

Regulations for Animal Experimentation in Hyogo College of Medicine

[Objective]

Article 1

The present Regulations aim to stipulate provisions to be abided by in performing animal experiments in Hyogo College of Medicine (“the College” hereafter) pursuant to “Act on Partial Amendment of Act on Welfare and Management of Animals” (Act No. 68, dated June 1, 2005), “Act on Welfare and Management of Animals” (Act No.8, dated March 29, 1993 (“Act” hereafter) , “Standards Relating to the Care and Management of Laboratory Animals and Relief of Pain” (Notice No. 88 of the Ministry of the Environment, dated April 28, 2006) (“Care and Management Standards” hereafter) and ” Fundamental Guidelines for Proper Conduct of Animal Experiment and Related Activities in Academic Research Institutions” (Notice of the Ministry of Education and Science, dated June 1, 2006) (“Fundamental Guidelines” hereafter) and in accordance with “Guidelines for Proper Conduct of Animal Experiments” (Science Council of Japan, dated June 1, 2006) to ensure that animal experiments are conducted properly not only from the scientific standpoint but also from the standpoint of animal welfare, environmental conservation, and safety of personnel engaged in animal experiments.

[The Scope of the Regulations]

Article 2

- (1) These Regulations shall be applicable to all animal experiments, education, training and certification using Experimental Animals in the College (“Animal Experiments, etc.” hereafter).
- (2) Every effort must be made to adhere to the Regulations when animals other than those specified in Article 3 are used for experiments and related activities.
- (3) When Animal Experiments are performed in an institute other than the College they shall be conducted properly in accordance with the regulations

of the institute involved.

[Definitions]

Article 3

(1) The following terms used in the Regulations are defined below.

(i) “Breeding and Maintenance Facility” A facility where Experimental Animals are constantly bred or maintained, or Animal Experiments, etc. are conducted, with the approval of the President,

(ii) “Laboratory” An animal laboratory where experimental procedures are carried out on Experimental Animals (including temporary holding of animals for less than 48 hours), with the approval of the President.

(iii) “Facility, etc.” A Breeding and Maintenance Facility and a Laboratory.

(iv) “Experimental Animal” An animal of mammalian, avian and reptilian species, bred and maintained in the Facility, etc. (including those animals in transit to the Facility, etc.) for Animal Experiments, etc.

(v) “Animal Experiment Protocol” A protocol prepared prior to the initiation of Animal Experiments, etc.

(vi) “Facility Manager” A person supervising and managing the Facility, etc. and the Manager specified in “Care and Management Standards”

(vii) “Experimental Animal Manager”

A person who assists the President in supervising every operation of breeding and maintenance of Experimental Animals in the College.

(viii) “Manager of Animal Breeding and Maintenance” A person who manages Breeding and Maintenance Facilities, with the approval of the President.

(ix) “Animal Experiment Researcher” An individual who performs Animal Experiments, etc., with the approval of the President.

(x) “Principal Animal Experiment Researcher” One of the Animal Experiment Researchers who manages the work related to the conduct of Animal Experiments, with the approval of the President.

(xi) “Animal Technician” An individual engaged in breeding and maintenance of Experimental Animals under the Facility Manager or the

Experimental Animal Manager.

(xii) “Manager, etc.,” The Facility Manager, the Experimental Animal Manager, the Manager of Animal Breeding and Maintenance, the Animal Experiment Researcher, and the Animal Technician.

(xiii) “Law, etc.” Laws (including pertinent government decrees and ministerial ordinances), bylaws, regulations, standards, directives and guidelines, shown in Table 1.

[Responsibility of the President]

Article 4

(1) The President shall bear ultimate responsibility for the conduct of Animal Experiments, etc. and the breeding and maintenance of Experimental Animals in the College and shall be responsible for the following items.

(i) Maintenance of the Breeding and Maintenance Facility.

(ii) Establishment of an Animal Experiment Committee.

(iii) Approval of Animal Experiment Protocols, maintaining knowledge of the status of operation and the outcome, and measures for improvement.

(iv) Approval of appointment of the Manager of Animal Breeding and Maintenance, the Principal Animal Experiment Researcher and the Animal Experiment Researcher.

(v) Approval of the Breeding and Maintenance Facility and the Laboratory.

(vi) Safety management of Animal Experiments, etc.

(vii) Implementation of education and training.

(viii) Measures, such as self-inspection and -evaluation, and public disclosure of information, etc., to enhance the trust of society with respect to Animal Experiments, etc.

(ix) Other measures necessary for proper conduct of Animal Experiments, etc.

