

Regulations Regarding Animal Experiments by the Obihiro University of Agriculture and Veterinary Medicine

(Regulations No. 21, May 21, 2008)

Amended on: Regulations No. 21, March 27, 2009 Regulations No. 25, March 15, 2012
Regulations No. 4, February 12, 2014 Regulations No. 15, March 28, 2017
Regulations No.2, January 18, 2018

(Preamble)

Research in life science using animals at a university is a necessary method for not only human health, welfare, and advanced medicine development, but also for advancement in the research field of animal health enhancement.

On the other hand, an order for the partial revision of the Act on Welfare and Management of Animals (Act No. 68, 2005) was issued in June 2005 to include principles on animal experiments, commonly called the "3Rs", namely "Refinement" (in cases where use of an animal is required for scientific purposes, a method that minimizes the pain and distress to the animal shall be used), "Replacement" (use of an alternative method that does not use animals to achieve the purpose of scientific research as much as possible), and "Reduction" (in cases where use of an animals is required to achieve the purpose of scientific research, the number of animals provided for such use shall be reduced as much as possible).

With the acceptance of the changes in the environment surrounding animal experiments, the National University Corporation Obihiro University of Agriculture and Veterinary Medicine (hereinafter referred to as "This University") has established the following regulations for the appropriate implementation of animal experiments not only for scientific needs, but also in accordance with the provisions of the Act on Welfare and Management of Animals (Act No. 105, 1973; hereinafter referred to as "Act"), 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, 2006; hereinafter referred to as "Fundamental Guidelines"), Standards Relating to the Care and Management of Laboratory Animals and Relief of Pain (Ministry of the Environment, Notice No. 88, 2006; hereinafter referred to as "Care and Management Standards"), and other relevant laws and regulations (hereinafter referred to as "Relevant Laws and Regulations"), and from the scientific viewpoint, the viewpoint of animal welfare and environment conservation, that of the safety assurance of officials and students who carry out animal experiments, and that of not infringing life, body, and assets of others, mainly local residents.

Chapter 1 General Provisions

(Fundamental Principles)

Article 1 The animal experiments are as prescribed in these regulations, beyond what are provided for in the Act, Fundamental Guidelines, Care and Management Standards, and Relevant Laws and Regulations.

(Definitions)

Article 2 The terms used in the following items in these regulations are defined according to each corresponding item below:

- (1) Laboratory Animals: Animals, including mammals, birds, or reptiles which are cared for or managed in the facilities for use in animal experiments (including animals in transport to the Facilities);

- (2) Animal Experiments: Provision of Laboratory Animals to use for education (such as lectures and training), test and research, manufacture of biological drug products, or other scientific purpose;
- (3) Animal Experiment Facilities: Facilities and equipment used to continuously care for or manage Laboratory Animals, or conduct Animal Experiments;
- (4) Laboratory: A Laboratory used to conduct experiments with Laboratory Animals (including temporary management up to 48 hours), other than Animal Experiment Facilities;
- (5) Facilities: Animal Experiment Facilities and Laboratories;
- (6) Animal Experiment Protocol: Protocol followed for the implementation of the Animal Experiments;
- (7) Animal Experiment Researcher: A person who conducts the Animal Experiments;
- (8) Animal Experiment Manager: Among persons conducting the Animal Experiments under the same research subject, the person who is responsible for the overall management of operations carried out for the said Animal Experiments;
- (9) Manager: A person who manages Laboratory Animals and Facilities (Department Chair, Director of each center, Director of Veterinary Medical Center, Director of Health Care Administration Center, and Office Chief of Animal Experiment Facilities) under the order of the University President;
- (10) Laboratory Animal Manager: A person who assists the Manager, and has knowledge and experience regarding Laboratory Animals and is in charge of managing the Laboratory Animals (such as a full-time teacher);
- (11) Animal Technician: A person cares for or manages the Laboratory Animals under the direction of a Laboratory Animal Manager or Animal Experiment Researcher;
- (12) Managers: The University President, Managers, Laboratory Animal Managers, Animal Experiment Researchers and Animal Technicians.

