Osaka University Regulations on Animal Experiments

(Purpose)

Article 1:

The purpose of these Regulations is to stipulate matters relating to the establishment of the Osaka University Animal Experiment Committee, the formulation of animal experiment plans and other related activities to ensure the proper conduct of animal experiments and appropriate care and management of laboratory animals at Osaka University (“University”) in compliance with the Act on Welfare and Management of Animals (Act No. 105 of October 1, 1973) and other applicable laws and regulations (“Applicable Laws”), thereby guaranteeing the adequacy of animal experiments in terms of scientific propriety, welfare of animals, environmental preservation and safety of the University’s staff and students involved in animal experiments.

(Definitions)

Article 2:

1. The following terms as used herein shall have the meanings set forth below:
2. The term “Animal Experiment” shall mean the utilization of Laboratory Animals for education, testing, research, manufacture of biological products or for other scientific purposes.
3. The term “Animal Care and Management Facility” shall mean a facility or equipment used for the care or management of Laboratory Animals or for conducting Animal Experiments.
4. The term “Animal Care and Management Room” shall mean a room or area used for the care or management of Laboratory Animals or for conducting Animal Experiments, other than an Animal Care and Management Facility.
5. The term “Laboratory” shall mean an animal laboratory used exclusively for carrying out experimental operations on Laboratory Animals.
6. The term “Facility” shall mean any of Animal Care and Management Facility, Animal Care and Management Room, and Laboratory.
7. The term “Laboratory Animals” shall mean animals of mammalian, avian or reptilian species that are cared for and/or managed in a Facility for use in Animal Experiments and include those being transported to said Facility.
8. The term “Animal Experiment Plan” shall mean a plan relating to implementation of an Animal Experiment.
9. The term “Animal Experiment Researcher” shall mean a person who conducts an Animal Experiment.
10. The term “Animal Experiment Manager” shall mean a person responsible for supervising affairs relating to an Animal Experiment, who shall be appointed from among Animal Experiment Researchers.
11. The term “Laboratory Animal Manager” shall mean a person with knowledge and experience in handling Laboratory Animals, who is responsible for assisting the Division Director and who is in charge of the management of Laboratory Animals, and an Animal Care and Management Facility or Animal Care and Management Room (collectively “Animal Care and Management Facilities”).
12. The term “Animal Technician” shall mean a person responsible for the care or management of Laboratory Animals under a Laboratory Animal Manager or Animal Experiment Researcher.
13. The term “Division” shall mean any of the Graduate School of Human Sciences, the Graduate School of Science, the Graduate School of Medicine, the Graduate School of Dentistry, the Graduate School of Pharmaceutical Sciences, the Graduate School of Engineering, the Graduate School of Engineering Science, the Graduate School of Frontier Biosciences, the Research Institute for Microbial Diseases, the Institute of Scientific and Industrial Research, the Institute for Protein Research, and the Immunology Frontier Research Center.
14. Terms not defined in the preceding Paragraph shall have the meanings used in the Applicable Laws.

(Scope of Application)
Article 3:

1. These Regulations shall apply to all Animal Experiments conducted at the University.
2. To conduct an Animal Experiment at an external research institute (“External Institute”), the Animal Experiment Manager shall obtain approval as stated below in advance:
3. Approval of the deliberative body on Animal Experiments of the External Institute if any, in addition to the approval of the relevant Division Director of the University.
4. Approval of the relevant Division Director of the University, if the External Institute does not have a deliberative body on Animal Experiments.

(Obligation of President)

Article 4:

The President of the University shall be ultimately responsible for Animal Experiments conducted at the University and shall take the following measures to ensure appropriate implementation thereof:

1. To establish, amend and/or abolish internal regulations following the deliberation by the Committee stated in Article 6.
2. To take other measures necessary to ensure appropriate implementation of Animal Experiments at the University.