(2) The President shall be able to delegate part of the responsibilities listed in the preceding section to the Animal Experiment Committee, the Facility Manager and the Experimental Animal Manager.

[Animal Experiment Committee]

Article 5

(1) Hyogo College of Medicine Animal Experiment Committee (“Committee” hereafter) shall be established in the College.

(2) The Committee, with a mandate from the President, shall review or investigate the following matters and submit reports or advice to the President.

(i) Conformity of Animal Experiment Protocols with the Law, etc. and the present Regulations.

(ii) The appointment of the Manager of Animal Breeding and Maintenance, the Principal Animal Experiment Researcher and the Animal Experiment Researcher.

(iii) The status of operation and the outcome of Animal Experiment Protocols.

(iv) The Facility, etc. and the breeding and maintenance of Experimental Animals.

(v) The content or the system of education and training on Animal Experiments, proper handling of Experimental Animals, and the Law, etc.

(vi) Self-inspection and -evaluation and Disclosure of information.

(vii) Other necessary matters concerning proper conduct of Animal Experiments, etc.

(3) The Committee shall consist of the following members.

(i) Several individuals with excellent knowledge and experience regarding Animal Experiments, etc.

(ii) Several individuals with excellent knowledge and experience regarding Experimental Animals.

(iii) Several individuals of scholarship and experience.

(4) Selection and the terms of office of the Committee members and the Committee chairperson and other matters related to the composition and operation of the Committee shall be stipulated separately.

[Notification under Prefectural Acts]

Article 6

(1) The representative of Hyogo College of Medicine Educational Corporation (“Educational Corporation” hereafter) shall notify the Governor of Hyogo Prefecture (“Governor” hereafter) of breeding and maintenance of Experimental Animals (including changes) in the Breeding and Maintenance Facility of the College, in accordance with Act No. 25.

(2) When the Facility Manager of a breeding and maintenance facility other than the Animal Experiment Facility obtains President’ s approval of the Breeding and Maintenance Facility, he shall request the Educational Corporation to submit a notification of the Breeding and Maintenance Facility to the Governor, in accordance with the Act.

(3) When matters under Act No. 25-(2)-(ii), -(iv) and -(v) (concerning the species of Experimental Animals, the structure and scale of the Facility, and the procedures for breeding and maintenance) are to be changed or a Breeding and Maintenance Facility is to be closed, the Facility Manager shall promptly submit a request similar to that stated in the preceding section.

(4) The Educational Corporation shall designate a person responsible for the management of Experimental Animals in accordance with Act No. 32 and report to the Governor without delay.

(5) The Experimental Animal Manager shall be designated as the person responsible for the management of Experimental Animals under Act No. 32.

[Establishment of Breeding and Maintenance Facility]

Article 7

(1) To establish a Breeding and Maintenance Facility (including a change), an “Application for the Establishment of the Breeding and Maintenance Facility” (Form No. 5) shall be submitted to the President for approval. The Breeding and Maintenance Facility shall not be established within medical treatment facilities, such as hospital, etc.

(2) Experimental Animals shall not be reared or maintained outside the

Breeding and Maintenance Facility.

(3) The President shall have the Committee review the proposed Breeding and Maintenance Facility and, on the basis of advice from the Committee, decide to grant or not to grant approval.

(4) The President shall have the Experimental Animal Manager periodically examine whether the Breeding and Maintenance Facility is managed properly or not.

(5) The Experimental Animal Manager shall report the results of inspection to the Committee and, in case of a problem, report to the President.

(6) When a problem is pointed out by the Experimental Animal Manager, the President shall direct and advise the Facility Manager to manage the Breeding and Maintenance Facility properly.

(7) The Facility Manager shall remedy the problem in accordance with the directions and advice of the President.

(8) The Facility Manager of the Breeding and Maintenance Facility shall designate, with the approval of the President, an individual with knowledge and experience regarding animal experimentation as Manager of Animal Breeding and Maintenance and have him manage the Breeding and Maintenance Facility properly.

[Requirements for Breeding and Maintenance Facility]

Article 8

(1) The Breeding and Maintenance Facility shall fulfill the following requirements.

(i) It is structured in such a way as to maintain proper temperature, humidity, air circulation, and brightness.

(ii) It has breeding equipment and facilities that match the species and number of animals under care.

(iii) It is made of floors and walls that are easily cleaned and sterilized and has sanitary equipment for cleaning and sterilization of instruments.

(iv) It has a design and sufficient strength to prevent Experimental Animals from escaping.

(v) It is equipped with measures to prevent adverse effects on the surrounding environment due to odor, noise and waste, etc.

(vi) It has a Manager of Animal Breeding and Maintenance.

