

Nara Medical University
Institutional Animal Care and Use Committee Statement
(Animal Experiment Management Regulations)

(Aim and basic principles)

- Article 1** These regulations prescribe requirements for properly conducting animal experiments and related activities at Nara University (Hereinafter, “this university.”) from the perspective of science, animal welfare and environmental protection, as well as ensuring the safety of faculty, staff, students and others in performing experiments.
- 2 Animal experiments and related activities are governed by these regulations, in addition to the Act on Welfare and Management of Animals (Act No. 79 of 2012. Hereinafter, “the Act.”), Standards Relating to the Care and Management of Laboratory Animals and Relief of Pain (2013 Ministry of the Environment Notice No. 84, hereinafter “Basic Rule for Keeping and Managing Laboratory Animals.”), 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, “Fundamental Guidelines.”), Guidelines for Proper Conduct of Animal Experiments prepared by Science Council of Japan (Hereinafter, “Guidelines.”), and other laws and statutes.

(Definitions)

- Article 2** In these regulations, the meanings of the terms listed below are respectively prescribed in each line:
- 1) Animal experiments and related activities: Refers to providing animals for education, experiment and research, manufacturing biological preparations, and other scientific uses
 - 2) Facilities: Refers to facilities and equipment for ongoing breeding and keeping of experimental animals, and animal experiments and related activities (Hereinafter, “breeding and keeping facilities.”. Also refers to animal laboratories for animal experiments and related activities (Hereinafter, “laboratories.”).
 - 3) Experimental animals: Refers to animals belonging to mammals, birds or reptiles raised or kept in facilities to be provided for use in experiments and other activities (Including those transported for introduction into facilities)
 - 4) Animal experiment design: Refers to designs related to conducting animal experiments and related activities.
 - 5) Animal experimenters: Refers to persons conducting animal experiments and related activities.
 - 6) Animal experiment supervisors: Refers to animal experiments managing work related to conducting animal experiments and related activities.
 - 7) Managers: Refers to persons managing experimental animals and facilities under the university president (facility directors prescribed in Nara Medical University Nara Medical University Advanced Medical Research Organization Facilities Management and Operating Regulations).
 - 8) Experimental animal managers: Refers to persons assisting managers having knowledge and experience related to experimental animals and responsible for management of experimental animals.
 - 9) Animal experiment safety director: Refers to persons assisting the university president related to ensuring the safety of animal experiments.
 - 10) Animal experiment utilities managers: Refers to persons managing work that includes the operation and maintenance of utilities in animal experiment facilities, including power and plumbing systems.
 - 11) Animal caretakers: Refers to persons engaged in breeding or keeping experimental animals under experimental animal managers or animal experimenters.
 - 12) Managers: Refers to the university president, managers, animal experiment safety directors, experimental animal managers, animal experimenters and animal caretakers.
 - 13) Guidelines: Refers to Fundamental Guidelines and Guidelines.

(Scope of application)

- Article 3** These regulations apply to all animal experiments using animals belonging to mammals, birds and reptiles conducted at this university.
- 2 An effort shall be made so that animals other than mammals, birds and reptiles for experiments and other activities are also provided in accordance with the aims of these regulations.
- 3 In the event that animal experiments and related activities are contracted to a different institution, animal experiments and related activities are confirmed to be properly conducted in accordance with Fundamental Guidelines or other rules and regulations related to animal experiments and related activities prescribed by other ministries and government offices.

(University president)

- Article 4** The university president establishes systems, including utilities and support organizations for animal experiment facilities (Hereinafter, “facilities.”), and performs the professional duties listed below so that animal experiments are conducted safely and properly.
- 1) Establishes an animal experiment committee (Hereinafter, “committee.”), and approves animal experiment designs through deliberation by the committee.
 - 2) Enacts, revises and abolishes rules and regulations through deliberation by the committee.
 - 3) Appoints the animal experiment safety director (Hereinafter, “safety director”).

- 4) Conducts education, training, and health management for animal experiments.
- 5) Is involved in self-inspections, evaluations and disclosing information.
- 6) Handles other necessary matters.

