○Doshisha University Regulations on the Conduct of Animal Experiments and Related Activities (Established June 30, 2007)

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Chapter 1 General Provisions

(Purpose)

Article 1 These regulations, based on the provisions in the Act on Welfare and Management of Animals (Act No. 105 of October 1, 1973) (hereinafter "Animal Welfare Act"), Standards Relating to the Care and Management of Laboratory Animals and Relief of Pain (Notice No. 88 of the Ministry of the Environment, April 28, 2006) (hereinafter "Care and Management Standards"), Standards relating to the Methods of Destruction of Animals (Notice No. 40 of the Prime Minister's Office, July 4, 1995) (hereinafter "Animal Destruction Standards") and Fundamental Guidelines for Proper Conduct of Animal Experiment and Related Activities in Academic Research Institutions (Notice No. 71 of the Ministry of Education, Culture, Sports, Science and Technology, June 1, 2006) (hereinafter "Animal Experiment Guidelines"), set out necessary matters for the appropriate conduct of animal experiments and related activities from the standpoints of scientific rationale and animal welfare, as well as of environmental preservation and assurance of security of faculty, staff and students engaging in animal experiments and related activities.

(Fundamental Principle)

Article 2 Animal experiments and related activities shall be conducted according to the provisions of these regulations as well as the provisions of Animal Welfare Act, Care and Management Standards, Animal Destruction Standards, Animal Experiment Guidelines and other laws and ordinances.

2. When utilizing animals for scientific purposes, it must be conducted in conformity to the following principles on animal experiments and related activities.

（1） Methods must be employed which cause as little pain and stress as possible to the laboratory animals, while still allowing attainment of the scientific objective.

（2） Efforts must be made to replace laboratory animals with other research materials where possible, while still allowing attainment of the scientific

objective.

(3) Efforts must be made to reduce the number of animals used to as few as possible, while still allowing attainment of the scientific objective.

(Definitions)

Article 3 The following terms in these regulations are defined as below:

(1) Animal experiments and related activities refer to utilization of animals for education, testing, research and development, manufacture of biological products, or other scientific purposes.

(2) Laboratory animals refer to animals of mammalian, avian or reptilian species, reared or maintained in animal experimentation facilities, for use in animal experiments and related activities.

(3) Animal experiment protocol refers to a protocol planned beforehand for conduct of an animal experiment or related activities.

(4) Animal experimentation facilities refer to laboratories for conducting animal experiments and related activities and facilities for rearing and maintaining laboratory animals.

(5) Director of animal experimentation facilities refers to an individual who presides over the management of all the animal experimentation facilities, etc. of the university.

(6) Operation director refers to an individual who manages laboratory animals as well as animal experimentation facilities.

(7) Laboratory animal manager refers to an individual with knowledge and experience in laboratory animals who manages laboratory animals.

(8) Animal experiment researcher refers to an individual who performs animal experiments and related activities.

(9) Principal investigator refers to an animal experiment executor who presides over operations related to the execution of animal experiments and related activities.

(10) Animal technician refers to an individual who engages in rearing or maintenance of laboratory animals under the laboratory animal manager or the animal experiment researcher.

(Responsibilities in Conducting Animal Experiments and Related Activities)

Article 4 The responsibilities at Doshisha University to appropriately conduct animal experiments and related activities shall be as follows.

(1) The President shall ultimately assume the responsibility for all matters concerning the conduct of animal experiments and related activities.

(2) The director of animal experiment facilities shall be responsible for managing all animal experimentation facilities. The vice president of the Center for Environment and Laboratory Studies Support shall be appointed as the director of animal experiment facilities.

(3) The President shall appoint an operation director for each animal experimentation facility. The operation director shall be recommended by the

director of animal experimentation facility and commissioned by the President.

(４) The operation director shall appoint a laboratory animal manager for each animal experimental facility. At the laboratory which the principal investigator supervises, the principal investigator shall assume the responsibility of the laboratory animal manager,

(5) The animal experiment researcher shall perform the animal experiment under the supervision of the principal investigator. A principal investigator shall be a full-time faculty member of Doshisha University.

(6) The laboratory animal manager or the principal investigator shall appoint an animal technician. Animal technicians shall engage in these duties under the laboratory animal manager or animal experiment researcher.