(Obligation of Division Directors)
Article 5:

Division Directors shall be responsible for Animal Experiments conducted at the respective Divisions and shall take the following measures to ensure appropriate implementation thereof:

1. To establish, amend and/or abolish animal experiment regulations of the respective Divisions.
2. To determine whether to approve or reject Animal Experiment Plans.
3. To keep themselves informed of the results of Animal Experiments.
4. To determine whether to approve or reject the establishment of Animal Care and Management Facilities.
5. To be responsible for affairs relating to the maintenance and improvement of Facilities.
6. To prepare manuals (standard operating procedures) and familiarize all people concerned therewith.
7. To organize and retain records on the care and management of Laboratory Animals.
8. To offer information on Laboratory Animals to be transferred.
9. To be responsible for the transport of Laboratory Animals.
10. To prevent hazards caused by Laboratory Animals.
11. To respond to emergency situations.
12. To take other measures necessary to ensure appropriate implementation of Animal Experiments at the respective Divisions.

(Committee)
Article 6:

1. An Animal Experiment Committee (“Committee”) shall be established within the University to ensure appropriate implementation of Animal Experiments at the University.
2. The Committee shall deliberate or inspect the following matters and report the results thereof or give advice thereon to the President as necessary:
3. Matters deliberated or inspected by the Animal Experiment Committee of each Division (“Divisional Committee”)
4. Contents of education and training stipulated in Article 24
5. Other matters necessary for ensuring the appropriate implementation of Animal Experiments at the University
6. In addition to performing the duties stated in the preceding Paragraph, the Committee may request a Divisional Committee to report on the appropriateness of Animal Experiments or may give advice or guidance thereon to said Committee as necessary.
7. The Committee members shall have advanced knowledge on Animal Experiments or Laboratory Animals and the ability to make judgments relating thereto from a broad perspective. Thus the Committee shall consist of:
8. A few persons selected from among members of each Divisional Committee
9. A few professors and/or associate professors in humanities and social sciences
10. Other person(s) deemed necessary by the Committee in addition to those stated in the preceding Items
11. The Committee shall have a Chairperson who shall be elected by mutual vote from among the Committee members.
12. The Chairperson shall serve a term of two (2) years and may be reappointed.
13. The Chairperson shall convene and preside over Committee meetings.
14. The Committee may allow non-member(s) to attend a Committee meeting and present opinions when deemed necessary by the Chairperson. However, non-member(s) cannot participate in decision-making.
15. Committee members shall be appointed in the name of the President and the President shall allow each Division Director to appoint Committee members stated in Item (1) of Paragraph 4 at their own discretion.
16. When a Division Director has appointed or dismissed a Committee member at his or her discretion pursuant to the preceding Paragraph, the Division Director shall notify the President of the appointment or dismissal.
17. Committee members stated in Items (2) and (3) of Paragraph 4 shall serve a term of two (2) years. In case a vacancy arises in the Committee, the term of service of the member who filled the vacancy shall be the remaining term of service of the predecessor.
18. The Committee member stated in the preceding Paragraph may be reappointed.
19. The administrative work relating to the Committee shall be carried out by the Research Promotion Division of the Department of Research Promotion.
20. Matters relating to the administration of the Committee not specified herein shall be set forth separately.

(Divisional Committee)
Article 7:

1. A Divisional Committee shall be established within each Division.
2. The Divisional Committee shall deliberate or inspect the following matters at the request of the Division Director and report the results thereof or give advice thereon to the Division Director:
3. Establishment, amendment and/or abolishment of animal experiment regulations of the Division
4. Contents and methods of Animal Experiment Plans
5. Facilities used for Animal Experiments
6. Appropriate care and management of Laboratory Animals
7. Self-inspection/evaluation of how an Animal Experiment has been conducted
8. Other matters necessary for ensuring the appropriate implementation of Animal Experiments at the Division
9. The administrative work relating to the Divisional Committee shall be carried out by the Administration Department of the Division.
10. Matters necessary for a Divisional Committee, including the organization and operation thereof, shall be set forth by each Division.