Chapter 2 Scope of Application

(Scope of Application)

Article 3 These regulations are applied to all the Animal Experiments using the living bodies of mammals, birds, and reptiles which are implemented in This University.

2 If entrusting the implementation of the Animal Experiments to an organization other than This University, the Animal Experiment Manager must confirm that the Animal Experiments are also implemented in such organization pursuant to the Act, Fundamental Guidelines, Care and Management Standards, and Relevant Laws and Regulations.

3 The Animal Experiments which the staff of This University and students conduct in another research institution are to be implemented pursuant to the internal regulations of the said research institution.

Chapter 3 Animal Experiment Committee

(Establishment of Animal Experiment Committee)

Article 4 As an organization which deliberates, reviews, reports, or gives advice on necessary matters concerning the Animal Experiments in This University, an Animal Experiment Committee of the National University Corporation Obihiro University of Agriculture and Veterinary Medicine (hereinafter referred to as "Committee") shall be established.

(Duties of Committee)

Article 5 The Committee shall deliberate or review the following matters, and report them to or advise the University President:

- (1) Matters regarding compliance with laws related to the Animal Experiment Protocol, Fundamental Guidelines, Care and Management Standards, Relevant Laws and Regulations and these regulations;
- (2) Matters regarding implementation and results of the Animal Experiment Protocol;
- (3) Matters regarding the Facilities and caring for and managing the Laboratory Animals;
- (4) Matters regarding the contents and system of education and training related to Animal Experiments;
- (5) Matters regarding self-inspection and evaluation related to Animal Experiments;
- (6) Other necessary matters regarding proper implementation of Animal Experiments.

2 In the event another research institution that does not have a body equivalent to a review committee requests the review of an Animal Experiment Protocol, the University President shall consult with the Committee.

(Organization of Committee)

Article 6 The Committee is to consist of the following committee members:

- (1) Office Chief of Animal Experiment Facilities;
- (2) A few persons whom the University President nominates from among those who have great insight into the Animal Experiments;
- (3) A few persons whom the University President nominates from among those who have great insight into the Laboratory Animals;
- (4) A few persons whom the University President nominates from among experts (excluding the experts in the field of the Animal Experiments or the Laboratory Animals);
- (5) Chief of Facilities Section;
- (6) Chief of Research Support Section;
- (7) Other persons whose participation is deemed necessary by the University President.

2 The committee members referred to in the preceding paragraph, items (2), (3) and (6) shall have a tenure of two years and be eligible for reappointment; provided, however, that the term of office of substitute or added committee members is the remaining term of the predecessors or the present members.

(Committee Chairman)

Article 7 A Committee Chairman shall be established in the Committee, and a full-time professor of This University whom the University President nominates from among the committee members set forth in the preceding Article, paragraph 1 shall serve as the Committee Chairman.

2 A Vice Committee Chairman shall be established in the Committee, and a person whom the Committee Chairman nominates from among the committee members set forth in the preceding Article, paragraph 1 shall serve as the Vice Committee Chairman.

3 The Committee Chairman shall call the Committee and serve as the chairperson thereof.

4 The Vice Committee Chairman shall assist the Committee Chairman, and assume his/her duties if the Committee Chairman is not available because of an accident.

(Meeting)

Article 8 The Committee may not hold a meeting unless a majority of committee members are present.

2 The Committee's decisions shall be effected by a majority of the committee members present; in case of a tie vote, they will be effected by the chairperson.

3 If the chairperson has deemed this necessary, it is possible to direct a person other than the committee members to attend the meeting to ask for his/her explanations or opinions.

4 A committee member may not join the review for the Animal Experiment Protocol submitted by him/herself as the Animal Experiment Manager.

(Prompt Review)

Article 9 Regarding a matter falling under any of the following items, the Committee Chairman may allow the committee members to take turns conducting a prompt review:

(1) A minor change in a research project;

(2) A research project categorized in conformance with the research project which has already been approved by the Committee;

(3) A research project which is a joint research and has already been approved by the Animal Experiment Committee in a research organization other than This University.