(Scope of Application)

Article 5 These regulations shall apply to all animal experiments and related activities performed at Doshisha University that use living bodies of mammals, birds and reptiles as designated in Animal Welfare Act, Care and Management Standards, Animal Destruction Standards, and Animal Experiment Guidelines.

２ In the event animal experiments or related activities other than described in the previous paragraph are to be performed, efforts must be made to perform such experiments in compliance with the purpose of these regulations.

３ These regulations do not apply to rearing and maintenance of animals that aims at observing their ecology.

(Institutional Animal Experiment Committee)

Article 6 In order to achieve the purpose of these regulations, Doshisha University establishes Doshisha University Institutional Animal Experiment Committee (hereinafter referred to as “Committee”) under its Research Ethics Committee.

２ Matters concerning the Committee shall be stipulated separately.

Chapter 2 Conduct of Animal Experiments

(Submission of Animal Experiment Protocol)

Article 7 The principal investigator who intends to perform an animal experiment or related activities must prepare an animal experiment protocol based on the principles set out in paragraph 2 of Article 2 and submit the prescribed “Animal Experiment Protocol Form” to the President for approval.

(Preparation of Animal Experiment Protocol)

Article 8 When preparing an animal experiment protocol, the following items should be taken into consideration and proper methods of animal experiment must be selected in terms of the significance of the research and the necessity of animal experiment and related activities, as well as within the scope that allows attainment of the scientific objective.

(１) The animal experiment protocol must be prepared based on scientific rationality and from the standpoint of assuring the reliability of data obtained from the animal experiment and related activities.

(2) When selecting laboratory animals, it is necessary to consider what animal species are appropriate for the purpose of the animal experiment and related activities, the number of laboratory animals which will determine the accuracy and reproducibility of the results of the animal experiment, the genetic and microbiological quality, and the rearing conditions.

(Review of Animal Experiment Protocol)

Article 9 Matters concerning the review of animal experiment protocols shall be stipulated separately.

(Safety Management)

Article 10 When an animal experiment and related activities are to be conducted which involve physical or chemical agents or pathogens, or which may affect the safety or health of humans or the surrounding environment, the principal investigator must pay special attention to assurance of safety and maintenance of the health of the animal experiment researchers and follow the respective law and/or regulation, in accordance with the conditions of the facilities and equipment.

2 When an animal experiment and related activities that might affect the ecosystem are to be performed, such as an animal experiment or related activities using living modified organisms, special attention shall be given to prevention of escape or other undesirable events of the living modified organisms, in accordance with the conditions of the facilities and equipment.

(Acquisition, etc. of knowledge relating to zoonotic diseases)

Article 11 The principal investigator, the animal experiment researchers, as well as the animal technicians must endeavor to acquire sufficient knowledge relating to zoonotic diseases and to collect information. Additionally, they must endeavor to establish a communication system with public health organizations, etc. in order to swiftly take necessary measurements in the case of zoonotic disease outbreak.

(Experimental Procedures)

Article 12 Animal experiments and related activities must be performed using properly maintained and managed facilities and equipment.

2 The principal investigator must give consideration to the following points when performing the experimental procedures.

(1) Test reagents, drugs and laboratory equipment must be retained appropriately. Particular attention should be paid to the storage of controlled substances such as narcotics.

(2) Dead bodies of laboratory animals and laboratory waste must be disposed of appropriately. Particular attention should be paid to the disposal of controlled waste.

3 The animal experiment researcher must take into consideration the following points when performing the experimental procedures.

(1) To comply with provisions in the pre-approved “animal experiment protocol” and other relevant guidelines.

(2) To attend the last lecture of the education and training on handling laboratory-animals recommended by the Committee.

(3) To perform the procedures with necessary skills in restraining laboratory animals, administering drugs, obtaining samples, surgical procedures and so on.

(4) Highly invasive major surgery should be conducted under the guidance of a specialist with sufficient knowledge and experience.

(5) Even when food and water restrictions are required for research reasons, animals should be supplied the minimum amount of food and water required.

(6) Measures must be taken to reduce pain suffered by laboratory animals through the use of appropriate anesthetics, analgesic and sedative procedures and postoperative management.