(Application for Approval of Animal Experiment Plans, Review and Reporting)

Article 8:

1. The Animal Experiment Manager shall develop an Animal Experiment Plan that meets the following requirements to ensure the reliability of data obtained from the Animal Experiment and apply for approval therefor to the Division Director using the prescribed form:
2. The purpose, significance and necessity of the Animal Experiment shall be defined.
3. The possibility of using an alternative method that does not require Laboratory Animals shall be considered to ensure optimum use of Laboratory Animals.
4. A Laboratory Animal species that best serves the purpose of the experiment, the number of Laboratory Animals necessary to achieve the expected accuracy and reproducibility of the experiment results, and genetic and microbiological quality and raising conditions thereof shall be considered to reduce the number of Laboratory Animals to be used.
5. The Animal Experiment shall be conducted in a manner that alleviates pain in Laboratory Animals.
6. Setting a Humane Endpoint, which as used herein shall mean the timing to put an end to the experiment to relieve Laboratory Animals from intense pain, shall be considered when developing a plan for an Animal Experiment that causes a high degree of pain to Laboratory Animals, including but not limited to lethal toxicity test, infection experiment, and irradiation experiment.
7. Animal Experiment Plans developed pursuant to the preceding Paragraph shall be valid for up to five (5) years.
8. Upon receipt of an application pursuant to Paragraph 1, the Division Director shall consult the Divisional Committee, determine whether to accept or reject the application based on the report on the results of the deliberation or advice given by said Committee, and notify the Animal Experiment Manager of the determination.
9. The Animal Experiment Manager shall not conduct any Animal Experiment without obtaining approval for the Animal Experiment Plan from the Division Director.
10. Upon notifying the Animal Experiment Manager of the approval pursuant to Paragraph 3, the Division Director shall report thereon to the President without delay.
11. When an approved Animal Experiment is terminated, suspended or not implemented, the Animal Experiment Manager shall notify the Division Director of the termination, suspension or non-implementation thereof using the prescribed form.
12. If an Animal Experiment Plan is to be changed after approval, the Animal Experiment Manager shall file an application for change to the Division Director for approval using the prescribed form in advance, provided, however, that in the following cases, the Animal Experiment Manager may change the Animal Experiment Plan only by notifying the Division Director of the change and without obtaining approval:
13. The Animal Experiment Manager is to be changed.
14. The Animal Experiment Researcher is to be changed.
15. The Laboratory Animal species to be used is to be changed.
16. The period of the Animal Experiment Plan is to be changed within five (5) years.
17. The Animal Experiment Manager shall report on the progress of the Animal Experiment to the Division Director using the prescribed form by the end of each academic year during the period of the Animal Experiment Plan.

(Implementation of Animal Experiment)
Article 9:

The Animal Experiment Researcher shall comply with all the Applicable Laws and meet the following requirements:

1. The Animal Experiment shall be conducted in an appropriately maintained Facility.
2. The conditions shown in the prescribed form for Animal Experiment Plans as well as the conditions stated in (a) to (d) below shall be met:
3. Anesthetic or analgesic drugs shall be used as appropriate.
4. Consideration shall be given to the timing to put an end to the Animal Experiment (including Humane Endpoint).
5. Post-operative care shall be provided as appropriate.
6. Euthanasia shall be selected as appropriate.
7. Experiments that require special safety management measures (e.g. experiments using physically or chemically hazardous materials, pathogens, or living modified organisms) shall be conducted in compliance with all the Applicable Laws and relevant regulations of the University.
8. When conducting an Animal Experiment using physically or chemically hazardous materials or pathogens, a facility and/or equipment necessary to ensure safety shall be in place.
9. The Animal Experiment Researcher shall master necessary experiment techniques prior to conducting an Animal Experiment.
10. The Animal Experiment Researcher shall follow the instructions of an experienced researcher when conducting highly invasive major surgery on a Laboratory Animal.