2 If the review referred to in the preceding paragraph was conducted, the Committee Chairman is to report the said review results to all the committee members promptly.

3 The committee members who received the report referred to in the preceding paragraph may ask the Committee Chairman to conduct a review in the Committee again for the said matter, in writing with the reason attached. In this case, if any adequate grounds are found, the Committee Chairman must hold the Committee promptly and review the said matter.

(Confidentiality)

Article 10 No one must divulge any information learned in the course of duties about the Animal Experiment Protocol to a third party. The same also applies after his/her retirement, unless otherwise required by laws and regulations.

(Office in Charge)

Article 11 The general affairs of the Committee shall be handled by the Research Support Section.

Chapter 4 Implementation of Animal Experiments

(General Management)

Article 12 The University President shall exercise general management of the proper implementation of the Animal Experiments in This University.

(Drafting, Review, and Procedure of Animal Experiment Protocol)

Article 13 From the viewpoint of securing the reliability of the data acquired by the Animal Experiments, the Animal Experiment Manager must draft the Animal Experiment Protocol considering the following matters, submit a separately prescribed Animal Experiment Protocol to the University President, and obtain his/her approval:

- (1) The purpose, meaning, and necessity of the research;
- (2) The adoption of an alternative;
- (3) The selection of laboratory animal species adequate for the purpose of the Animal Experiments so as to reduce the number of the Laboratory Animals to be used, number of the Laboratory Animals which influences the accuracy and repeatability of experimental results, genetic quality and microbiological quality, and caring conditions;
- (4) The relief of pain;
- (5) The consideration of establishing a humane endpoint (the timing to abandon the experiment to release the Laboratory Animals from severe pain) in the planning stage of the Animal Experiments, if the Animal Experiments to be conducted are very painful (e.g., fatal toxicity test, infection experiment, and irradiation experiment).

2 To change or renew the Animal Experiment Protocol, the Animal Experiment Manager must make application to the University President with a separately prescribed Animal Experiment Protocol and obtain his/her approval.

3 When receiving the Animal Experiment Protocol from the Animal Experiment Manager, the University President is to refer deliberations to the Committee.

4 When they are referred to by the University President, the Committee is to deliberate whether the program for the said Animal Experiments has satisfied the requirements prescribed in the Act, Fundamental Guidelines, Care and Management Standards, Relevant Laws and Regulations, and these regulations, and report the result to the University President.

5 In the process of the deliberations, as necessary, the Committee may take the necessary measures such as advising the Animal Experiment Manager or directing him/her to amend the details of the application.

6 When receiving the report referred to in paragraph 4, the University President is to decide whether to approve the application referred to in paragraphs 1 and 2, and give notice to the Animal Experiment Manager promptly.

7 When receiving the approval referred to in the preceding paragraph, the Animal Experiment Manager is to report that to the Manager of the Facilities where the Animal Experiments are conducted.

8 Before receiving the University President's approval for the Animal Experiment Protocol, the Animal Experiment Manager may not conduct any animal experiment.

9 If having terminated or discontinued the Animal Experiment Protocol, the Animal Experiment Manager must report that to the University President with a separately prescribed Animal Experiment Termination Report.

(Experiments)

Article 14 In the implementation of the Animal Experiments, the Animal Experiment Researcher shall comply with the Act, Fundamental Guidelines, Care and Management Standards, and the following matters:

- (1) The Animal Experiments shall be conducted in the Facilities which are properly maintained and managed;
- (2) The matters described in the Animal Experiment Protocol referred to in paragraph 1 of the preceding Article and the following matters shall be observed;
 - (a) Proper use of anesthetics and analgesics
 - (b) Consideration for the timing of completion of the experiment (including a humane endpoint (to release the Laboratory Animals from severe pain))
 - (c) Appropriate postoperative management
 - (d) Selection of the appropriate method of euthanasia
- (3) Experiments which require special attention in safety management (experiments using physically or chemically dangerous materials, pathogens, or gene-modified animals) shall be conducted in compliance with the Relevant Laws and Regulations and the relevant rules in This University;
- (4) The Animal Experiments which use physically or chemically dangerous materials or pathogens shall be conducted in the appropriate facility and with equipment that can ensure safety;
- (5) The Animal Experiment Researcher shall seek to learn experiment techniques needed to conduct the Animal Experiments;
- (6) In cases where highly invasive surgery on live animals is required, the said surgery shall be performed under the guidance of a person with extensive experience in the Animal Experiments.

