Education (1-5 individuals)

(Term and conduct of IACUC)

Article 7

- 1) The term of IACUC service is one year, and members may be reappointed.
After the unexpected retirement of an IACUC member during the appointment term, the successor shall serve until the ending date of the predecessor's term.
- 2) An IACUC conference shall be held once per year.
- 3) An IACUC conference may be held on an ad hoc basis if needed.

Chapter 3 Enforcement of Regulations for Animal Experiments

(Drafting, review, and performance of the animal experiment protocol)

Article 8

- 1) The Principal Investigator shall draft the animal experiment protocol describing the following matters from the viewpoint of data reliability and shall submit the protocol to the President.
 - (1) Purpose, objective, and need for research and education.
 - (2) Potential replacement of laboratory animals with phylogenetically lower species ("Replacement" in the three R's).
 - (3) Potential for reduction of the number of laboratory animals used by considering the species suitable for the purpose, the appropriate number of animals to establish the accuracy and reproducibility of experimental results, and the quality of genetic and microbiologic control and breeding conditions ("Reduction" in the three R's).
 - (4) Appropriate use and handling of animals for the mitigation of pain ("Refinement" in the three R's).
 - (5) Establishment of a humane endpoint (time to quit the experiment for ethical reasons) in any animal experiment protocol involving a high degree of pain (e.g., lethal toxicity tests or experiments involving infection and/or irradiation).
- 2) The President shall notify the results of review of the animal experiment protocol to the Principal Investigator together with the IACUC's recommendations.
- 3) The Principal Investigator shall not start animal experiments without the approval of the animal experiment protocol by the President.

(Experimental technique)

Article 9

- 1) Any person who performs animal experiments shall follow the Standards Relating and Guidelines, and shall observe the following:
 - (1) Carry out all activities described in the animal experiment protocol:
 - (i) Use suitable anesthetic, analgesic, and other drugs for mitigation of pain

- (ii) Consider the end-term (accepted as the humane endpoint) of the experiment
- (iii) Provide suitable postoperative management
- (iv) Select a suitable means of euthanasia
- (2) Conduct the animal experiments in the Facility, animal room, or laboratory, with suitable maintenance and management.
- (3) Follow the Standards Relating and Guidelines for the use of potential hazards (e.g., physically and chemically dangerous materials, pathogenic organisms, and transgenic animals).
- (4) Reserve the appropriate facility and equipment for the use of potential hazards (e.g., physically and chemically dangerous materials, pathogenic organisms, and transgenic animals).
- (5) Strive to master required experimental techniques (in cases of invasive surgery, follow advice from experts).
- 2) The Principal Investigator shall report the number of animals, any deviations from the approved protocol, and the results of the completed experiments to the President.

Chapter 4 Breeding and Facility

(Establishment of the facility)

Article 10

- 1) As facilities for breeding, maintenance, housing, research, and education involving animal models for human diseases, the University has established the “Education and Research Center for Animal Models of Human Diseases” (hereinafter CAMHD) on the Toyoake-main campus, the “Nanakuri Laboratory for Animal Models of Human Diseases (hereinafter NAMHD) on the Nanakuri campus, and the “Banbuntane Laboratory or Animal Models of Human Diseases (hereinafter BAMHD) on the Nakagawa campus.
- 2) As the person with overall responsibility in the Facility for proper and safe conduct of animal studies under the President of the University, a Director is assigned in CAMHD. In NAMHD and BAMHD, a Chief is assigned to each.
- 3) Management in each facility follows its regulations.

(Application and permission for the use of the Animal Room and Laboratory except for the use of CAMHD, NAMHD, or BAMHD)

Article 11

The Principal Investigator/Investigator must use the Animal Room and Laboratory (except for the use of CAMHD, NAMHD, or BAMHD). The required documents should be submitted to the President through the Director/Chief of CAMHD, NAMHD, or BAMHD and must be approved by the President.

(Required condition of Animal Rooms and Laboratories)

Article 12

Animal Rooms and Laboratories shall satisfy the following requirements.

- (1) Structural design of the Animal Room or
- (2) Laboratory must address the following requirements:
 - ① Measures to prevent escape of animals and facilitate capture if laboratory animals do escape.
 - ② Measures to promote easy cleaning or disinfecting (e.g., excrement or blood) and disposal of wastes.
 - ③ Measures to limit the levels of odor and noise.
- (3) Any person responsible for animal breeding or an animal experiment must be instructed by the Director or Laboratory Animal Manager on the above matters.

(Maintenance and management of Animal Rooms and Laboratories)

Article 13

- 1) The applicant applying for use of an Animal Room or Laboratory (hereinafter the Applicant) is required to ensure proper maintenance and management of animal rooms and laboratories. The Applicant shall strive to conserve the living environment around the rooms by avoiding environmental contamination, odors, and noxious insects.

(Closure/Discontinuation of use of Animal Rooms and Laboratories)

Article 14

- 1) The Applicant shall present documents to the President through the Director/Chief of CAMHD, NAMHD, or BAMHD before the ending date for use of an Animal Room or Laboratory.
- 2) The Applicant shall strive to transfer all animals to other facilities in cooperation with the Director and Laboratory Animal Manager.

