

Note: This translation is for reference purposes only. Should any discrepancies arise between the English and Japanese versions, the Japanese version is the authoritative version, thus the Japanese version will be deemed valid.

Nara Institute of Science and Technology Animal Experiment and Related Activities Regulations

March 27, 2008
Regulations No. 4

Article 1 (Purpose)

1. These Regulations specify the requirements for the proper performance of animal experiments and related activities at the Nara Institute of Science and Technology (hereinafter referred to as “NAIST”) from the points of view of science, animal welfare, and safety assurance of employees and students who are involved in the experiments and related activities.
2. The performance of animal experiments and related activities at NAIST shall be governed by the Act on Welfare and Management of Animals (Act No. 105, 1973; hereinafter referred to as the “Animal Welfare Act”), the Standards Relating to the Care and Management of Laboratory Animals and Relief of Pain (Notice No. 88, 2006 of the Ministry of the Environment; hereinafter referred to as the “Care and Management Standards”), the Fundamental Guidelines for Proper Conduct of Animal Experiments and related activities in Academic Research Institutions (Notice No. 71, 2006 of the Ministry of Education, Culture, Sports, Science and Technology; hereinafter referred to as the “Animal Experiment Guidelines”), and the provisions of other laws and regulations, as well as the provisions of these Regulations.

Article 2 (Basic policy)

When performing animal experiments and related activities, proper performance must be ensured based on the following 3Rs (Replacement, Reduction, Refinement), principles of animal experiments and related activities:

- (1) Replacement: substituting animal models with non-animal techniques, as long as the scientific objective is achieved,
- (2) Reduction: minimizing the number of animals provided for such use, as long as the scientific objective is achieved, and
- (3) Refinement: using techniques to reduce pain and distress to animals, as long as the scientific objective is achieved.

Article 3 (Definitions)

As used in these Regulations, the terms below shall be defined as follows:

- (1) “Animal Experiments, etc.” refers to providing animals for use in education, testing, and research or the manufacture of biological preparations or for any other scientific use,
- (2) “Laboratory Animals” refers to animals belonging to mammals, birds, and reptiles provided for use in

Animal Experiments, etc.,

- (3) “Animal Experimental Protocol” refers to a protocol designed in advance of Animal Experiments, etc., for which the experimental performance period shall be up to five years,
- (4) “Animal Experiment Researchers” refers to persons performing Animal Experiments, etc. properly,
- (5) “Animal Experiment Manager” refers to one Animal Experiment Researcher who is responsible for the work related to each individual Animal Experimental Protocol,
- (6) “Manager” refers to a person who manages Laboratory Animals and facilities and the Animal Experiment Facility Manager specified in Article 3 of the Nara Institute of Science and Technology Research and Education Center for Genetic Information Experiment Facilities Management and Operation Regulations (Regulations No. 10, 2005; hereinafter referred to as the “Experiment Facilities Management Operation Regulations”) shall be assigned to serve as the Manager,
- (7) “Laboratory Animal Manager” refers to a person who assists the Manager and is responsible for Laboratory animal management, who shall be appointed by the Manager,
- (8) “Caretakers” refers to the persons who are involved in the care and management of Laboratory Animals under the direction of Animal Experiment Researchers or the Laboratory Animal Manager,
- (9) “Managers, et al.” refers to the Manager, the Laboratory Animal Manager, Animal Experiment Researchers, and Caretakers,
- (10) “Care and Management Facilities” refers to the facilities used for the care or management of Laboratory Animals or performing Animal Experiments, etc.,
- (11) “Laboratory” refers to a room or area where Laboratory Animal experimental procedures are performed,
- (12) “Facilities, etc.,” refers to the Care and Management Facilities and laboratories.
- (13) “Humanitarian Endpoint” refers to the timing to end the experiment through euthanasia to relieve Laboratory Animals from intense pain,
- (14) “Animal Welfare Act, etc.,” refers to the Animal Welfare Act, the Care and Management Standards, and the Animal Experiment Guidelines.

Article 4 (Overall management)

The President shall oversee and manage the proper performance of Animal Experiments, etc. at NAIST.

Article 5 (Animal experiment committee)

The President shall establish the animal experiment committee (hereinafter referred to as the “Committee”) for the proper performance of Animal Experiments, etc. at NAIST.

Article 6 (Matters for discussion, etc.)

