

Tokai National Higher Education and Research System Regulations on Animal Care and Use in Research

(Regulation No. 74 of April 1, 2020)

Article 1 (Purpose)

- (1) These Regulations shall prescribe necessary matters pertaining to the proper and safe conduct of Animal Experiments and Related Activities at the Tokai National Higher Education and Research System (hereinafter referred to as "THERS").
- (2) Animal Experiments and Related Activities shall be governed by the provisions of the Act on Welfare and Management of Animals (Act No. 105 of 1973; hereinafter referred to as "the Law"), the Standards Relating to the Care and Keeping and Reducing Pain of Laboratory Animals (Notice of the Ministry of the Environment No. 88 of 2006; hereinafter referred to as "Standards"), the Fundamental Guidelines for Proper Conduct of Animal Experiments and Related Activities in Academic Research Institutions (Notice of the Ministry of Education, Culture, Sports, Science and Technology No. 71 of 2006), Standards Relating to the Methods of Destruction of Animals (Notice of the Prime Minister's Office No. 40 of 1995), the Guidelines for Proper Conduct of Animal Experiments (Science Council of Japan, 2006), other relevant laws and regulations, if any, and these Regulations.
- (3) Persons conducting Animal Experiments and Related Activities must strictly comply with the Law and Standards, and conduct Animal Experiments and Related Activities properly based on the 3R Principles: Replacement (the application of alternative methods that do not require the use of animals within limits that allow scientific objectives to be achieved); Reduction (the use of as few animals as possible within limits that allow scientific objectives to be achieved); and Refinement (the application of methods that do not distress the animals or subject them to pain within limits required for scientific use).

Article 2 (Scope of Application)

- (1) These Regulations shall be applied to all Animal Experiments and Related Activities conducted at THERS.
- (2) In addition to what is provided for in these Regulations, other details regarding Animal Experiments and Related Activities conducted at National Universities established at THERS (hereafter referred to as "Universities") shall be prescribed by the Universities.

Article 3 (Responsibility of the Chancellor).

The Chancellor shall be responsible for overseeing proper conduct of Animal Experiments and Related Activities at THERS.

Article 4 (Miscellaneous Rules)

In addition to the matters prescribed in these Regulations, other necessary matters pertaining to Animal Experiments and Related Activities at THERS shall be separately prescribed by the Chancellor.

Supplementary Provision

These Regulations shall come into force on April 1, 2020.

Nagoya University Regulations on Animal Care and Use in Research

(Regulation No. 71, March 12, 2007)

Revision	Regulation No. 106, March 28, 2007	Regulation No. 117, March 31, 2008
	Regulation No. 43, March 16, 2010	Regulation No. 89, March 21, 2010
	Regulation No. 10, June 18, 2013	Regulation No. 125, March 26, 2014
	Regulation No. 107, March 7, 2017	Regulation No. 136, March 30, 2017
	Regulation No. 99, February 20, 2018	Regulation No. 35, April 1, 2020
	Regulation No. 105, December 1, 2020	Regulation No. 120, January 20, 2021

Article 1 (Purpose)

These Regulations shall prescribe necessary matters pertaining to the proper and safe conduct of Animal Experiments and Related Activities at Nagoya University (hereinafter referred to as "the University") in accordance with the Article 2, Paragraph (2) of the Tokai National Higher Education and Research System Regulations on Animal Care and Use in Research (THERS Regulation No. 74 of 2020).

Article 2 (Fundamental Principles)

Persons conducting Animal Experiments and Related Activities must strictly comply with the Act on Welfare and Management of Animals (Act No. 105 of 1973, hereinafter referred to as "the Law"), the Standards Relating to the Care and Keeping and Reducing Pain of Laboratory Animals (Notice of the Ministry of the Environment No 88 of 2006; hereinafter referred to as "Standards"), and conduct Animal Experiments and Related Activities properly based on the 3R Principles: Replacement (the application of alternative methods that do not require the use of animals within limits that allow scientific objectives to be achieved); Reduction (the use of as few animals as possible within limits that allow scientific objectives to be achieved); and Refinement (the application of methods that do not distress the animals or subject them to pain within limits required for scientific use).

Article 3 (Definitions)

In these Regulations, the meanings of the terms listed in the following items shall be as prescribed respectively in those items:

- (i) The term "Animal Experiments and Related Activities" as used in these Regulations shall mean the utilization of animals as prescribed in item (v) of this Article for education, testing, research and development, manufacture of biological products, or other scientific purposes.
- (ii) The term "Rearing and Care Facility" as used in these Regulations shall mean a facility or equipment where Laboratory Animals are permanently reared and cared or where Animal Experiments and Related Activities are conducted.

- (iii) The term "Animal Laboratory" as used in these Regulations shall mean an animal laboratory where experimental procedures are carried out on Laboratory Animals (including cases where Laboratory Animals are temporarily cared for no longer than 48 hours).
- (iv) The term "Facilities" as used in these Regulations shall mean a Rearing and Care Facility and an Animal Laboratory.
- (v) The term "Laboratory Animals" as used in these Regulations shall mean animals (including those in transport to Facilities for introduction) of mammalian, avian or reptilian species that are reared or maintained in Facilities for use in Animal Experiments and Related Activities.
- (vi) The term "Animal Experiment Protocol" as used in these Regulations shall mean a protocol for the conduct of the Animal Experiments and Related Activities.
- (vii) The term "Animal Experiment Researcher" as used in these Regulations shall mean a person who performs the Animal Experiments and Related Activities.
- (viii) The term "Principal Investigator" as used in these Regulations shall mean the Animal Experiment Researcher who is responsible for all activities concerning the Animal Experiment and Related Activities.
- (ix) The term "Manager" as used in these Regulations shall mean a person in charge of comprehensive management of Laboratory Animals and Facilities (e.g. the Dean/Director of a School/Graduate School or Research Institute/Center).
- (x) The term "Facility/Laboratory Manager" as used in these Regulation shall mean a person in charge of comprehensive management to properly maintain respective Rearing and Care Facilities and Animal Laboratories.
- (xi) The term "Laboratory Animal Manager" as used in these Regulations shall mean a person with knowledge and experience related to Laboratory Animals, who assists the Manager and the Facility/Laboratory Manager and is in charge of the care of Laboratory Animals.
- (xii) The term "Animal Technician" as used in these Regulations shall mean a person engaged in the rearing and care of Laboratory Animals under the supervision of the Facility/Laboratory Manager, the Laboratory Animal Manager or the Animal Experiment Researcher.
- (xiii) The term "Manager, etc." as used in these Regulations shall mean the President, the Manager, the Facility/Laboratory Manager, the Laboratory Animal Manager, the Animal Experiment Researcher and the Animal Technician.
- (xiv) The term "Guidelines, etc." as used in these Regulations shall mean the fundamental standards and guidelines related to Animal Experiments and Related Activities specified by government agencies.