(Preservation of health and safety of laboratory animals)

Article 16

Every responsible person (e.g., Director, Laboratory Animal Manager, Principal Investigator, Investigator, and/or Animal Technician) participating in breeding and/or experiments shall preserve the health and safety of the laboratory animals in accordance with the Standards Relating.

(Introduction of laboratory animals)

Article 17

- 1) The Director, Laboratory Animal Manager, Principal Investigator, Investigator, and/or Animal Technician shall carry out appropriate breeding, housing, and maintenance in accordance with the Act, Standards Relating, Fundamental Guidelines, Basic Policies, and Guidelines when laboratory animals are imported from other universities, institutions, and/or facilities.
- 2) The Laboratory Animal Manager shall carry out appropriate quarantine and isolation procedures of the laboratory animals.
- 3) The Laboratory Animal Manager shall carry out acclimatization and training procedures for the laboratory animals' new environment.

(Feeding and water supply)

Article 18

The Principal Investigator, Investigator, and Animal Technician shall carry out appropriate feeding and supply of water in accordance with advice on the physiology, ecology, and behavior of the animals from the Director and Laboratory Animal Manager.

(Maintenance of health)

Article 19

The Principal Investigator, Investigator, and Animal Technician shall carry out appropriate maintenance of healthy conditions for laboratory animals in accordance with advice from the Director and Laboratory Animal Manager to avoid unexpected injuries, wounds, or infectious diseases.

(Breeding and housing of multiple species in the Facility)

Article 20

The Director and Laboratory Animal Manager shall consider the balance and combination of the breeding and housing location between multiple species.

(Preservation and reporting of animal records)

Article 21

- 1) Records of importation, breeding, and occurrences of infectious disease should be reported by the Laboratory Animal Manager, Principal Investigator, Investigator, and Animal Technician and be preserved by the Director.
- 2) The Director shall report the number of species and animals to the President once every year.

(Transfer of laboratory animals)

Article 22

To ship animals to other universities, institutions, or facilities, the Principal Investigator and Investigator shall submit documents describing care, management, and microbiologic quality to the Director and Laboratory Animal Manager. The Principal Investigator and Investigator shall provide descriptions of these matters to the responsible person (e.g. Director) within the recipient institution.

(Transport)

Article 23

To ship animals to other universities, institutions, or facilities, the Principal Investigator and Investigator shall keep animals under healthy conditions and avoid any hazards to humans in accordance with the Standards Relating. The Director and Laboratory Animal Manager shall support the process and procedure.

Chapter 6 Safety Management

(Hazard prevention)

Article 24

- 1) The Director shall provide the procedures and methods for capture of escaped animals.
- 2) If escaped animals are potentially hazardous to humans, society, or the natural environment, the President must contact government- and public-affiliated agencies immediately.
- 3) The Director, Laboratory Animal Manager, Principal Investigator, and Animal Technician shall immediately protect any transmission of infectious diseases and injuries from laboratory animals.
- 4) The Director shall prevent individuals in the general public from being involved in any care and use of laboratory animals.

(Disposal of waste materials)

Article 25

Carcasses of euthanized animals shall be cremated, and laboratory wastes shall be disposed of properly.

(Dealing with emergencies)

Article 26

- 1) The Director shall generate emergency manuals (e.g., for earthquakes or fire) and communicate their contents to the responsible persons in advance.
- 2) In an emergency, the Director shall strive to protect laboratory animals and avoid possible hazards from escaped animals.

Chapter 7 Education and Training

(Education and training)

Article 27

- 1) The required education and training program shall be provided to the Principal Investigator, Investigator, and Animal Technician before the animal experiment protocol is performed.
- 2) Attendance of symposia, seminars, and meetings may be accepted as an alternative way of educating and training the Laboratory Animal Manager.
- 3) The contents of education and training programs for animal experiments are based on “Points of education-and-training implementation in animal experiments”.

(Preservation of education and training records)

Article 28

The Director shall make a record and retain the name of the attendee, the date, content, and the name of the instructor for each education and training program.

Chapter 8 Other

(Self-inspections and self-assessments)

Article 29

- 1) The President shall order the IACUC to conduct periodic self-inspections and self-assessments to determine whether the experiments comply with the Standards Relating. The IACUC shall report the results of self-inspections and self-assessments to the President.
- 2) The IACUC may order the Director, Laboratory Animal Manager, Principal Investigator, Investigator, and Animal Technician to disclose documents for the self-inspections and self-assessments.
- 3) The President shall endeavor to have an uninterested (third) party evaluate the results of self-inspections and self-assessments.

(Disclosure)

Article 30

As an annual report, the President shall disclose the information related to animal experiments, in-house regulation, care and management of laboratory animals, and self-inspections and self-assessments with their results in printed form or by internet website, once every year.

(Other)

Article 31

If required, additional Acts shall be provided separately by the President.

(Supplementary provision)

This regulation is revised partially on June 27, 2012.

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