The Committee shall discuss and review the following matters:

- (1) Matters relating to conforming with the Animal Welfare Act, etc., and these Regulations on Animal Experimental Protocols,
- (2) Matters relating to adequacy of performance status and results of Animal Experimental Protocols,
- (3) Matters relating to adequacy of care and management status of Facilities, etc., and Laboratory Animals,

- (4) Matters relating to the education and training on performance of Animal Experiments, etc.,
- (5) Matters relating to the self-inspection and assessment of performance of Animal Experiments etc.,
and
- (6) Other necessary matters relating to proper performance of Animal Experiments, etc.

Article 7 (Committee members)

1. The Committee is composed of the following members:

- (1) Executive Director appointed by the President
 - (2) Director of the Research and Education Center for Genetic Information
 - (3) Director of the Health Care Center
 - (4) Manager
 - (5) Professors or Associate Professors, several who are involved in the performance of Animal Experiments, etc. and appointed by the President
 - (6) Director of Environment, Safety and Health Management Office
 - (7) Other persons deemed necessary by the President
2. A member may not participate in the review of an Animal Experimental Protocol for which the member serves as an Animal Experiment Manager.
3. Members under Paragraph 1, items (5) and (7) hereof, serve for a term of office of two years and may be re-appointed; provided, however, that the period of service of such members shall not exceed the period of service of the President who appointed or commissioned the relevant members.
4. Members shall not disclose to a third party or steal any information acquired on Animal Experimental Protocols. This provision shall apply past the resignation of members.

Article 8 (Chairperson)

1. A chairperson shall be appointed for the Committee, and the person of Paragraph 1, item (1), of the preceding article shall be assigned to serve as the chairperson.
2. The chairperson shall preside over the Committee.

Article 9 (Vice-chairperson)

1. A vice-chairperson shall be assigned to the Committee and appointed by the chairperson from among the members.
2. The vice-chairperson shall assist the chairperson and perform duties on behalf of the chairperson as necessary.

Article 10 (Procedures for resolution)

1. The Committee may not hold a meeting with agenda items and adopt a resolution unless at least two-thirds of the members will be present at the meeting.
2. The agenda items of the Committee shall be adopted by majority votes of the present members, and a tie vote shall be resolved by the chairperson.

Article 11 (Attendance of non-members)

1. The Committee may, if it considers it necessary to do so, invite persons other than members to attend a meeting to hear their opinions.

Article 12 (Approval, review, designing and changes of Animal Experimental Protocol)

1. The Animal Experiment Manager must, when performing Animal Experiments, etc., apply for prior approval of the animal experiment protocol to the President and obtain the approval thereof.
2. The President shall refer the applied Animal Experimental Protocol to the Committee for review and decide whether to approve or reject it based on the result thereof.
3. The Animal Experiment Manager must design Animal Experimental Protocol with the objective of ensuring the reliability of the data obtained from the Animal Experiments, etc., considering the following matters:
 - (1) Matters relating to the objective and significance of and the need for Animal Experiments, etc.,
 - (2) Matters relating to appropriate experimental techniques based on 3R (Replacement, Reduction, Refinement) principles under Article 2 hereof,
 - (3) Matters relating to the time (including a Humanitarian Endpoint; hereinafter the same shall apply) to end Animal Experiments, etc., and
 - (4) Performing Animal Experiments, etc. using Facilities, etc. properly maintained under Articles 15 and 17 hereof.
4. The provisions of the preceding three paragraphs apply mutatis mutandis to changes to the description of the approved Animal Experimental Protocol; provided, however, that prior notification to the President of such changes shall be sufficient for any of the following items:
 - (1) Changes to Animal Experiment Researchers and Caretakers,
 - (2) Changes to the experimental performance period of the Animal Experimental Protocol, or
 - (3) Changes to the system of the Laboratory Animals.

Article 13 (Performing of Animal Experiments, etc.)

1. Animal Experiment Researchers must, when performing Animal Experiments, etc., comply with the Animal Welfare Act and the following provisions for the proper performance:
 - (1) Observe the descriptions of the Animal Experimental Protocol and the following items:
 - a. Use of proper anesthetics and analgesics
 - b. Considerations for the time to end the experiment
 - c. Appropriate postoperative management
 - d. Selection of proper euthanasia techniques
 - (2) Comply with applicable laws and regulations, Nara Institute of Science and Technology Safety and Health Management Regulations (Regulations No. 1, 2004), and other relevant NAIST Regulations, and provide adequate facilities and equipment for safe Animal Experiments, etc. (using physically or chemically hazardous substances, pathogens, or genetically modified animals, etc.) in which attention should be paid to safety management,
 - (3) Endeavor to learn the necessary experimental procedures before performance of the experiment,
 - (4) Conduct highly invasive, major surgery under the guidance of a sufficiently experienced specialist, etc.