Article 4 (Scope of Application)

- (1) These Regulations shall be applied to all Animal Experiments and Related Activities which utilize living animals of mammalian, avian and reptilian species conducted at the University.
- (2) The Principal Investigator must, where the Animal Experiments and Related Activities is entrusted to an outside institution, confirm that the Animal Experiments and Related Activities will be properly

conducted at the institution in accordance with the Law, Standards, Fundamental Guidelines for Proper Conduct of Animal Experiment and Related Activities in Academic Research Institutions (Notice of the Ministry of Education, Culture, Sports, Science and Technology No. 71 of 2006, hereinafter referred to as "Fundamental Guidelines") and other related laws and regulations (hereinafter referred to as "Related Laws and Regulations").

Article 5 (Responsibilities of the President)

The President shall be responsible for overseeing proper conduct of Animal Experiments and Related Activities, as well as proper rearing and care of Laboratory Animals at the University.

Article 6 (Animal Care and Use Committee)

The President shall establish the Nagoya University Animal Care and Use Committee (hereinafter referred to as "the Committee") as a body that provides reports and advice on the approval of an Animal Experiment Protocol, the implementation status and results of the Animal Experiment Protocol, the approval of the establishment of a Rearing and Care Facility and an Animal Laboratory, education and training, self-inspections and evaluations, information disclosure, and other matters concerning proper conduct of Animal Experiments and Related Activities.

Article 7 (Tasks of the Committee)

- (1) The Committee shall, in response to inquiries from the President, discuss or investigate matters listed in the following items and provide the President with reports or advice on those matters:
 - (i) Matters pertaining to the compliance of an Animal Experiment Protocol with Related Laws and Regulations, and these Regulations.
 - (ii) Matters pertaining to the implementation status and results of the Animal Experiment Protocol.
 - (iii) Matters pertaining to Facilities, and the rearing and care conditions of Laboratory Animals.
 - (iv) Matters pertaining to Animal Experiments and Related Activities and proper handling of Laboratory Animals as well as contents and systems of education and training concerning Related Laws and Regulations.
 - (v) Matters pertaining to self-inspections and evaluations concerning Animal Experiments and Related Activities.
 - (vi) Other matters pertaining to the proper conduct of Animal Experiments and Related Activities.
- (2) In addition to the provisions of the preceding paragraph, the Committee may provide necessary guidance or advice to the Department Committees defined in Article 16.
- (3) The Committee may advise the President to suspend experimentation or to take other necessary measures when it has deemed that Animal Experiment Protocol is not being implemented properly.
- (4) The Committee may consign some of its duties concerning Animal Experiments and Related Activities at the Higashiyama Campus to the Center for Animal Research and Education (CARE), to ensure that Animal Experiments and Related Activities are performed properly and safely at the Higashiyama Campus.

Article 8 (Composition of the Committee)

- (1) The Committee shall consist of the Committee members listed in the following items:
 - (i) One professor, associate professor, or lecturer from each of the following : the Graduate School of Informatics, Graduate School of Science, Graduate School of Medicine (Tsurumai Campus), Graduate School of Medicine (Daiko Campus), Graduate School of Engineering, Graduate School of Bioagricultural Sciences, Graduate School of Environmental Studies, Graduate School of Pharmaceutical Sciences, Research Institute of Environmental Medicine, University Hospital, Radioisotope Research Center, Bioscience and Biotechnology Center, Cellular and Structural Physiology Institute, Center for Animal Research and Education, and the Research Center of Health, Physical Fitness and Sports.
 - (ii) One professor, associate professor, or lecturer to represent all of the following: the Graduate School of Humanities, Graduate School of Education and Human Development, Graduate School of Law, and Graduate School of Economics.
 - (iii) Other faculty members deemed necessary by the President.
- (2) The Committee must include at least one member from each of the following: those possessing excellent insight on Animal Experiments and Related Activities, those possessing excellent insight on animals used in experimentation, and those with other scholarly experience.
- (3) The President shall appoint the Committee members prescribed in the respective items of Paragraph (1).

Article 9 (Term of Office)

- (1) The term of office of the Committee members shall be two years. However, the Committee members may be reappointed for a subsequent term.
- (2) In the event of a vacancy, a replacement member shall be appointed. In this case, the term of office of the replacement member shall be the remaining term of office of his or her predecessor.

Article 10 (Chairperson)

- (1) The Committee shall have a Chairperson. The Chairperson shall be selected by the Committee from among its members.
- (2) The Chairperson shall convene all meetings of the Committee and preside over such meetings.

Article 11 (Vice-Chairperson)

- (1) The Committee shall have a Vice-Chairperson. The Vice-Chairperson shall be appointed by the Chairperson.
- (2) The Vice-Chairperson shall assist the Chairperson and act for the Chairperson where he or she is absent or incapacitated.

Article 12 (Quorum)

- (1) A majority shall constitute a quorum at any meeting of the Committee.

- (2) The agenda items of meetings shall be decided by a majority of the Committee members present. In the event of an equality of votes, the Chairperson shall cast the deciding vote.

Article 13 (Opinion Hearing)

The Committee may, when it deems it necessary, request non-members to attend meetings and to present their opinions.

Article 14 (General Affairs)

The Research Planning Division, Research Cooperation Department shall be responsible for the general affairs of the Committee.

Article 15 (Responsibility of the Dean/Director of a School/Graduate School or Research Institute/Center)

The Dean/Director of a School/Graduate School or Research Institute/Center shall be responsible for matters necessary for proper conduct of Animal Experiments and Related Activities of the School/Graduate School or Research Institute/Center.