(Facilities organization)

Article 5 The positions listed below are established in addition to the positions prescribed in the Nara Medical University Nara Medical University Advanced Medical Research Organization Facilities Management and Operating Regulations, for the benefit of animal experiment safety and proper breeding management of experimental animals.

- 1) Experimental animal manager
- 2) Safety director
- 3) Animal experiment utilities managers

(Committee establishment)

Article 6 A committee is established in order to ensure proper conduct and safety of animal experiments at this university.

- 2 The committee consists of the persons listed below.
 - 1) Select faculty of this university involved in animal experiments
 - 2) Managers
 - 3) Experimental animal managers
 - 4) Safety directors
 - 5) Nara Medical University recombinant DNA experimental safety committee chairman
 - 6) Animal experiment utilities managers
 - 7) Other select persons deemed necessary by the university president
- 3 The committee members in line 1) of the preceding clause are appointed by the university president through discussion by the educational research council.
- 4 The term of office of the committee members appointed according to line 1) and line 7) in clause 2 is two years with possibility of reappointment. However, if there is a vacancy in committee members, the term of office of any replacement shall be equal to the remaining term of their predecessor.
- 5 A committee chairman shall be established for the committee, and shall be elected by committee members by mutual vote.
- 6 The committee chairman shall convene the committee as necessary and act as its present.
- 7 If the committee chairman should be incapacitated, then a committee member previously designated by the committee chairman shall act on their behalf.
- 8 The committee may not be convened if two-thirds or more subcommittee members are not in attendance.

(Professional duties of the committee)

Article 7 The committee shall deliberate and survey the matters listed below in accordance with inquiries and similar requests by the university president, and shall submit or report to the university president anything regarding these matters, and provide guidance and advice to experiments as necessary.

- 1) Matters related to the enactment and abolition of regulations and other rules.
 - 2) Matters related to animal experiment design.
 - 3) Matters related to the status and results of animal experiment design.
 - 4) Matters related to animal experiment facilities and the breeding and keeping status of experimental animals.
 - 5) Matters related to education, training and health management related to experiments.
 - 6) Matters related to self-inspection and evaluation of animal experiments.
 - 7) Matters related to corrective action and improvements needed when hazards or accidents arise.
 - 8) Other matters related to ensuring the safety of experiments.
- 2 The committee may request reporting to animal experiment supervisors and safety director as necessary.
 - 3 The committee may seek the attendance of non-committee members and may hear their opinions when deemed necessary.

(Safety director)

Article 8 Safety directors shall perform the professional duties listed below in order to assist the university president in ensuring the safety of experiments.

- 1) Provide guidance and advice to animal experiment supervisors.
- 2) Be involved in managing and keeping copies of documents related to approval of animal experiment designs.
- 3) Confirm that animal experiment supervisors and animal experimenters are properly carrying out experiments according to these regulations.
- 4) Be involved in matters concerning ensuring the safety of all other experiments.

(Experimental animal manager)

Article 9 Experimental animal managers are appointed from among the faculty of this university by the university president.

- 2 Experimental animal managers shall provide the supervision necessary so facilities are used safely and without hazards, and perform the professional duties listed below for the breeding of animals in accordance with animal experiment designs.
 - 1) Duties related to permission to use animal breeding rooms in accordance with animal experiment designs.

- 2) Provide guidance and advice to animal experiment supervisors and animal experiments in animal breeding.
- 3) Duties related to permission for animal experiment supervisors and animal experiments to use laboratories.
- 4) Other duties necessary for management.

(Animal experiment utilities managers)

Article 10 Animal experiment utilities managers (Hereinafter, "utilities managers.") manage work including the operation and maintenance of utilities, including power, plumbing and ventilation systems according to the instructions of experimental animal managers.

- 2 Utilities managers act as property manager.

(Animal experiment supervisors)

Article 11 Animal experiments shall prescribe animal experiment supervisors per each animal experiment design when conducting experiments.

- 2 Animal experiment supervisors shall act as faculty for the classrooms to which animal experimenters belong.

(Professional duties of animal experiment supervisors)

Article 12 Animal experiment supervisors shall perform the professional duties listed below for proper animal experiment design.