Chapter 5 Facilities

(Establishment of Animal Experiment Facilities)

Article 15 To establish, change, or renew the Animal Experiment Facilities, the Manager must make application to the University President with a separately prescribed Written Application for Approval for Establishment of Animal Experiment Facilities and obtain his/her approval.

2 Unless the Animal Experiment Facilities have obtained the approval under the provision of the preceding paragraph, the Manager may not care for or manage the Laboratory Animals, or direct the Animal Experiments to be conducted.

3 When receiving the application referred to in paragraph 1, the University President is to refer deliberations to the Committee to direct it to investigate the Animal Experiment Facilities for the said application, decide whether to approve the application according to the advice thereof, and give notice to the Manager.

(Requirements for Animal Experiment Facilities)

Article 16 The Animal Experiment Facilities must satisfy the following requirements:

- (1) They shall have such a structure as can keep appropriate temperature, humidity, ventilation, and brightness;
- (2) They shall have the rearing equipment which fits the animal species and the number of animals cared for and managed;

- (3) They shall have the sanitary equipment to wash and disinfect apparatus, whose floor and inner walls are structured to be easily cleaned and disinfected;
- (4) They shall have such a structure and strength as will not let the Laboratory Animals run away;
- (5) The measures to prevent odors, noise, and waste from affecting the surrounding environment shall have been taken;
- (6) The Laboratory Animal Manager shall be established.

(Establishment of Laboratory)

Article 17 To establish, change, or renew the Laboratory other than the Animal Experiment Facilities, the Manager must make application to the University President with a separately prescribed Written Application for Approval for Establishment of Laboratory and obtain his/her approval.

2 When receiving the application referred to in the preceding paragraph, the University President is to refer deliberations to the Committee to direct it to investigate the Laboratory for the said application, decide whether to approve the application according to the advice thereof, and give notice to the Manager.

3 Unless the Laboratory has obtained the approval under the provision of the preceding paragraph, the Manager of the Laboratory may not direct the Animal Experiments (including temporary management up to 48 hours) to be conducted; provided, however, that conducting them exceeding 48 hours including the time for temporary management is still prohibited.

(Requirements for Laboratory)

Article 18 The Laboratory must satisfy the following requirements:

- (1) It shall have such a structure and strength as will not let the Laboratory Animals run away, and maintain such an environment as will enable the Laboratory Animals to be easily captured even if they run away indoors;
- (2) It shall be structured to be easily cleaned and disinfected against any contamination such as excreta and blood;
- (3) It shall always be kept in a sanitary condition, and the measures to prevent odors, noise, and waste from affecting the surrounding environment shall have been taken.

(Maintenance and Improvement of Facilities)

Article 19 The Manager must endeavor to maintain and improve the Facilities necessary for the proper management of the Laboratory Animals and the execution of the Animal Experiments.

2 The Manager shall secure the environment for caring for or managing the Laboratory Animals taking the types and habits thereof into consideration.

(Closing of Facilities)

Article 20 To close the Facilities, the Manager is to notify the University President with a separately prescribed Notification of Closing of Facilities.

2 To close the Facilities, the Manager must endeavor to transfer the Laboratory Animals being cared for and managed to the other Animal Experiment Facilities, as necessary, in cooperation with the Animal Experiment Manager.

Chapter 6 Care and Management of Laboratory Animals

(Preparation and Familiarization of Standard Operating Procedure)

Article 21 The Manager and the Laboratory Animal Manager must establish a concrete handling procedure for the care and management of the Laboratory Animals in the Animal Experiment Facilities which they manage, and familiarize the Animal Experiment Researcher and Animal Technician who use the said Animal Experiment Facilities with that procedure.