Article 16 (Animal Care and Use Committee of a School/Graduate School or Research Institute/Center)

- (1) An Animal Care and Use Committee of a School/Graduate School or Research Institute/Center (hereinafter referred to as "Department Committee(s)") shall be established at each School/Graduate School or Research Institute/Center that is to conduct Animal Experiments and Related Activities.
- (2) The Department Committee shall, in response to inquire from the Dean/Director of the School/Graduate School or Research Institute/Center, discuss or investigate matters listed in the following items and provide the Dean/Director of the School/Graduate School or Research Institute/Center with reports or advice on those matters:
 - (i) Matters pertaining to the compliance of an Animal Experiment Protocol with Related Laws and Regulations, and the Regulations.
 - (ii) Matters pertaining to the implementation status and results of the Animal Experiment Protocol.
 - (iii) Matters pertaining to Facilities and the rearing and care conditions of Laboratory Animals.
 - (iv) Matters pertaining to Animal Experiments and Related Activities and proper handling of Laboratory Animals as well as contents and systems of education and training concerning Related Laws and Regulations.
 - (v) Matters pertaining to self-inspections and evaluations concerning Animal Experiments and Related Activities.
 - (vi) Other matters necessary for the proper conduct of Animal Experiments and Related Activities.
- (3) Notwithstanding the provision set forth in the paragraph (1), if any of the Schools/Graduate Schools or Research Institutes/Centers is not capable of establishing a Department Committee for organizational reasons related to Animal Experiments and Related Activities, the Committee must assume the responsibilities of the Department Committee on its behalf.

Article 17

- (1) A majority shall constitute a quorum at any meeting of the Department Committee.
- (2) The agenda items of meetings shall be decided by a majority of the members present of the Department Committee. In the event of an equality of votes, the Chairperson shall cast the deciding vote.

Article 18

- (1) The Dean/Director of the School/Graduate School or Research Institute/Center shall provide necessary matters pertaining to the organization and operation of a Department Committee. In which case, the Department Committee shall be organized around the following members, with at least one member being a professor or associate professor of the School/Graduate School or Research Institute/Center:
 - (i) One or more members possessing excellent insight on Animal Experiment and Related Activities;
 - (ii) One or more members possessing excellent insight on Laboratory Animals;
 - (iii) One or more members possessing other scholarly experience in addition to those listed in the two items above.
- (2) The Dean/Director of the School/Graduate School or Research Institute/Center must, when matters prescribed in the preceding paragraph have been determined or amended, promptly report to that effect to the President.

Article 19 (Approval by the Dean/Director of a School/Graduate School or Research Institute/Center)

- (1) The Dean/Director of a School/Graduate School or Research Institute/Center may, when he or she determines that there are no problems associated with an Animal Experiment Protocol for which approval has been sought, approve it after the Department Committee has examined said Protocol.
- (2) The Dean/Director of the School/Graduate School or Research Institute/Center must, where he or she has approved the Animal Experiment Protocol pursuant to the provision of the preceding paragraph, promptly submit to the President a copy of the Form for Animal Experiment Protocol provided in Article 21.

Article 20 (Exclusion of Committee Member)

Notwithstanding the provisions of Paragraph (1) of Article 12 and Paragraph (1) of Article 17, a member of the Committee (including the Department Committees) shall not have a voting right at any meeting if the approval of an Animal Experiment Protocol with which he or she is involved as the Principal Investigator is under deliberation. In this case, the member shall not be included in the members present prescribed in Paragraph (2) of Article 12 and Paragraph (2) of Article 17.

Article 21 (Form for Animal Experiment Protocol)

- (1) The Principal Investigator must, where an Animal Experiment and Related Activities are to be conducted, prepare an Animal Experiment Protocol and fill out the required form for the Animal Experiment Protocol (Attached Form 1) considering matters prescribed in the following items, then submit the form to the Dean/Director of a School/Graduate School or Research Institute/Center, in order to assure the reliability of data obtained from said Animal Experiment and Related Activities:
 - (i) Matters pertaining to purpose, significance, and necessity of the research related to the Animal Experiment and Related Activities.
 - (ii) Matters pertaining to appropriate use of Laboratory Animals giving due consideration to Replacement with alternative methods.
 - (iii) Matters pertaining to Reduction in the number of Laboratory Animals to be used, considering the selection of species appropriate for the purpose of the Animal Experiment and Related Activities, the number of Laboratory Animals which may influence the accuracy and reproducibility of results of the Animal Experiment, and the genetic and microbiological quality, and the rearing and care conditions of animals.
 - (iv) Matters pertaining the reduction of pain and stress in relation to proper conduct of the Animal Experiment and Related Activities.
 - (v) Matters pertaining to the setting of a Humane Endpoint (i.e., timing of terminating an experiment to release a Laboratory Animal from severe pain and distress. The same shall apply hereinafter.) at the planning stage of Animal Experiments and Related Activities which may involve a high degree of pain and distress (i.e., those including lethal toxicity studies, infection experiments and radiation experiments).
- (2) The Dean/Director of the School/Graduate School or Research Institute/Center must, upon receiving the form for the Animal Experiment Protocol prescribed in the preceding paragraph, decide whether to approve or reject the Protocol after deliberation by the Department Committee. The decision must be notified to the Principal Investigator.
- (3) The Principal Investigator shall not be allowed to conduct the Animal Experiment and Related Activities until an Animal Experiment Protocol is approved by the Dean/Director of the School/Graduate School or Research Institute/Center.
- (4) The Principal Investigator must, where any changes or additions are to be made to an Animal Experiment Protocol after the Animal Experiment and Related Activities started, submit an Application for Approval of (Change/Addition) to Animal Experiment Protocol (Attached Form 2) to the Dean/Director of the School/Graduate School or Research Institute/Center and must obtain the approval.
- (5) The Principal Investigator must, where an Animal Experiment Protocol is to be completed or suspended, submit a Report on Animal Experiment (Termination/Suspension) (Attached Form 3) to the Dean/Director of the School/Graduate School or Research Institute/Center for reporting.