(7) To consider the appropriate timing of termination of the experiment (humane endpoint).

(8) To acquire knowledge and skills related to euthanasia procedures and perform appropriate procedures.

(Reports of Animal Experiment Results)

Article 13 Immediately after the completion of the animal experiment and related activities, the principal investigator must report the number of laboratory animals used, whether any changes were made to the protocol, and the results of the experiment to the President, using the prescribed "Report of Animal Experiment".

(Suspension of Animal Experiment)

Article 14 In the case an animal experiment researcher violated these regulations, the President may suspend the said animal experiment.

Chapter 3 Rearing of Laboratory Animals

(Fundamentals of Rearing and Maintenance)

Article 15 In rearing and maintaining laboratory animals, the operation director and the laboratory animal manager must give consideration to the safety and health of humans and laboratory animals as well as influences on the ecosystem.

(Introduction of Laboratory Animals)

Article 16 The laboratory animal manager must introduce laboratory animals appropriately in compliance with applicable laws and ordinances.

2 Each time a laboratory animal is introduced, the laboratory animal manager must check abnormalities in its external appearance and other points and perform appropriate quarantine and acclimatization suitable for the species and conditions of the facilities.

(Supply of Food and Water)

Article 17 The laboratory animal manager, experimenters, and caretakers (hereinafter referred to as "laboratory animal manager, etc.") must supply laboratory animals with food and water appropriately, according to the animals' physiology, ecology and behavior.

(Health Management)

Article 18　To prevent injuries and diseases unrelated to the objective of the animal experiment, the laboratory animal manager, etc. must conduct necessary health management of laboratory animals, including conducting quarantine as required.

2　In the event of injury or disease unrelated to the objective of the animal experiment, the laboratory animal manager, etc. must provide affected laboratory animals with appropriate treatment.

(Rearing Different Animal Species or Multiple Animals)

Article 19　When rearing and maintaining different animal species or multiple laboratory animals in the same facilities, the laboratory animal manager, etc. must take into consideration the appropriate combination of animals according to their physiology, ecology and behavior.

(Retention and Report of Records)

Article 20　The laboratory animal manager, etc. must compile and maintain records of laboratory animal sources, rearing history, history of disease, etc.

2　The laboratory animal manager must report to the President the species and numbers of laboratory animals that reared and maintained each year.

(Provision of Information on Delivery of Animals)

Article 21　When delivering laboratory animals, the laboratory animal manager must provide information on the animal's features, rearing and maintenance methods, microbiological quality, infectious diseases, etc.

(Transportation)

Article 22　When transporting laboratory animals, the laboratory animal manager must endeavor to take care of the health and safety of the laboratory animals and to prevent any hazard, etc. for humans occurring due to the animals.

(Prevention of Injury)

Article 23　The operation director must determine methods of capturing escaped laboratory animals in advance.

2　If a laboratory animal that might injure or cause harm to humans escapes from a facility, the operation director must contact relevant authorities immediately.

3　To rear and maintain poisonous animals such as poisonous snakes, the operation director must separately stipulate necessary provisions in accordance with the Care and Management Standards to prevent the animals from causing harm to humans.

4　The operation director and the laboratory animal manager must prevent animal technicians from suffering infectious diseases and bites by laboratory animals, and must take necessary measures immediately if any of these occurs.

5　The operation director and the laboratory animal manager must take necessary measures to prevent people who are not involved in the rearing of laboratory animals or in animal experiments and related activities from touching laboratory animals.

(Emergency Measures)

Article 24　The operation director must draw up plans of measures to be implemented in the event of an emergency such as an earthquake or fire in advance and make the plans

known to relevant parties.

2 In an emergency situation, the operation director and the laboratory animal manager must endeavor to protect laboratory animals and prevent injury or harm to humans due to escape of laboratory animals.

Chapter 4 Animal Experimentation Facilities

(Establishment of Facilities)

Article 25 When establishing animal experimentation facilities, the operation director shall apply to and obtain approval from the President.

(Requirements for Rearing and Maintenance Facilities)

Article 26 Facilities for rearing and maintenance shall meet the following conditions, and the operation director must endeavor to appropriately maintain and manage the facilities and equipment.