- 1) Collect animal experiment designs and apply to the president of the university for approval.
- 2) Provide guidance and advice to animal experimenters in experimental animals and animal experiments.
- 3) Perform other duties necessary for ensuring the safety of experiments.

(Animal experimenters)

Article 13 Animal experimenters shall comply with the requirements listed below when conducting animal experiments.

- 1) Propose animal experiment designs, submit them to the university president through animal experiment supervisors, and obtain approval.
- 2) Respect the advice of the committee, safety directors and experimental animal managers on experimental animals and animal experiments, and follow their guidance.
- 3) Particularly follow the directions of experimental animal managers regarding genetic and microbiological quality when selecting test animals.

(Proposal, application and approval of animal experiment design)

Article 14 Animal experiment supervisors shall propose animal experiment designs based on the requirements listed below from the viewpoint of ensuring the scientific rationality of data obtained from animal experiments and related activities and the ethics of animal experiments, and then submit an Animal Experiment Design Application Approval Form (which also serves as Breeding Ground Use Application Form. Form No. 1) to the university president, and obtain approval for animal experiment designs and breeding room use.

- 2 The points listed below shall be considered in making proposals.
 - 1) Within the feasible scope of achieving the aims of scientific use, experimental animals shall be properly used, including the use of substitutes instead of providing experimental animals as much as possible.
 - 2) Within the feasible scope of achieving the aims of scientific use, experimental animals shall be properly used, including minimizing the number of experimental animals provided for use as much as possible. In which case, the selection of experimental animal species suitable for the aims of animal experiments and related activities, the number of experimental animals governing the accuracy and reproducibility of animal experiment results, genetic and microbiological quality, and breeding conditions shall be considered.
 - 3) To the extent necessary for scientific use, experimental animals will be caused no pain as much as possible.
 - 4) The aims, significance and necessity of the study shall be clarified.
 - 5) If highly painful animal experiments and related activities are conducted (lethal toxicity testing, infection experiments, radiation exposure experiments and other activities), then the establishment of cut-off times (Hereinafter, "human endpoints.") in order to alleviate experimental animals of severe pain shall be investigated at the stage of planning animal experiments and related activities.
- 3 Animal experiment supervisors may not conduct experiments unless it is after obtaining the approval of the university president for animal experiment designs.
- 4 The university president shall notify the relevant persons of the results from reviews of the content of application forms in the preceding clause by the committee and other bodies with a Final Review Results Notification Form (Form No. 2).
- 5 In the event that the scope of use encompasses radioisotope experiment facilities, recombinant DNA experiment facilities, and university joint research facilities, facility use shall be approved after obtaining the consent of each facility.

(Use of facilities)

Article 15 All animal experiments conducted by animal experimenters shall be conducted within facilities. However, this does not apply to experiments performed outside of facilities pursuant to discussion by the committee, particularly those deemed appropriate by the university president. However, animals may not be brought back into facilities.

- 2 Users of facilities shall comply with the requirements listed below in order to maintain order and cleanliness within facilities.
 - 1) Enter and exit facilities through reserved doors, and once inside facilities change to indoor footwear, put on protective clothing and wear protective masks and headgear.
 - 2) Use the south-side down way for transport of clean breeding equipment that has been washed and sterilized, for example. Store clean breeding equipment in the breeding equipment storage room. Use the east-side down way only for transport of dead animal bodies or unclean used breeding equipment, for example.
 - 3) Use elevators in the middle of facilities only for moving experimenters and animals.
 - 4) Do not enter and exit breeding rooms and laboratories other than areas permitted pursuant to an Animal Experiment Design Form.
 - 5) Comply with any specially prescribed knowledge and work procedures for the use of breeding rooms and laboratories.
 - 6) Follow any other special requirements directed by experimental animal managers.
 - 7) In principle, the cleaning of breeding rooms and laboratories is always performed by animal experimenters.
 - 8) Facility lights are turned on and off at prescribed times, so animal experimenters shall notify experimental animal managers and obtain permission in advance when turning lights on and off outside of normal operating hours.

(Animal purchasing and transport)

Article 16 Managers shall endeavor to introduce experiment animals from institutes properly managed pursuant to relevant laws, regulations and guidelines.