- (6) The Principal Investigator must, after implementing an Animal Experiment Protocol, report to the Dean/Director of the School/Graduate School or Research Institute/Center using the Report on Animal Experimental Results (Attached Form 4) detailing the number of utilized animals, any deviations from the original protocol, and the experimental results, etc.
- (7) The Dean/Director of the School/Graduate School or Research Institute/Center must, when an Animal Experiment (Termination/Suspension) Report described in Paragraph (5) and an Animal Experiment Results Report described in the preceding paragraph has been submitted, promptly submit a copy of the report to the President.

Article 22 (Animal Experiment Suspension Order)

- (1) When deemed necessary on the basis of advice from the Committee that an animal experiment is not being performed properly, the President may issue an order for the suspension, etc. of the experiment to the Dean/Director of the School/Graduate School or Research Institute/Center in charge.
- (2) The provisions of the preceding paragraph notwithstanding, when the Dean/Director of the School/Graduate School or Research Institute/Center in charge deems it necessary to immediately suspend the animal experiment being conducted based on the Animal Experiment Protocol, due to the occurrence of an unforeseen situation, etc., the Dean/Director of the School/Graduate School or Research Institute/Center may order the suspension of such experiment. In such cases, the Dean/Director of the School/Graduate School or Research Institute/Center must promptly report the reasons for ordering the suspension to the President.

Article 23 (Matters to be Observed)

The Animal Experiment Researcher must, when he or she conducts an Animal Experiment and Related Activities, observe the following items in addition to Related Laws and Regulations, and these Regulations:

- (i) The Animal Experiment Researcher must conduct Animal Experiments and Related Activities in properly managed and maintained Facilities.
- (ii) The Animal Experiment Researcher must observe the following items in addition to the matters stated in the Animal Experiment Protocol:
 - a. Application of appropriate anesthetics and analgesics, etc.
 - b. Due consideration to timing of terminating the experiment (including Humane Endpoint)
 - c. Proper post-experimental and post-operative management
 - d. Choice of appropriate method of euthanasia
- (iii) The Animal Experiment Researcher must, when he or she conducts Animal Experiments and Related Activities that may require special attention to safety management (i.e., those involving physically and chemically dangerous agents, pathogens, or genetically modified animals, etc.),

observe Related Laws and Regulations as well as related rules, etc of the University, and secure appropriate safety facilities and equipment.

- (iv) The Animal Experiment Researcher must endeavor to acquire the necessary skills for experiments in advance.
- (v) The Animal Experiment Researcher must conduct any large-scale invasive life-sustaining operation on Laboratory Animals under the guidance of a person who has sufficient knowledge and experience in such operations and related activities.

Article 24 (Establishment of a Rearing and Care Facility and Related Matters)

- (1) The Facility/Laboratory Manager must, when a Rearing and Care Facility is established, submit an Application for Approval to Establish a Rearing and Care Facility (Attached Form 5) to the Dean/Director of the School/Graduate School or Research Institute/Center and must obtain the approval.
- (2) The Dean/Director of the School/Graduate School or Research Institute/Center shall request the Department Committee to investigate the Rearing and Care Facility for which approval has been sought, and decide whether to approve or reject it based on the investigation results and advice offered by the Department Committee.
- (3) The Facility/Laboratory Manager, Laboratory Animal Manager, Animal Experiment Researchers, and Animal Technicians shall not be allowed to rear, care, and use Laboratory Animals in the Rearing and Care Facility unless it has been approved by the Dean/Director of the School/Graduate School or Research Institute/Center.
- (4) The Facility/Laboratory Manager must, when changing or adding to the contents of the Application for Approval to Establish a Rearing and Care Facility after installation of the facility in question, submit an Application for Approval (Change/Addition) to Rearing and Care Facility / Animal Laboratory (Attached Form 7; hereinafter referred to as "Change/Addition Application") to the Dean/Director of the School/Graduate School or Research Institute/Center and must obtain the approval.

Article 25 (Requirements of a Rearing and Care Facility)

A Rearing and Care Facility must fulfill the requirements as prescribed in the following items:

- (i) It must have a structure, etc. that can maintain appropriate temperature, humidity, ventilation and lighting.
- (ii) It must have rearing equipment suitable for the species of Laboratory Animals and the number of Laboratory Animals to be reared and cared, etc.
- (iii) It must have a design that the floors and inner walls, etc. are easy to clean or sterilize, etc. and have sanitary equipment for the washing and sterilizing of apparatus.
- (iv) It must have a design and sufficient strength to prevent Laboratory Animals from escaping.

- (v) Measures must be taken to prevent negative impacts on the surrounding environment due to odor, noise and waste, etc.
- (vi) It must have a Facility/Laboratory Manager and a Laboratory Animal Manager.

Article 26 (Establishment of an Animal Laboratory and Related Matters)

- (1) The Facility/Laboratory Manager must, when an Animal Laboratory is established in addition to the Rearing and Care Facilities, submit an Application for Approval to Establish an Animal Laboratory (Attached Form 6) to the Dean/Director of the School/Graduate School or Research Institute/Center and must obtain the approval.
- (2) The Dean/Director of the School/Graduate School or Research Institute/Center must request the Department Committee to investigate the Animal Laboratory for which approval is sought, and decide whether to approve or reject it based on the investigation results and advice offered by the Department Committee.
- (3) The Facility/Laboratory Manager, Laboratory Animal Manager, Animal Experiment Researchers, and Animal Technicians shall not be allowed to conduct Animal Experiments and Related Activities (including cases where Laboratory Animals are temporarily cared for no longer than 48 hours) in such Animal Laboratory unless it has been approved by the Dean/Director of the School/Graduate School or Research Institute/Center.
- (4) The Facility/Laboratory Manager must, when changing or adding to the contents of the Application for Approval to Establish an Animal Laboratory after establishment of the laboratory in question, submit a Change/Addition Application to the Dean/Director of the School/Graduate School or Research Institute/Center and must obtain the approval.

Article 27 (Requirements of an Animal Laboratory)

An Animal Laboratory must fulfill the requirements as prescribed in the following items:

- (i) It must have a design and sufficient strength to prevent Laboratory Animals from escaping, and it must maintain an indoor environment where Laboratory Animals, should they escape, are easy to capture.
- (ii) It must have a design that contamination by excrement and blood, etc. is easy to clean and sterilize.
- (iii) It must be maintained in a sanitary condition, and measures must be taken to prevent negative impacts on the surrounding environment due to odor, noise and waste, etc.
- (iv) It must have a Facility/Laboratory Manager.