[Installment of Laboratory]

Article 9

(1) When a Laboratory (including a change) is to be established outside the Breeding and Maintenance Facility, an “Application for Permission to Install a Laboratory” (Form No. 6) shall be submitted to obtain President’s approval. Except for special cases, the Laboratory shall not be installed within medical treatment facilities, such as hospital, etc.

(2) The President shall have the Committee review the proposed Laboratory and, on the basis of advice from the Committee, decide to approve or not to approve the Laboratory.

(3) No animal experiments shall be permitted outside the Breeding and Maintenance Facility and the Laboratory.

(4) In principle, Experimental Animals shall not be held in the Laboratory for more than 48 hours.

[Requirements for Laboratory]

Article 10

(1) The Laboratory shall fulfill the following requirements.

(i) It has a structural design and strength to prevent Experimental Animals from escaping, and maintains an indoor environment where Experimental Animals, should they escape, are easy to capture.

(ii) It has a structural design that facilitates cleaning and sterilization of places contaminated by excrements and blood, etc.

(iii) It maintains clean conditions and is equipped with measures to prevent adverse effects on the surrounding environment due to odor, noise and waste, etc.

[Maintenance and Improvement of Facility, etc.]

Article 11

The Facility Manager shall strive to conduct proper management of Experimental Animals and ensure maintenance and improvement of the Facility, etc. that are necessary for the conduct of Animal Experiments, etc.

[Abolishment of Facility, etc.]

Article 12

(1) When a Facility, etc. are to be abolished, the Facility Manager shall notify the President by submitting a “Notification of Abolishment of the Facility, etc.” (Form No.7).

(2) The Facility Manager shall try to transfer Experimental Animals under care to other Breeding and Maintenance Facilities, as required, in collaboration with the Manager of Animal Breeding and Maintenance and the Principal Animal Experiment Researcher.

[Animal Experiment Facility]

Article 13

(1) Hyogo College of Medicine Institute for Animal Experimentation (“Animal Experimentation Facility” hereafter) shall be established as Breeding and Maintenance Facility in the College.

(2) The organization and operation of the Animal Experiment Facility shall be stipulated separately.

(3) An Administrator of the Institute for Animal Experimentation (“Facility Administrator” hereafter) shall be designated as Facility Manager of the Animal Experimentation Facility.

(4) The Facility Administrator, with a mandate from the President, shall ensure proper maintenance of a breeding environment in the Animal Experimentation Facility and of the building and equipment, etc.

(5) The Experimental Animal Manager shall be designated as Manager of Animal Breeding and Maintenance of the Animal Experimentation Facility.

[Principal Animal Experiment Researcher]

Article 14

(1) The President shall approve the appointment of a Principal Animal Experiment Researcher based on Form No. 8 submitted.

(2) The President shall be able to delegate deliberations on the appointment of the Principal Animal Experiment Researcher to the Committee.

[Animal Experiment Researcher]

Article 15

(1) The President shall approve the appointment of an Animal Experiment Researcher based on Form No. 9 and certificates submitted.

(2) The President shall be able to delegate deliberations on the appointment of the Animal Experiment Researcher to the Committee.

[Preparation, Review and Procedures of Animal Experiment Protocol]

Article 16

(1) The Principal Animal Experiment Researcher shall prepare an Animal Experiment Protocol considering the following matters from the standpoint of proper execution of Animal Experiments, etc. and submit Form No. 1 Animal Experiment Protocol to the President.

(i) Objective, significance and necessity of research

(ii) Consideration must be given to proper use of Experimental Animals by adopting alternative protocols in which Experimental Animals are replaced with other research materials where possible.

(iii) Consideration must be given to the appropriate use of Experimental Animals by reducing the number of animals used to as few as possible. In these cases, it is necessary to consider the selection of Experimental Animal species appropriate for the purpose of Animal Experiments, etc., the number of Experimental Animals that will determine the accuracy and reproducibility of the results, the genetic and microbiological quality, and the rearing conditions.

(iv) Methods must be used that cause as little pain and distress as possible to Experimental Animals, while still allowing attainment of the scientific objective.

(v) Establishment of a humane endpoint must be considered, at the planning stage, for Animal Experiments, etc. with a high degree of suffering of Experimental Animals, such as lethal toxicity tests, infection experiments, and irradiation experiments, etc.

(2) When an Animal Experiment Protocol is submitted by a Principal Animal Experiment Researcher, the President shall delegate review of the Protocol to the Committee and notify the Principal Animal Experiment Researcher of the results in Form No. 2.

(3) The Principal Animal Experiment Researcher shall not initiate experiments until after the President approves the Animal Experiment Protocol.