- 2 Animal experiments who have received approval according to article 14, clause 4 shall order and transport purchased animals in accordance with a Final Review Results Notification Form (Form No. 2).
- 3 The approval of an experimental animal manager shall be obtained for the transport of special animals.

(Animal acceptance inspection and quarantine)

Article 17 Experimental animal managers shall confirm the ordering conditions of animals and whether or not there are any errors when transporting animals to facilities, and then make a record including the state of the animals, the transportation method and the transportation time.

- 2 Experimental animal managers shall properly quarantine and isolate experimental animals when introducing them.
- 3 Experimental animal managers shall take the necessary corrective action so experimental animals acclimatize and adapt to their breeding environments.

(Preparation and dissemination of standard operating procedures)

Article 18 Managers and experimental animal managers shall prescribe manuals for animal breeding and keeping, and disseminate them among animal experimenters and animal caretakers.

(Breeding management of experimental animals)

Article 19 Experimental animal managers, animal caretakers and animal experimenters shall cooperate in complying with the requirements listed below.

- 1) Endeavor to properly maintain and manage facilities and equipment, and perform proper breeding management, including feeding, watering and managing animal waste as required by the physiology, ecology and habits of experimental animals.
- 2) Endeavor to properly maintain lighting and other environmental conditions in breeding rooms and laboratories (including climate factors, habitat factors, cohabitation factors and microbial contamination).
- 3) Closely monitor the status of animals and take appropriate steps throughout all periods; naturally during experiments, but also from facilities transport to disposal.

(Experiment operation)

Article 20 When conducting animal experiments and related activities, animal experimenters shall follow the Act, the Basic Rule for Keeping and Managing Laboratory Animals, and Guidelines, and especially the requirements listed below.

- 1) Use properly maintained and managed facilities to conduct animal experiments and related activities.
- 2) Refer to requirements listed in Animal Experiment Design Form and Guidelines, and consider the following matters.
 - A. Use of proper anesthetics and analgesics
 - B. Consideration of ending times for experiments (including humane end points)
 - C. Proper postoperative management
 - D. Selection of proper euthanasia
- 1) Endeavor to learn the necessary experimental techniques prior to conducting experiments.
- 2) Conduct highly-invasive, large-scale in vivo surgery under the guidance of an experienced person.
- 2 Animal experimenters shall seek the judgment of experimental animal managers or the committee when necessary.

(Steps after terminating or interrupting experiments)

Article 21 Animal experiments shall comply with the requirements listed below when ending or interrupting experiments.

- 1) In the event that an experiment is ended or interrupted, animals shall be promptly euthanized according to standards, and an Animal Experiment End Report Form (Form No. 3) is submitted to the university president.

- 2) Endeavor to prevent generation of foul odors or biological hazards from pathogens when storing animal corpses.
- 3) Animal corpses and waste shall be incinerated during breeding or after experiments in accordance with the requirements listed below.
 - A. Corpses or waste shall be sealed in a prescribed plastic bag, and then placed in a location designated by an experimental animal manager.
 - B. When a facility director takes the necessary steps in accordance with the preceding clause, all users shall follow their directions.
- 2 The work of storing or incinerating animal corpses or waste may be partially entrusted to experimental animal managers and animal caretakers.

(Maintenance and management of facilities)

Article 22 Managers shall endeavor to properly manage experimental animals and maintain and manage facilities necessary for carrying out animal experiments and related activities.

- 2 Animal breeding and keeping facilities shall meet the requirements listed below.
 - 1) Facilities shall be constructed capable of maintaining the proper temperature, humidity, ventilation and brightness.
 - 2) Facilities shall have breeding equipment in accordance with animal species and the number of animals being kept and bred.
 - 3) Facilities shall have floors and inner walls constructed for easy cleaning and sterilization, and shall have hygiene equipment for washing and sterilizing tools.
 - 4) Facilities shall be constructed strong enough to prevent experimental animals from escaping.
 - 5) Facilities shall have corrective actions in place to prevent the surrounding environment from being affected by foul odors, noises or waste.
 - 6) Facilities shall have experimental animal managers in place.
- 3 Animal experimenters shall use laboratories within facilities, and when transporting tools and equipment shall submit a Laboratory Use and Tool and Equipment Transport Application Form (Form No. 4), and obtain the approval of a facility director.
- 4 Animal experimenters shall promptly remove tools and equipment after an experiment has ended, and restore laboratories to their state prior to use.