Article 28 (Maintenance and Management of Facilities)

- (1) The Facility/Laboratory Manager must endeavor to maintain and improve the Facilities that are needed to properly rear and care Laboratory Animals and conduct Animal Experiments and Related Activities.

- (2) The Facility/Laboratory Manager must ensure that a rearing and care environment is provided for Laboratory Animals that takes their species, habits, and other particulars into consideration.

Article 29 (Dismantling of Facilities)

- (1) The Facility/Laboratory Manager must, where the Facilities, etc. are dismantled, submit the Notification of Dismantling of a Rearing and Care Facility/Animal Laboratory (Attached Form 8) to the Dean/Director of the School/Graduate School or Research Institute/Center.
- (2) The Facility/Laboratory Manager shall, where the Facilities, etc. are dismantled, endeavor to transfer Laboratory Animals that have been reared and cared in the Facilities to other Rearing and Care Facilities, cooperating with the Principal Investigator where necessary.

Article 30 (Preparation of and Familiarization with a Rearing and Care Manual)

The Facility/Laboratory Manager and Laboratory Animal Manager must prepare a manual on rearing and caring Laboratory Animals and ensure that Animal Experiment Researchers and Animal Technicians become familiar with the contents of the manual and follow it.

Article 31 (Health and Safety Maintenance of Laboratory Animals)

The Facility/Laboratory Manager, Laboratory Animal Manager, Animal Experiment Researchers, Animal Technicians, and Manager must observe Standards and must endeavor to keep the health and safety of Laboratory Animals.

Article 32 (Introduction of Laboratory Animals)

- (1) The Manager, etc. must introduce Laboratory Animals from institutions which are properly managed pursuant to Related Laws and Regulations.
- (2) The Facility/Laboratory Manager and Laboratory Animal Manager must properly conduct quarantine and isolated rearing, etc. of Laboratory Animals to be introduced, and take necessary measures to acclimatize and adapt the Laboratory Animals introduced to the rearing environment.

Article 33 (Food and Water)

The Facility/Laboratory Manager, Laboratory Animal Manager, Animal Experiment Researchers, and Animal Technicians must ensure that Laboratory Animals receive appropriate food and water according to their physiology, ecology, and behavior.

Article 34 (Health Management)

- (1) The Facility/Laboratory Manager, Laboratory Animal Manager, Animal Experiment Researchers, and Animal Technicians must manage the health care of Laboratory Animals to prevent injuries or diseases other than those for experiment purposes.

- (2) The Facility/Laboratory Manager, Laboratory Animal Manager, Animal Experiment Researchers, and Animal Technicians must ensure that a rearing and care environment is provided for Laboratory Animals that takes their species, habits, and other particulars into consideration.
- (3) The Facility/Laboratory Manager, Laboratory Animal Manager, Animal Experiment Researchers, and Animal Technicians must, where Laboratory Animals suffer an injury or a disease other than those for experiment purposes, provide appropriate treatment, etc. for them.

Article 35 (Breeding of Different Species or Multiple Animals)

The Facility/Laboratory Manager, Laboratory Animal Manager, Animal Experiment Researchers, and Animal Technicians must, where different species of Laboratory Animals or multiple Laboratory Animals are reared and cared in the same facility, accommodate them taking their combination into consideration.

Article 36 (Preservation and Reporting of Records)

- (1) The Facility/Laboratory Manager and Laboratory Animal Manager must organize and retain records for five years on Laboratory Animal sources, breeding histories and histories of diseases, etc. of Laboratory Animals.
- (2) The Manager must report each academic year to the Dean/Director of the School/Graduate School or Research Institute/Center the species and the number, etc. of Laboratory Animals that are reared and cared.

Article 37 (Provision of Information upon Transfer)

The Manager, etc. must, where Laboratory Animals are transferred, provide the recipient with necessary information including their traits, rearing and caring methods, infectious diseases.

Article 38(Transport)

The Manager, etc. must, where Laboratory Animals are transported, comply with Standards, and ensure that the health and safety of the Laboratory Animals is secured and measures are taken to prevent them from causing harm to humans.

Article 39 (Risk Prevention)

- (1) The Manager, etc. must determine in advance the capture method, etc. in case that Laboratory Animals escape from Facilities.
- (2) The Manager, etc. must, where Laboratory Animals that are potentially harmful to humans have escaped from Facilities, promptly notify related organizations.
- (3) The Manager, etc. must take necessary measures in advance to prevent infectious diseases derived from Laboratory Animals, bites by Laboratory Animals, and so on, and deal with such infectious diseases, etc. when Managers of Laboratory Animals, Animal Experiment Researchers and Animal Technicians are affected by them.

- (4) The Manager, etc. must, where poisonous Laboratory Animals such as poisonous snakes are reared and cared, determine necessary matters separately in accordance with Standards to prevent the occurrence of harm to humans.
- (5) The Manager, etc. must make every effort to take appropriate measures that is technologically possible such as attaching tags, leg bands, microchips, or other identifying devices to laboratory animals, if they may inflict harm on people.
- (6) The Manager, etc. must take necessary measures to prevent anyone who has no official role in the rearing and care of Laboratory Animals or the conduct of Animal Experiments and Related Activities from contacting with Laboratory Animals, etc.

Article 40 (Emergency Measures)

- (1) The Manager, Facility/Laboratory Manager, and Laboratory Animal Manager must prepare a plan for emergency measures in times of crisis such as an earthquake or fire and ensure that the persons concerned become familiar with the content.
- (2) The Manager, etc. must, in times of crisis, take necessary measures to protect Laboratory Animals and to prevent the occurrence of harm to humans due to the escape of Laboratory Animals.

Article 41 (Prevention and Handling of Zoonoses)

- (1) The Facility/Laboratory Manager, Laboratory Animal Manager, Animal Experiment Researchers, and Animal Technicians must endeavor to thoroughly acquire knowledge about zoonoses and to gather information about zoonoses that are transmissible between humans and animals.
- (2) The Manager, Facility/Laboratory Manager, Laboratory Animal Managers, and Animal Experiment Researchers must endeavor to maintain a contact system with public health institutions and similar organizations so that in the event an outbreak of a zoonosis occurs, the necessary responses may be taken swiftly.