(4) When the objective or conditions of the experiment, the species or strain of Experimental Animals or dietary conditions are to be changed or when three years have passed since the Animal Experiment Protocol of the same content was submitted and reviewed, the Principal Animal Experiment Researcher shall file a new application, not a revised application.

(5) When a change in the Animal Experiment Protocol other than the objective or conditions of the experiment, the species or strain of Experimental Animals and dietary conditions is to be introduced, the Principal Animal Experiment Researcher shall submit Form No.3 for approval.

(6) When the Principal Animal Experiment Researcher is to be changed, a new application must be submitted even if the Animal Experiment Protocol is the same or the change is one stipulated in section (5).

[Experimental Procedures]

Article 17

(1) The Animal Experiment Researcher shall conduct animal experiments based on the Law, etc. and in strict accordance with the following terms.

(i) Animal Experiments, etc. shall be conducted in appropriately maintained

and managed Facilities, etc.

(ii) Terms stated in the Animal Experiment Protocol and below.

(a) Use of proper anesthetics and analgesics.

(b) Consideration of the timing of completion of an experiment (including the humane endpoint).

(c) Proper postoperative management

(d) Selection of proper euthanasia

(iii) Euthanasia in the preceding item shall be properly performed according to “Directives related to Methods of Disposal of Animals” (General Administrative Agency of the Cabinet Notification No. 40) and also in consideration of international guidelines, etc.

(iv) Experiments that require safety management (experiments using physically and chemically hazardous materials, pathogens, and genetically engineered animals, etc.) shall meet the Law, etc. and relevant regulations, etc. of the College.

(v) When Animal Experiments, etc. involving physically or chemically hazardous materials or pathogens are to be conducted, proper facilities and equipment shall be secured for safety and the Animal Technician, etc. shall be provided with relevant information.

(vi) Prior to the initiation of the experiment, necessary experimental techniques, etc. shall be acquired.

(vii) A major, highly invasive, operation on a living animal shall be performed under supervision of a person of experience, etc.

(2) When an Animal Experiment Protocol is completed or discontinued, the Principal Animal Experiment Researcher shall report the number of animals used and the results obtained, etc. to the President using Form No. 4.

[Introduction and Transfer of Experimental Animals]

Article 18

(1) The Facility Manager and the Animal Experiment Researcher shall observe the following matters in introducing and transferring Experimental Animals.

- (i) Confirmation of the health condition and the presence or absence of abnormality of the animal, and health inspection and quarantine, as needed.
- (ii) Transfer of genetically engineered animals and specific alien animals in conformity with the Law, etc.
- (iii) Measures necessary for acclimatization and adaptation of Experimental Animals to the breeding environment.

[Breeding and Maintenance of Experimental Animals]

Article 19

- (1) The Animal Technician and the Animal Experiment Researcher, under the guidance of the Experimental Animal Manager, shall supply food and water to Experimental Animals properly according to physiology, ecology and habit, etc., observe the condition of the animals and report any abnormality, if found, to the Facility Manager and the Experimental Animal Manager during the entire period from the time of introduction of the Experimental Animals to the time of completion or discontinuation of the experiment.
- (2) The Facility Manager shall undertake necessary healthcare management for Experimental Animals to protect them from injury and disease not related to the experimental purpose.
- (3) When an Experimental Animal suffers injury or illness not related to the experimental purpose, the Facility Manager, with proper advice from the Experimental Animal Manager, shall prevent zoonosis and the spread of disease in the premises by means of treatment or selection,
- (4) The Experimental Animal Manager shall provide appropriate advice with respect to the treatment or selection of Experimental Animals described in the preceding section.

[Retention of Records and Reporting]

Article 20

- (1) The Manager, etc. shall retain up-to-date records on the source of supply, breeding history and disease history, etc. of Experimental Animals.
- (2) The Facility Manager shall annually report to the President the species

and number of Experimental Animals reared and maintained.

[Transportation]

Article 21

In transportation of Experimental Animals, the Manager, etc. shall strive to maintain good health and safety of Experimental Animals and to prevent them from inflicting harm on people, in strict compliance with the Care and Management Standards.

[Prevention of Harm]

Article 22

(1) The Facility Manager shall establish measures for capturing escaped Experimental Animals.

(2) When an Experimental Animal that potentially harms people escapes from the Facility, etc., the Manager, etc. shall promptly report to the President and relevant authorities.

(3) The Facility Manager shall establish preventive measures against infectious diseases originating from Experimental Animals and bite injuries, etc. caused by Experimental Animals and take necessary steps in such event.