(Establishment of laboratories)

Article 23 In the event that laboratories are established for performing experiment operations on experimental animals at non-breeding and keeping facilities, a supervisor shall submit an Animal Laboratory Setup Approval Application Form (Form No. 5) to the university president, and shall obtain approval.

- 2 Animal experimenters may not conduct animal experiments and related activities at such facilities unless they have obtained the approval of the university president to establish laboratories.
- 3 The university president shall have the animal experiment committee survey applied for laboratories, and based on their advice determined whether or not to give approval.

(Laboratory requirements)

Article 24 Laboratories shall meet the requirements listed below.

- 1) Laboratories shall be constructed strong enough to prevent experimental animals from escaping, and environments shall be maintained so that experimental animals are easily recaptured even if they escape.
- 2) Laboratories shall be constructed for easy cleaning and sterilization of contamination from animal wastes, blood or other substances.
- 3) Laboratories shall be always be maintained in a clean state, and have corrective actions in place to prevent the surrounding environment from being affected by foul odors, noises or waste.

(Animals feed management)

Article 25 Animal experimenters shall obtain the approval of an experimental animal manager when purchasing feed for each experimental animal.

- 2 Storage and other tasks related to feed shall be separately determined by the university president.

(Maintaining health and safety of experimental animals)

Article 26 Experimental animal managers, animal experimenters and animal caretakers shall comply with Basic Rule for Keeping and Managing Laboratory Animals, and shall endeavor to maintain the health and safety of experimental animals.

(Education and training)

Article 27 The president of the university shall implement the education and training necessary for experimental animal managers, animal experimenters and animal caretakers to properly conduct animal experiments and related activities, and breed and keep experimental animals, and otherwise take the necessary corrective action to improve their skill levels.

(Regulations for special experiments)

Article 28 Animal experimenters shall comply with the requirements listed below.

- 1) Follow the relevant laws, statutes and agency regulations for experiments requiring observance of safety management (experiments using biologically or chemically hazardous materials, pathogens, or genetically modified animals), and ensure the proper facilities and equipment necessary for safety.
- 2) Follow Nara Medical University Research-Related Radiation Hazard Prevention Regulations (enacted October 1993) for experiments using radioactive isotopes and radiation, and Nara Medical University Recombinant DNA Experiment Safety Management Regulations (enacted October 1991) for experiments using genetically modified organisms, and respectively conduct the experiments at radioisotope experiment facilities and recombinant DNA experiment facilities. However, this does not apply to experiments deemed by the committee to be “using highly safe genetically modified animal specimens with no new genetic manipulation.”
- 3) Breeding and experiments using living pathogens shall not be performed outside of infected animal laboratories.
- 4) Experiments using special chemical substances, mutagens or substances that are not verifiably safe shall be conducted after thorough consideration of safety issues.

(Handling of accidents and similar occurrences)

Article 29 Persons discovering animals with symptoms of unknown cause or suspected infection shall immediately notify a safety director.

- 2 When safety directors have received the notification in the preceding clause and takes the necessary steps, all users shall follow their directions.
- 3 In the event of breakdown or damage of any tools, equipment or fixtures installed in a facility, the manager shall immediately be notified through an experimental animal manager.
- 4 Managers shall sometimes request compensation for damages attributable to users after receiving the notification in the preceding clause.
- 5 In the event of fire or other calamity, animal experimenters shall take emergency measures to protect experimental animals, prevent injury from escaping experimental animals, and stop pathogens, special substances, mutagens or substances that are not verifiably safe from leaking outside of facilities; immediately report to managers, the committee chairman, safety directors, experimental animal managers, utilities managers, and managers prescribed in Nara Medical University Fire Prevention Management Regulations; take the proper corrective action under the guidance and advice of a safety director; and promptly submit an Accident Processing Report Form (Form No. 6) to the university president.