(Maintenance of Health and Safety of Laboratory Animals)

Article 22 The Animal Experiment Researchers must observe the Care and Management Standards, and endeavor to maintain the health and safety of the Laboratory Animals.

(Transport of Laboratory Animals to Animal Experiment Facilities)

Article 23 The Manager shall procure the Laboratory Animals from a facility that carries out the appropriate management pursuant to the Relevant Laws and Regulations.

2 The Laboratory Animal Manager shall carry out proper quarantine and isolation rearing when introducing the Laboratory Animals.

3 The Laboratory Animal Manager shall take the necessary measures to acclimatize the Laboratory Animals to the rearing environment.

(Feeding and Water Supply)

Article 24 The Laboratory Animal Manager, Animal Experiment Researcher, and Animal Technician (hereinafter referred to as "Laboratory Animal Managers") must properly feed and supply water to the Laboratory Animals according to the physiology, ecology, and habits thereof.

(Health Care)

Article 25 The Laboratory Animal Managers must administer necessary health care to the Laboratory Animals in order to prevent any injuries or diseases other than those required for an experiment on the Laboratory Animals.

2 The Laboratory Animal Managers must administer appropriate treatment to the Laboratory Animals, if the Laboratory Animals suffer any injuries or diseases other than those required for an experiment.

(Rearing of Different Species of or Multiple Animals)

Article 26 If caring for and managing different species or multiple Laboratory Animals in the same Facilities, the Laboratory Animal Managers must take the combinations thereof into consideration when accommodating them.

(Keeping and Reporting of Records)

Article 27 The Manager is to maintain the records concerning where the Laboratory Animals are obtained from, rearing history, and medical history, and must keep them for five years.

2 The Manager must submit the report which describes the types and number of uses of the Laboratory Animals cared for and managed in the previous year, by the end of April every year, to the University President.

(Information Provision in Transfer)

Article 28 In the transfer of the Laboratory Animals, the Managers must provide the information on the characteristics, methods for the care and management, and infectious diseases of the said Laboratory Animals.

(Transport)

Article 29 In the transport of the Laboratory Animals, the Managers must observe the Care and Management Standards, and take the measures to maintain the health and safety of the Laboratory Animals and to prevent harm to persons.

Chapter 7 Safety Management

(Prevention of Harm)

Article 30 The Manager must in advance establish the method to capture the Laboratory Animals in case the Laboratory Animals should run away.

2 If the Laboratory Animals which are likely to do harm to persons run away from the Facilities, the Manager must contact the relevant organizations promptly.

3 The Manager must endeavor to prevent any Laboratory Animals-derived infectious diseases, bites of the Laboratory Animals, and allergies, and also take the necessary measures immediately in case of the said infectious diseases, bites, and allergies.

4 If caring for or managing such animals as are likely to do harm to the human life, body, and assets (e.g. poisonous animals such as a poisonous snake), the Manager must establish necessary matters separately pursuant to the Care and Management Standards in order to prevent harm to persons.

5 The Managers shall endeavor to identify the Laboratory Animals which are likely to do harm to persons as much as technically possible, e.g. by attaching name tags, bird bands, and microchips.

6 The Manager must take the necessary measures to prevent those who are not involved in the care of the Laboratory Animals and the implementation of the Animal Experiments from touching the Laboratory Animals.

(Emergency Response)

Article 31 The Manager must in advance draw up the plan of the measures to take in emergencies such as an earthquake and fire, and familiarize relevant persons with that plan.

2 In case of emergency, the Manager must endeavor to protect the Laboratory Animals and prevent harm caused by the Laboratory Animals running away.

(Measures against Infectious Diseases Common to Humans and Animals)

Article 32 The Laboratory Animal Manager, Animal Experiment Researcher, and Animal Technician shall endeavor to acquire sufficient knowledge and collect information about the infectious diseases common to humans and animals.