(4) When poisonous or noxious animals are bred or maintained, the Facility Manager shall stipulate necessary provisions to prevent them from inflicting harm on people, based on the Care and Management Standards.

(5) When Animal Experiments, etc. that might affect the ecosystem, such as Animal Experiments, etc. using genetically engineered animals, etc., are to be performed, the Facility Manager shall pay special attention to the prevention of escape, etc. in consideration of the condition of the Facility, etc.

(6) The Facility Manager shall take necessary measures to prevent people not involved in the breeding of Experimental Animals or the conduct of Animal Experiments, etc. from contacting with Experimental Animals, etc.

[Education and Training, etc.]

Article 23

(1) The Facility Manager and the Experimental Animal Manager shall attend conferences, etc. organized by relevant ministries and academic societies, etc. to acquire knowledge and information, etc. necessary for the proper conduct of Animal Experiments, etc. and for the proper breeding and maintenance of Experimental Animals.

(2) The Experimental Animal Manager, with a mandate from the President, shall periodically implement educational and training programs involving the following items to ensure that Animal Experiment Researchers and Animal Technicians shall acquire the basic knowledge for the proper conduct of Animal Experiments, etc. and for the proper breeding and maintenance of Experimental Animals.

(i) The Law, etc. and the Regulations, etc. of the College.

(ii) The methodology of animal experiments and the handling of Experimental Animals.

(iii) Breeding and maintenance of Experimental Animals.

(iv) Security and safety management.

(v) The use of the Facility, etc.

(vi) Other items concerning the proper conduct of Animal Experiments, etc.

(3) The President shall give consideration to proper implementation of item (1) and (2). (4) Records on the date of instructions, educational content, and the names of the instructors and those receiving instructions shall be retained.

(5) The President shall ascertain the effect of the education and training provided and have those students with inadequate results take the education and training program for the second time.

(6) Education and training shall be implemented continually as needed.

(7) The President shall issue "Certificate of Education and Training" to those who have completed the education and training program.

[Self-inspection and -evaluation]

Article 24

(1) The Committee, with a mandate from the President, shall periodically implement self-inspection of compliance with the Fundamental Guidelines with respect to the breeding and maintenance of Experimental Animals and the conduct of Animal Experiments, etc. in the College and report the self-evaluation of the self-inspection to the President.

(2) The President shall endeavor to have the self-evaluation in the preceding section verified by a third party, independent of the College.

[Disclosure of Information]

Article 25

The President shall publicly disclose information regarding the Animal Experiments, etc. in the College (Regulations for Animal Experimentation, etc., the status of breeding and maintenance of Experimental Animals, and the results of the self-inspection and -evaluation and the verification, etc.) once a year through distribution of an annual report, etc.

[Penalty]

Article 26

(1) The President shall immediately halt animal experiments by those who have violated the present Regulations and prohibit them from conducting animal experiments for a certain period of time.

(2) The President shall be able to seek advice from the Committee on the imposition of penalty.

[Compliance]

Article 27

Concrete methods for proper conduct of Animal Experiments, etc. and proper breeding and maintenance of Experimental Animals in the College shall be governed by and construed under the "Guidelines" .

[Miscellaneous Provision]

Article 28

The President shall separately stipulate necessary provisions other than those in the present Regulations.

[Supplementary Provision]

The present Regulations shall come into effect beginning October 1st, 2007.

[Supplementary Provision]

The revised Regulations shall come into effect beginning December 15th, 2009.

Table 1.” The Law, etc.” described in Article 3-(1)-(xiii).

1) With respect to introduction and transfer of experimental animals.

Act on Welfare and Management of Animals

Ordinance on Welfare and Management of Animals (Hyogo Prefecture)

Standards relating to the care and management of laboratory animals and relief of pain

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

Guidelines for Proper Conduct of Animal Experiments

Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms

Law Concerning Prevention of Infection of Infectious Diseases and Patients with Infectious Diseases

Act on Domestic Animal Infectious Diseases Control

Rendering Plant Control Law

Wildlife Protection and Hunting Law

Invasive Alien Species Act

Quarantine Act

Rabies Prevention Act

2) With respect to other matters related to the conduct of animal experiments

Act on Prevention of Irradiation Damages by Radioactive Isotopes, etc.

Pharmaceutical Affairs Law

Regulatory Rules for Drugs and Medicines for Animal Use

Poisonous and Deleterious Substances Control Law

Narcotics and Psychotropics Control Law

Stimulants Control Law

Industrial Safety and Health Law

Working Environment Measurement Law

Health Promotion Law

Labor Standards Law

School Health Act

Law for Securing the Proper Operation of Worker Dispatching Undertakings
and Improved Working Conditions for Dispatched Workers