(1) Having an appropriate structure according to the requirements for conduct of the research, as well as laboratory animals' physiology, ecology and behavior

(2) Having a structure that allows easy cleaning and disinfection of floors, inside walls, ceilings, and auxiliary equipment in the facilities, and meets the requirements for sanitary management

(3) Having a structure that maintains proper space, temperature, humidity, ventilation, lighting, etc. that allow laboratory animals to keep their body in a comfortable state

(4) Having a structure that eliminates the possibility of laboratory animals being injured or stressed by projections, holes, depressions, inclined planes, etc.

(5) Having a structure that enables animal technicians to perform daily operations easily without risk

(6) Assurance of structures and strength to prevent laboratory animals from escaping

(7) Measures are taken to prevent adverse effect on the surrounding environment caused by odor, noise and waste material

(8) Having rearing equipment suitable for the animal species and the number of animals reared

(9) A laboratory animal manager is appointed

(Requirements for Laboratory)

Article 27 A laboratory shall meet the following requirements, and the operation director must endeavor to appropriately maintain and manage the facilities and equipment.

(1) Having a structure that allows easy cleaning and disinfection to prevent contamination by blood and excrement

(2) Having a structure and strength to prevent laboratory animals from escaping, as well as maintaining the environment in which an escaped laboratory animal can be easily recaptured.

(3) Clean, hygienic conditions should be maintained at all times, and measures

should be taken to prevent adverse effect on the surrounding environment caused by odor, noise and waste material

(4) In the case an experiment in which laboratory animals are kept for more than one day is conducted in the laboratory, it must fulfill requirements for a "rearing and maintenance facility".

(Maintenance and Management of Facilities)

Article 28 The operation director must endeavor to properly maintain, manage and improve the facilities and equipment to prevent laboratory animals from being harmed by contamination of the rearing environment.

2 The operation director must take appropriate measures for managing entrance to and departure from the animal experimentation facilities.

(Closure of Facilities)

Article 29 In the event an animal experimentation facility is to be closed, the operation director must notify the President and, in cooperation with the principal investigator, endeavor to transfer the laboratory animals to other rearing and maintenance facilities.

Chapter 5 Education and Training, Self-inspections, Evaluations and Verification, Information Disclosure

(Education and Training)

Article 30 The President must implement necessary measures for providing the prescribed education and training on the following matters to animal experiment researchers, laboratory animal managers and animal technicians.

(1) Matters concerning related laws, ordinances, guidelines and these regulations

(2) Matters concerning methods of animal experiment and handling of laboratory animals

(3) Matters concerning rearing and maintenance of laboratory animals

(4) Matters concerning assurance of security and safety management

(5) Matters concerning the use of animal experimentation facilities

(6) Matters concerning zoonotic diseases

(7) Other matters concerning the proper conduct of animal experiments and related activities

2 Other necessary matters concerning education and training shall be stipulated separately.

(Self-inspections, Evaluations and Verification)

Article 31 To promote scientific animal experiments and related activities that give consideration to animal welfare, the President shall periodically perform self-inspections, evaluations and verification of compliance with the regulations.

2 Other necessary matters concerning self-inspections and evaluations shall be stipulated separately.

(Public Disclosure of Information)

Article 32　The President shall endeavor to increase the social transparency of the conduct of animal experiments and related activities by publicly disclosing information regarding animal experiments and related activities (Doshisha University Regulations on the Conduct of Animal Experiments and Related Activities, results of self-inspections, evaluations and verification regarding animal experiments and related activities, and conditions of rearing and maintenance of laboratory animals) through appropriate means, with consideration to protection of personal information and research information.

２　Other necessary matters concerning information disclosure shall be stipulated separately.

Chapter 6 Auxiliary Provisions

(Auxiliary Provisions)

Article 33　In addition to the provisions in these regulations, other necessary matters shall be stipulated separately.

(Administration)

Article 34　Administration of these regulations shall be handled by the Office of Center for Environment and Laboratory Studies Support and the Office of Ethics Review.

(Amendment and Termination)

Article 35　Amendment and termination of these regulations shall be determined by the President after discussion by the committee, the Research Ethics Committee, and the Committee of Deans and Directors.

Additional Clause

These regulations shall come into effect on January 1, 2026.