(Animal Care and Management Facility)
Article 10:

1. To set up or change an Animal Care and Management Facility, the Laboratory Animal Manager shall file an application for approval to the Division Director using the prescribed form in advance.
2. Upon receipt of an application pursuant to Paragraph 1, the Division Director shall consult the Divisional Committee, determine whether to accept or reject the application based on the report on the results of the deliberation or advice given by said Committee, and notify the Laboratory Animal Manager of the determination.
3. The Laboratory Animal Manager or Animal Experiment Manager shall provide care and management of Laboratory Animals or conduct an Animal Experiment only at the Animal Care and Management Facility approved by the Division Director.
4. Upon notifying the Laboratory Animal Manager of the determination pursuant to Paragraph 2, the Division Director shall report thereon to the President without delay.
5. The Animal Care and Management Facility shall meet the following conditions:
6. The Animal Care and Management Facility shall be structured in a manner that maintains the temperature, humidity, airflow and illumination at appropriate levels.
7. The Animal Care and Management Facility shall be structured in a manner suitable for the species and number of Laboratory Animals cared for and managed therein.
8. The Animal Care and Management Facility shall be structured in a manner that allows easy cleaning and sterilization of its floor, inner walls and other parts, and a sanitary facility shall be in place for the cleaning and sterilization of equipment used therein.
9. The Animal Care and Management Facility shall have enough structural integrity and strength to prevent Laboratory Animals from escaping.
10. Appropriate measures shall be in place to prevent adverse impacts on the surrounding environment caused by odor, noise, waste, or other nuisance.
11. The Animal Care and Management Facility shall be placed under the charge of the Laboratory Animal Manager.
12. To abolish an approved Animal Care and Management Facility, the Laboratory Animal Manager in charge thereof shall file an application for approval for the abolishment thereof to the Division Director using the prescribed form in advance.
13. Upon receipt of an application stated in the preceding Paragraph, the Division Director shall notify the President thereof without delay.
14. When abolishing an Animal Care and Management Facility pursuant to Paragraph 6, the Laboratory Animal Manager, in cooperation with the Animal Experiment Manager, shall endeavor to transfer the Laboratory Animals cared for and/or managed therein to another Animal Care and Management Facility as necessary. However, if sacrificing Laboratory Animals is unavoidable, the Laboratory Animal Manager shall endeavor to adhere to the Guidelines on Methods of Sacrificing Animals (Notice of the Ministry of the Environment No. 105 of November 12, 2007).

(Laboratory)
Article 11:

The Laboratory shall meet the following conditions:

1. The Laboratory shall have enough structural integrity and strength to prevent Laboratory Animals from escaping, and maintain an environment where Laboratory Animals can be caught with ease should they escape.
2. The Laboratory shall be structured in a manner that enables easy removal of contamination caused by excrement, blood, or the like and sterilization of objects contaminated thereby.
3. The Laboratory shall be kept clean at all times, and appropriate measures shall be in place to prevent adverse impacts on the surrounding environment caused by odor, noise, waste or other nuisance.

(Maintenance and Improvement of Facility)

Article 12:

Division Directors shall endeavor to ensure the proper maintenance and improvement of the Facility necessary for appropriate management of Laboratory Animals and implementation of Animal Experiments.

(Preparation of and Familiarization with Manuals)

Article 13:

Division Directors shall prepare manuals for the care and management of Laboratory Animals (standard operating procedures) and familiarize Animal Experiment Researchers and Animal Technicians therewith.

(Health and Safety of Laboratory Animals)

Article 14:

Laboratory Animal Managers, Animal Experiment Researchers and Animal Technicians shall endeavor to maintain the health and safety of Laboratory Animals in compliance with all the Applicable Laws.