Article 42 (Education and Training)

- (1) The President must have the Facility/Laboratory Manager, Laboratory Animal Manager, Animal Experiment Researchers, and Animal Technicians receive specified education and training concerning the matters listed in the following items:
 - (i) Matters pertaining to Related Laws and Regulations, and regulations, etc. of the University.
 - (ii) Basic matters pertaining to the method of Animal Experiments and Related Activities.
 - (iii) Basic matters pertaining to the rearing and care of Laboratory Animals.
 - (iv) Matters pertaining to the assurance and management of safety concerning Animal Experiments and Related Activities, Laboratory Animals, and Facilities.
 - (v) Other matters pertaining to the proper conduct of Animal Experiments and Related Activities.
- (2) The Committee must implement the education and training, and the President must organize and retain records for five years on the dates of instruction, educational content, and the names of the instructors and those receiving education and training.

Article 43 (Self-inspections, Evaluations and External Evaluation)

- (1) The President must have the Committee conduct self-inspections and evaluations regarding conformity to Standards and Fundamental Guidelines.
- (2) The Committee must conduct self-inspections and evaluations concerning the implementation status etc. of Animal Experiments and Related Activities, and report the results to the President.
- (3) The Committee may request the Manager, Facility/Laboratory Manager, Principal Investigator, Laboratory Animal Manager, Animal Experiment Researchers and others to submit relevant materials in order to conduct self-inspections and evaluations.
- (4) The President must endeavor to conduct an external evaluation of the self-inspections and evaluation results.

Article 44 (Public Disclosure of Information)

The President shall publicly disclose information on Animal Experiments and Related Activities conducted at the University (i.e., information on the regulations for Animal Experiments and Related Activities, rearing and care conditions of Laboratory Animals, results of self-inspections and evaluations, external evaluation results, composition of the Committee, etc.) on an annual basis.

Article 45 (Confidentiality Obligations)

The Manager, etc., members of the Committee (including Department Committees), and staff members who are engaged in duties related to Animal Experiments and Related Activities must not disclose confidential information which they have learned in the course of their duties.

Article 46 (Application Mutatis Mutandis)

Animal Experiments and Related Activities in which animals other than those defined in item (v) of Article 3 are used must be conducted with due consideration to the intention of Standards.

Article 47 (Exemptions)

- (1) These Regulations shall not apply to Laboratory Animals reared or cared for the purpose of education, research or testing related to animal husbandry or for the purpose of improving breeding related to animal husbandry (in these cases, animal species are limited to those generally deemed to be industrial livestock) and shall not apply to the rearing and care of Laboratory Animals for the purpose of observation of their ecology only.
- (2) The provisions of the preceding paragraph notwithstanding, these Regulations shall be applied to the cases that research includes surgical procedures, research involves pharmacological experiments, Laboratory Animals will be provided for education and hands-on training into basic sciences such as anatomy, physiology, or pathology, or any other such circumstances are present.

- (3) The rearing and care of livestock animals must comply with the Standards Relating to the Care and Keeping of Industrial Animals (Notice of Ministry of the Environment No. 85 of 2013), and the rearing and care of Laboratory Animals for the purpose of performing ecological observation must comply with the Standards Relating to the Care and Keeping of Animals at home, etc. (Notice of Ministry of the Environment No. 104 of 2007).

Article 48 (Miscellaneous Rule)

In addition to the matters prescribed in these Regulations, the President shall separately provide necessary matters pertaining to Animal Experiments.

Supplementary Provisions

- (1) These Regulations shall come into force on March 12, 2007.
- (2) The Nagoya University Animal Experiment Guidelines (Guideline No. 1, 2004) and the Nagoya University Animal Experiment Committee Regulations (Regulation No. 19, 2004, hereinafter referred to as the "Committee Regulations") shall be abolished.
- (3) Upon the enforcement of these Regulations, those who have been committee members prescribed by Items (i) and (ii) of Article 2 of the Committee Regulations (hereinafter referred to as "Former Committee Members") shall remain as committee members prescribed by Items (i) and (ii), Paragraph (1) of Article 8 of these Regulations (hereinafter referred to as "New Committee Members"). In this case, the New Committee Members shall be appointed for the remainder of the term of the Former Committee Members, notwithstanding the provision set forth in Paragraph (1) of Article 9.

Supplementary Provision (Regulation No. 106, March 28, 2007)

These Regulations shall come into force on April 1, 2007.

Supplementary Provision (Regulation No. 117, March 31, 2008)

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

Supplementary Provision (Regulation No. 43, March 16, 2010)

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

Supplementary Provision (Regulation No. 89, March 21, 2012)

These Regulations shall come into force on April 1, 2012.

Supplementary Provision (Regulation No. 10, June 18, 2013)

These Regulations shall come into force on July 1, 2013.

Supplementary Provision (Regulation No. 125, March 26, 2014)

These Regulations shall come into force on April 1, 2014.

Supplementary Provision (Regulation No. 107, March 7, 2017)

These Regulations shall come into force on March 7, 2017.

Supplementary Provision (Regulation No. 136, March 30, 2017)

These Regulations shall come into force on April 1, 2017.

Supplementary Provision (Regulation No. 99, February 20, 2018)

These Regulations shall come into force on February 20, 2018.