2. Animal Experiments, etc. shall not be performed outside of the Facilities, etc.

Article 14 (Reporting of performance results)

1. The Animal Experiment Manager must, upon the performance of an Animal Experimental Protocol, report to the President the experimental results, presence or absence of changes from the original Animal Experimental Protocol, number of animals used, and outcomes.
2. The President shall, upon receipt of the report under the preceding paragraph, consult the Committee on the report and take corrective action for the proper performance of Animal Experiments, etc. as necessary.

Article 15 (Maintenance of Care and Management Facilities)

1. Care and Management Facilities for Laboratory Animals at NAIST shall be limited to animal experiment facilities defined in Article 2.1(2), of the Experiment Facilities Management Operation Regulations.
2. The Manager must assign a Laboratory Animal Manager to the Care and Management Facilities and endeavor to properly maintain the facilities to meet the following requirements:
 - (1) Construction to provide proper temperature, humidity, ventilation, and light,
 - (2) Provision of housing facilities according to the animal species and number of animals under care and management,
 - (3) Provision of flooring, interior walls, ceiling, and accessory equipment constructed for easy cleaning and disinfection and with sanitary equipment to clean and disinfect equipment,
 - (4) Maintain such a structure and strength that Laboratory Animals cannot escape, and
 - (5) Include measures to prevent adverse effects on surrounding environment by odor, noise, waste, etc.

Article 16 (Installation of Laboratory)

1. The Animal Experiment Manager must, if installing a Laboratory other than the Care and Management Facilities when performing Animal Experiments, etc., apply for prior approval to the President through the Manager and obtain the approval thereof.
2. If animal equipment and related activities are performed in a Laboratory that is installed other than the Care and Management Facilities, the duration of these shall be limited to a maximum of 24 hours.
3. The President shall refer the applying Laboratory to the Committee for review and decide whether to approve or reject it based on the result thereof.

Article 17 (Requirements for Laboratory)

A Laboratory must meet the following requirements:

- (1) Maintain such a structure and strength that Laboratory Animals cannot escape and an environment so that escaped Laboratory Animals can be easily captured inside the room.
- (2) Construction for easy cleaning or disinfection against contamination, such as excretion and blood.
- (3) Maintain a state of cleanliness and adopt measures to prevent adverse effects on the surrounding environment by odors, noise, waste, etc.

Article 18 (Abolishment of Laboratory)

In the event of the abolishment of a Laboratory approved under Article 16, the Animal Experiment Manager must notify the President in advance through the Manager.

Article 19 (Creation and dissemination of standard procedures)

The Manager must create standard procedures for care and management and disseminate them to Animal Experiment Researchers and Caretakers.

Article 20 (Maintaining animal health and safety)

Animal Experiment Researchers, the Laboratory Animal Manager, and Caretakers must comply with the Care and Management Standards, and without hindering the achievement animal experiment and related activities objectives, pay attention to the following items and endeavor to maintain Laboratory animal health and safety:

- (1) Feed and water Laboratory Animals properly, according to physiology, ecology, behavior, etc.
- (2) Except for those relating to the objective of Animal Experiments, etc., provide the necessary health care to prevent injury or disease of Laboratory Animals,
- (3) Except for those relating to the objective of Animal Experiments, etc., provide the appropriate medical care if Laboratory Animals are injured or ill, and
- (4) If different species or a number of Laboratory Animals are under care or management in the same facility, house them taking into consideration the combination thereof.

Article 21 (Laboratory Animal importation)

1. The Manager may, when importing Laboratory Animals, import such Laboratory Animals only from institutes in which Laboratory Animals are properly managed, in accordance with the Animal Welfare Act, and other applicable laws and regulations.
2. The Manager shall, when importing Laboratory Animals, conduct appropriate quarantine inspection and isolated care as necessary, and take the necessary precautions to promote acclimatization or adaptation to the care environment.

Article 22 (Record keeping and reporting)

1. The Managers, et al., must maintain and keep records of suppliers, care history, and case history of Laboratory Animals.
2. The Manager must report annually to the President the type and number of Laboratory Animals under care or management.