(Health management)

Article 30 Experimental animal managers, animal experimenters and animal caretakers shall perform the necessary health management in order to prevent experimental animals from causing injury or illness outside the aims of experiments.

- 2 Experimental animal managers, animal experimenters and animal caretakers shall provide proper treatment in the event that experimental animals cause injury or illness outside the aims of experiments.

(Breeding of heterogeneous or multiple animals)

Article 31 Experimental animal managers, animal experimenters and animal caretakers shall house heterogeneous or multiple experimental animals for breeding and keeping in the same facility after considering the combinations thereof.

(Recordkeeping and reporting)

Article 32 Managers shall organize and save records related to the sources, breeding histories and disease histories of experimental animals.

- 2 Managers shall report the species and numbers of experimental animals bred and kept each year to the university president.

(Providing information during transfer or other handling of animals)

Article 33 Managers shall provide information on experimental animals during their transfer, including their characteristics, breeding and keeping methods, and infectious diseases.

(Transport)

Article 34 Managers shall comply with Basic Rule for Keeping and Managing Laboratory Animals, and endeavor to ensure the health and safety of experimental animals, and prevent injury to persons, when transporting experimental animals.

(Hazard prevention)

Article 35 Managers and experimental animal managers shall prescribe methods for recapturing escaped experimental animals in advance.

- 2 Managers, experimental animal managers, animal experimenters and animal caretakers shall promptly contact relevant agencies in the event that an experimental animal at risk of injury a person escapes to outside a facility.
- 3 Managers, experimental animal managers, animal experimenters and animal caretakers shall promptly take the necessary corrective action either preventively or in response to infectious diseases originating from experimental animals or biting or other incidents involving experimental animals.

- 4 Managers and experimental animal managers shall separately prescribe requirements pursuant to Basic Rule for Keeping and Managing Laboratory Animals, in order to prevent hazards to people in the event of breeding or keeping poisonous animals such as snakes.
- 5 Managers, experimental animal managers, animal experimenters and animal caretakers shall take the necessary corrective action so that people unrelated to the breeding of experimental animals or conducting animal experiments and related activities do not come in contact with experimental animals.

(Self-inspections and similar activities)

Article 36 The university president shall self-inspect and evaluate conformity with fundamental guidelines for animal experiments and related activities on a regular basis.

- 2 The university president shall endeavor to receive verification from non-academic persons of the results of self-inspections and evaluations.

(Disclosing information)

Article 37 The university president shall publish information related to animal experiments and related activities at this university about once annually.

(Prevention of facility use)

Article 38 The university president may prevent the use of facilities and animal experiments and related activities in the event that experiments fail to comply with these regulations or other rules, and deviate from requirements for approval of animal experiment designs.

(General affairs)

Article 39 Necessary general affairs related to enforcing these regulations shall be performed by the research promotion division.

(Miscellaneous rules)

Article 40 In addition to the provisions of these regulations, any matters required of animal experiments shall be separately prescribed by the university president.

Supplementary provisions

(Effective date)

- 1 These regulations are effective as of October 1, 1993.

(Abolishment of other regulations)

- 2 Nara Medical University Animal Experiment Guidelines (enacted November 27, 1990) and Nara Medical University Experimental Animal Committee Regulations (enacted July 8, 1980) are abolished with the enactment of these regulations.

Supplementary provisions (March 28, 1995)

Effective as of April 1, 1995.

Supplementary provisions (July 9, 1996)

Effective as of April 1, 1996.

Supplementary provisions (December 12, 2000)

Effective as of December 12, 2000.

Supplementary provisions (October 9, 2001)

Effective as of October 9, 2001.

Supplementary provisions (July 13, 2004)

Effective as of April 1, 2004.

Supplementary provisions (April 2, 2007)

Effective as of April 1, 2007.

Supplementary provisions (February 7, 2008)

Effective as of April 1, 2008.

Supplementary provisions (May 7, 2009)

Effective as of May 7, 2009.

Supplementary provisions (October 28, 2013)

Effective as of October 28, 2013.

**Nara Medical University Animal Care and Use Committee
Committee Chairperson, Professor Hiroki Kuniyasu M.D., Ph.D.**

Signature



Date

2017/5/22.