Supplementary Provision (Nagoya University Regulation No. 35, April 1, 2020)

These Regulations shall come into force on April 1, 2020

Supplementary Provision (Nagoya University Regulation No. 105, December 1, 2020)

These Regulations shall come into force on April 1, 2021

Supplementary Provision (Nagoya University Regulation No. 120, January 20, 2021)

These Regulations shall come into force on April 1, 2021

Animal Experiment Protocol

To the (Dean/Director) of _____, Nagoya University

Submitted on: (Month/Date/Year)

Received on: (Month/Date/Year)

A	Principal Investigator	(Affiliation and Position) _____ (Name) _____ (Contact) TEL : _____ E-mail : _____
		(Course director's Name)
	List of Animal Experiment Researcher and technicians (describe all members name engaged in the animal experiment and their participant ID for the NU lecture on Animal Care and Use)	(Affiliation, Name and Participant ID) _____ (Contact) TEL : _____ E-mail : _____

B	Research title 1. Partial disclosure 2. Complete disclosure	1. New _____ 2. Continued (Academic Year: _____ Approval No. _____)
	Research objective (Expected outcomes) 1. Partial disclosure 2. Complete disclosure	
	Research plan and method 1. Partial disclosure 2. Complete disclosure	1. Sample collection 2. Drug administration 3. Surgical operation 4. Breeding / reproduction 5. Behavioral observation 6. Other (_____)
		1 The number of animals needed for the entire experiment (_____) 2 Grounds for the calculation (_____)
	Reason for the complete disclosure of the research content	

C	Term of animal experiment	From (Month/Date/Year) to (Month/Date/Year) (for months) (Until the end of the academic year, but may not exceed 5 years (60 months).)				
	Animal rearing location	Building name () Rearing room ()				
	Animal experiment location	Building name () Animal laboratory () Special animal laboratory ()				
	Animals to be used	(Species)	(Strain·Line)	(Sex)	(Number of animals)	(Breeder)
		Genetic quality	1. Guaranteed	2. Non-Guaranteed		
		Microbiologic quality	1. Guaranteed	2. Non-Guaranteed		
	Reasons why animal experiment, etc. is needed	1 There is no alternative method 3 Alternative methods are too expensive		2 Insufficient accuracy of alternative methods 4 Other ()		
	Safety hazards	1. None 2. Yes (1) Pathogens () (2) Hazardous materials () (3) Recombinant DNA () (4) Other ()				
	Assumed pain category	A B C D E (Circle the applicable letter based on the judgment made in accordance with the pain categories defined by the Scientist Center for Animal Welfare)				
	Types of pain and stress, and alleviation methods for animals	1. No measures implemented since pain is mild. 2. Anesthetics and analgesic will be used. Drug name () Dose () Method of administration () 3. Restraint and constraint for over 24 hours are unavoidable for the purpose of the experiment. 4. Although the experiment causes pain and stress to the animals, there is no way to alleviate the pain and stress. 5. When the experiment causes intolerable pain to the animals, the application of a humane endpoint will be considered at the appropriate timing (describe endpoint determination below). () 6. Other ()				
	Euthanasia procedures	1. Administration and inhalation of anesthetic Drug name() 2. Carbon dioxide 3. Other ()				

D	For Animal Care and Use Committee only	Opinion	Examined and approved by Online Application System as shown in the attached file.		
		Investigation result	Appropriate	Inappropriate	Investigation date: (Month/Date/Year)
	For Dean/Director of School or Research Institute/Center only	The experiment is approved (approved by Online Application System as shown in the attached file). Approval date: (Month/Date/Year) (To be expired on Month/Date/Year) Approval No. The (Dean/Director) of of Nagoya University			

Note: 1. This form must be submitted every academic year when new or continued experiments are conducted.
2. Circle the applicable boxes, letters, or numbers.

Attached Form 2 (related to paragraph 4 of Article 21)

Submission date: (Month/Date/Year)

Application for Approval of Animal Experiment Protocol (Change/Addition)

To the (Dean/Director) of _____, Nagoya University

The principal investigator

Affiliation:

Tel:

E-mail:

Position:

Name:

I hereby apply for approval of the change/addition as described below to the Animal Experiment Protocol approved as of _____ (Approval No. _____).

1. Change/addition

(1) Change/addition to animal experiment researcher

(Name and his/her participant ID for the NU lecture on Animal Care and Use)

(2) Change/addition to species, the number, etc of animals used

(3) Change to the term of the experiment

(4) Other

Note: When the content of the experiment or the principal investigator is changed, a new Animal Experiment Protocol form (Attached Form 1) must be submitted. Furthermore, when genetically modified animals are additionally used, an approval must be obtained from the Nagoya University Recombinant DNA Experimentation Safety Committee

2. Reasons for the change/addition

I hereby approve the change/addition to the animal experiment protocol as described above in this application.

Examined and approved by Online Application System as shown in the attached file.

Approval date: (Month/Date/Year)

The (Dean/Director) of _____, Nagoya University

Attached Form 3 (related to paragraph 5 of Article 21)

Submission date: (Month/Date/Year)

Report on Animal Experiment (Termination / Suspension)

To the (Dean/Director) of _____, Nagoya University

The principal investigator

Affiliation:

Tel:

E-mail:

Position:

Name:

I hereby report the termination / suspension as described below of the Animal Experiment Protocol approved as of _____ (Approval No. _____)

1 Date of termination / suspension:
(Month/Date/Year)

2 Date of disposal of laboratory animals:
(Month/Date/Year)

3 Remarks

Note: Circle "termination" or "suspension", whichever is applicable.

Report on Animal Experimental Results

To the (Dean/Director) of _____, Nagoya University

The principal investigator

Affiliation:

Tel:

E-mail:

Position:

Name:

I hereby report the animal experimental results as follows, pursuant to the provision of paragraph 6 of Article 21 of the Nagoya University Regulations on Animal Care and Use in Research.

1. Approval date and number	Date: (Month/Date/Year) No.
2. Research subject	
3. Number of animals used	
4. Experimental results (Mark the applicable box and give a brief summary)	<input type="checkbox"/> Implemented as planned <input type="checkbox"/> Implemented with some changes/additions (See note) <input type="checkbox"/> Suspended
	Summary of the results
5. Outcome (including future direction) (Provide details (e.g. author's name, title of the thesis, title of the journal, volume/number, publication year, page, publisher) if the outcomes are in the form of journal papers, books, intellectual property, and others. Use an attached sheet if necessary.)	
6. Special comments	

Note: An Application for Approval of Animal Experiment Protocol (Change/Addition) must have been submitted and approved in cases where some changes/additions were made to the animal experiment protocol.

Application for Approval to Establish a Rearing and Care Facility

To the Dean/Director of _____, Nagoya University

I hereby apply for approval to establish a rearing and care facility as follows, pursuant to paragraph 1 of Article 24 of the Nagoya University Regulations on Animal Care and Use in Research.