Chapter 8 Education and Training

Article 33 The University President must provide education and training to the Laboratory Animal Managers for the following matters:

- (1) Matters regarding the Act, Fundamental Guidelines, Care and Management Standards, Relevant Laws and Regulations, and rules specified by This University;
- (2) Basic items regarding the methods for the Animal Experiments;
- (3) Basic items regarding the care and management of the Laboratory Animals;
- (4) Matters regarding safety assurance and safety management;
- (5) Other matters regarding the appropriate implementation of the Animal Experiments.

2 The University President must record the date of education and training, contents of education, instructors, and participant names, and keep them for five years.

Chapter 9 Self-inspection, Evaluation, and Observation

Article 34 The University President is to direct the Committee to self-inspect and evaluate compliance with the Fundamental Guidelines.

2 The Committee must self-inspect and evaluate how the Animal Experiments are implemented, and report the result to the University President.

3 The Committee may direct the Manager and the Animal Experiment Researcher to submit the materials for self-inspection and evaluation.

4 The University President is to endeavor to receive the observation from off-campus people about the result of self-inspection and evaluation.

Chapter 10 Information Disclosure

Article 35 The University President is to publicize the information on the Animal Experiments in This University (including these regulations, how the Laboratory Animals are cared for and managed, results of self-inspection, evaluation, and observation, and composition of the Animal Experiment Committee) about once per year.

Chapter 11 Miscellaneous Provisions

(Mutatis Mutandis Application)

Article 36 Regarding the Animal Experiments which use animals other than the Laboratory Animals prescribed in Article 3, paragraph 1, an endeavor is to be made to conduct them according to the purport of the Care and Management Standards.

Article 37 In case of a medical and biological experiment protocol which uses mammalian, avian or reptilian tissue-derived biomaterial (tissue obtained from necropsy or slaughter, organs, tissue, cells, or blood, including embryonated eggs), a separately prescribed Animal Experiment Protocol shall be submitted to the University President, from the scientific viewpoint, the viewpoint of animal welfare and environment conservation, and that of the safety assurance of officials and students who carry out test and research.

Article 38 These regulations shall not apply to the care and management of the Laboratory Animals kept for the purpose of education or test and research of rearing management for stockbreeding, or breed improvement for stockbreeding (limited to the animal species which are generally viewed as industrial livestock), and the care and management of the Laboratory Animals kept for the purpose of ecological observation; provided, however, that an endeavor is still to be made to handle the animals according to the purport of these regulations, and a separately prescribed Animal Experiment Protocol shall be submitted to the University President pursuant to the provisions of Article 13.

(Miscellaneous Provisions)

Article 39 In addition to the provisions in these regulations, necessary matters concerning the Animal Experiments in This University shall be established by the University President through discussion at the Committee.

Supplementary Provisions

1 These regulations come into effect as of October 1, 2008.

2 The Animal Experiment Handling Regulations, Obihiro University of Agriculture and Veterinary Medicine (Regulations No. 54, 2004; hereinafter referred to as "Former Regulations") are repealed.

3 When these regulations are enforced, the Animal Experiment Protocol approved pursuant to the Former Regulations is deemed to have been approved pursuant to the provision of Article 13, paragraph 6.

4 When these regulations are enforced, the Facilities being used actually are deemed to have been approved pursuant to the provision of Article 15, paragraph 3 or Article 17, paragraph 2, within the limit of the period until March 31, 2009.

Supplementary Provisions (Regulations No. 21, March 27, 2009)

These regulations come into effect as of April 1, 2009.

Supplementary Provisions (Regulations No. 25, March 15, 2012)

These regulations come into effect as of April 1, 2012.

Supplementary Provisions (Regulations No. 4, February 12, 2014)

These regulations come into effect as of February 12, 2014.

Supplementary Provisions (Regulations No. 15, March 28, 2017)

These regulations come into effect as of April 1, 2017.

Supplementary Provisions (Regulations No. 2, January 18, 2018)

These regulations come into effect as of January 18, 2018.