Article 23 (Provision of information at the time of transfer)

The Manager must, when transferring Laboratory Animals, provide the transferee with information on their characteristics, care and management procedures, infections, and diseases.

Article 24 (Transport)

The Managers, et al., must, when transporting Laboratory Animals, comply with the Care and

Management Standards and endeavor to assure the health and safety of Laboratory Animals and to prevent the occurrence of harm to humans caused by Laboratory Animals.

Article 25 (Contract of Animal Experiments, etc.)

The Animal Experiment Manager may, when entrusting Animal Experiments etc. to an institute other than NAIST, entrust such experiments, etc. only to an institute which is confirmed to properly perform Animal Experiments, etc. in accordance with the Animal Welfare Act and other applicable laws and regulations.

Article 26 (Harm prevention and response upon its occurrence)

1. The Manager must prescribe, in advance, methods for capturing escaped Laboratory Animals and disseminate them to concerned parties.
2. If Laboratory Animals that may cause harm to humans escape the Facilities, etc., the Manager must promptly inform the relevant agencies.
3. The Manager must take preventive measures for any infections derived from Laboratory Animals and laboratory animal bites, and take the necessary precautions upon the occurrence of such infections.
4. The Manager must take the necessary precautions to prevent contact of Laboratory Animals with persons not involved in the care of Laboratory Animals, animal experiments or other activities.

Article 27 (Response in case of earthquake and fire)

1. The Manager must, in advance, prescribe the action plans to be taken in case of emergency, such as earthquake and fire, and disseminate them to all concerned parties.
2. The Manager must, in case of emergency, such as earthquake and fire, promptly inform the relevant agencies and take the necessary precautions to protect Laboratory Animals and to prevent harm caused by escaped Laboratory Animals.

Article 28 (Acquiring knowledge of zoonotic diseases)

1. The Managers, et al., must endeavor to acquire the necessary knowledge and information on zoonotic diseases.
2. The Manager, Animal Experiment Researchers, and the Laboratory Animal Manager must endeavor to develop communication systems with public health agencies so as to take the necessary precautions promptly in case of zoonotic diseases.

Article 29 (Education and training)

1. The Managers, et al., must receive education and training on the following matters:
 - (1) Matters relating to Animal Welfare Act, other applicable laws and regulations, as well as these Regulations,
 - (2) Basic issues relating to procedures of Animal Experiments, etc.,
 - (3) Basic issues relating to care and management of Laboratory Animals,
 - (4) Matters relating to safety assurance and safety management,
 - (5) Other necessary matters relating to proper performance of Animal Experiments, etc..
2. The Manager shall prepare and keep records of the content, dates of implementation, lecturers, and

participants in education and training.

Article 30 (Self-inspection, assessment and verification)

1. The Committee must conduct periodic self-inspections and assessments to assure the Animal Experiments, etc. conform with the Animal Welfare Act and these Regulations at NAIST, and report the results to the President.
2. The Committee may ask Managers, et al., to submit data for self-inspections and assessments.
3. The President must endeavor to ensure that the results of self-inspections and assessments are verified by third parties outside NAIST.

Article 31 (Information disclosure)

The President shall disclose information on Animal Experiments, etc. at NAIST, approximately once a year, except the parts thereof that may hinder the protection of personal information, research originality, or intellectual property rights.

Article 32 (Mutatis mutandis application)

Efforts must be made to perform Animal Experiments, etc., using animals other than Laboratory Animals, in line with the purpose of these Regulations.

Article 33 (Exceptions)

These Regulations shall not apply to livestock care or management education or examination research, Laboratory animal care or management (limited to animal species deemed industrial livestock) for livestock breeding improvement, or Laboratory Animal care or management for ecological observation.

Article 34 (Clerical work)

Clerical duties for the performance of Animal Experiments, etc. shall be the responsibility of the General Safety and Health Management Office.

Article 35 (Miscellaneous provisions)

In addition to the provisions of these Regulations, requirements concerning Animal Experiments, etc. shall be specified separately.

Supplementary provisions

These Regulations shall come into effect on April 1, 2008.

Supplementary provisions

These Regulations shall come into effect on April 1, 2010.

Supplementary provisions

These Regulations shall come into effect on April 1, 2013.

Supplementary provisions

These Regulations shall come into effect on April 1, 2015.

Supplementary provisions

These Regulations shall come into effect on April 18, 2017 and be applicable from April 1, 2017.