Application submitted on: (Month/Date/Year). Received on: (Month/Date/Year). Reception No.

1 Name of the rearing and care facility (hereinafter referred to as "the facility")	
2 Management system of the facility	<Facility/Laboratory Manager> Affiliation: _____ . Position: _____ . Name: _____ Tel: _____ E-mail: _____
	<Laboratory Animal Manager> Affiliation: _____ . Position: _____ . Name: _____ Tel: _____ E-mail: _____ Years of experience for animal experiment: Relevant qualifications:
3 Outline of the facility	(1) Structure of the building: (e.g. reinforced concrete structure) (2) Ventilation equipment: (e.g. room temperature/humidity control, air change rate) (3) Species of laboratory animals to be reared and cared: (4) Rearing and care equipment (e.g. rearing cage etc.) Specifications: Maximum capacity of housing: (5) Measures to prevent animals from escaping (e.g. locking of cage doors, the presence or not of a front room, means of blocking of windows /drains, and others) (6) Sanitation equipment (for cleaning, disinfection, sterilization etc.) Equipment: Specifications: (7) Measures to prevent negative impacts on the surrounding environment due to odor, noise, waste etc.

<p>4 Special remarks (e.g. the presence of a facility structure which is appropriate for experiments using hazardous chemicals or pathogenic agents)</p>	
<p>5 For Animal Care and Use Committee Only</p>	<p>Investigation date:</p> <p>Investigation results :</p> <p><input type="checkbox"/>The rearing and care facility for which approval is sought complies with the Nagoya University Regulations on Animal Care and Use in Research (Requirement <input type="checkbox"/> Some improvement is needed before starting operations.)</p> <p><input type="checkbox"/>The rearing and care facility for which approval is sought does not comply with the Nagoya University Regulations on Animal Care and Use in Research.</p> <p>Comments etc.</p>
<p>6 For Director/Dean of School or Research Institute / Center only</p>	<p>The application is approved.</p> <p>Approval No.</p> <p>Approval date: (Month/Date/Year) The (Dean/Director) of _____ of Nagoya University</p>

Note: The following materials must be attached:

1. A map indicating the location of the facility
2. The floor plan of the facility

Application for Approval to Establish an Animal Laboratory

To the (Dean/Director) of _____, Nagoya University

I hereby apply for approval to establish an animal laboratory as follows, pursuant to paragraph 1 of Article 26 of the Nagoya University Regulations on Animal Care and Use in Research.

Application submitted on: (Month/Date/Year). Received on: (Month/Date/Year). Reception No.:

1 Name of the animal laboratory	
2 Management system of the animal laboratory	<Facility/Laboratory Manager > Affiliation: _____ . Position: _____ . Name: _____ Tel: _____ E-mail: _____
3 Outline of the animal laboratory	(1) Area of the animal laboratory : _____ m ² (2) Species of animals to be used in the experiments : _____ (3) Experimental equipment (e.g. the presence or not of special equipment) (4) Measures to prevent animals from escaping (e.g. the presence or not of a front room, means of blocking of windows /drains and others) (5) Measures to prevent negative impacts on the surrounding environment due to odor, noise, waste etc.
4 Special remarks (e.g. the presence of a facility structure which is appropriate for experiments using hazardous chemicals or pathogenic agents)	
5 For Animal Care and Use Committee only	Investigation date: Investigation results : <input type="checkbox"/> The rearing and care facility for which approval is sought complies with the Nagoya University Regulations on Animal Care and Use in Research (Requirement <input type="checkbox"/> Some improvement is needed before starting operations.) <input type="checkbox"/> The rearing and care facility for which approval is sought does not comply with the Nagoya University Regulations on Animal Care and Use in Research. Comments etc.
6 For Dean/Director of School or Research Institute/Center only	The application is approved. Approval No. _____ Approval date: (Month/Date/Year) _____ The (Dean/Director) of _____ of Nagoya University

Note: The following materials must be attached:

1. A map indicating the location of the animal laboratory
2. The floor plan of the animal laboratory

Attached Form 7 (related to Paragraph 4 of Article 24 and Paragraph 4 of Article 26)

Submission Date: (Month/Date/Year)

To the (Dean/Director) of _____, Nagoya University

Application for Approval of (Change/Addition) to Rearing and Care Facility / Animal Laboratory

Facility/Laboratory Manager

Affiliation:

Tel:

E-mail:

Position:

Name:

In accordance with the provisions of Article 24 Paragraph 4 and Article 26 Paragraph 4 of the Nagoya University Regulations on Animal Care and Use in Research, I hereby apply for the following (Change/Addition) to the Application for Approval to Establish a Rearing and Care Facility / Animal Laboratory that was previously approved on (Month/Date/Year) with Approval No._____.

Change / Addition Details

1 (Change/Addition) Made

2 Reasons for the (Change/Addition)

I hereby approve the (Change/Addition) of this application.

Approval Date: (Month/Date/Year)

The (Dean/Director) of _____, Nagoya University

Note: Please circle either "Change" or "Addition", whichever is applicable

Notification of Dismantling of a Rearing and Care Facility / Animal Laboratory

To the (Dean/Director) of _____, Nagoya University

I hereby notify the dismantling of the rearing and care facility / animal laboratory as follows, pursuant to paragraph 1 of Article 29 of the Nagoya University Regulations on Animal Care and Use in Research.

1. Name of the rearing and care facility (hereinafter referred to as "the facility") or animal laboratory to be dismantled.	Date establishment was approved:(Month/Date/Year) Approval No.
2. Facility/Laboratory Manager	Affiliation: _____ . Position: _____ Name: _____ . Tel: _____ E-mail: _____
3. Date of dismantling	(Month/Date/Year)
4. Usage plan for the facility or animal laboratory after dismantled	
5. Measures to be taken with regard to the reared and cared animals at the time of dismantling (Give an answer only in the case where the facility is dismantled. Mark the applicable box)	The presence of reared and cared animals at the time of dismantling the facility. <input type="checkbox"/> Yes <input type="checkbox"/> No Measures to be taken when the answer is "yes."
6. Special comments	
7. For Animal Care and Use Committee only	
8. For Dean/Director of School or Research Institute / Center only	The (Dean/Director) of _____, Nagoya University