(Introduction of Laboratory Animals)
Article 15:

1. Division Directors shall introduce Laboratory Animals only from institutes where Laboratory Animals are appropriately managed in compliance with all the Applicable Laws.
2. Laboratory Animal Managers shall appropriately quarantine and isolate Laboratory Animals in compliance with all the Applicable Laws when introducing them.
3. Laboratory Animal Managers shall take measures necessary to help Laboratory Animals acclimatize and adapt to the new living environment.

(Food and Water)

Article 16:

Laboratory Animal Managers, Animal Experiment Researchers and Animal Technicians shall supply Laboratory Animals with food and water in a manner suited to the physiological, ecological and behavioral characteristics thereof.

(Health Management of Laboratory Animals)
Article 17:

1. Laboratory Animal Managers, Animal Experiment Researchers and Animal Technicians shall take appropriate health management measures for Laboratory Animals to prevent them from being injured or contracting a disease except for the purpose of the Animal Experiment.
2. If a Laboratory Animal has been injured or contracted a disease except for the purpose of the Animal Experiment, Laboratory Animal Managers, Animal Experiment Researchers and Animal Technicians shall provide appropriate medical treatment thereto.

(Care of Laboratory Animals of Different Species or Multiple Laboratory Animals)

Article 18:

If Laboratory Animals of different species or multiple Laboratory Animals are to be cared for or managed in the same Facility, the Laboratory Animal Manager, Animal Experiment Researcher and Animal Technician in charge shall find the optimal combination thereof for housing.

(Record-keeping)
Article 19:

Division Directors shall keep and retain records on the sources of Laboratory Animals, breeding and disease history thereof and other related matters.

(Provision of Information upon Transfer)
Article 20:

When a Laboratory Animal is to be transferred, the Division Director shall provide the transferee with information on the characteristics, and the method of care and management thereof, the risk of infection and other related matters.

(Transport)
Article 21:

Division Directors shall meet the following conditions when transporting Laboratory Animals to protect the health and safety thereof and prevent harm to humans therefrom:

1. Laboratory Animals shall be transported in a manner that requires the least possible travel time or otherwise minimizes discomfort and pain therein.
2. Laboratory Animals shall be appropriately supplied with food and water as necessary during transport, and the vehicle used for transport shall be maintained at an adequate temperature by ventilation or other means.
3. Laboratory Animals to be transported shall be grouped appropriately in a manner suited to the physiological, ecological and behavioral characteristics thereof, and a vehicle and container of suitable size and structure to protect the health and safety of the Laboratory Animals and prevent them from escaping shall be used for transport.
4. Appropriate measures shall be in place to prevent microorganisms in Laboratory Animals or waste materials therefrom from polluting the environment.

(Prevention of Harm)
Article 22:

1. Division Directors shall establish in advance the procedures to capture Laboratory Animals that may escape.
2. If a Laboratory Animal that may cause harm to humans has escaped from a Facility, the Division Director shall immediately notify relevant organizations of the incident.
3. Division Directors shall take measures necessary to protect Laboratory Animal Managers, Animal Experiment Researchers and Animal Technicians from the risk of being infected or bitten by Laboratory Animals and to deal with the situation when such an accident has occurred.
4. In case a poisonous animal, including but not limited to a poisonous snake, is kept in an Animal Care and Management Facility, the Division Director shall make antitoxin serum and other emergency medical supplies available at all times, and establish a procedure to ensure that emergency medical care will be immediately provided by a doctor in the event of an accident, with a view to preventing harm to humans by Laboratory Animals.
5. Division Directors shall take appropriate measures to prevent persons not involved in the care and management of Laboratory Animals or in Animal Experiments from coming into contact therewith.

(Emergency Measures)
Article 23:

1. Division Directors shall establish measures to be taken in case of emergency, including but not limited to earthquake and fire, and familiarize all people concerned therewith.
2. In the event of an emergency, Division Directors shall endeavor to protect Laboratory Animals and prevent harm caused by Laboratory Animals that have escaped.

(Education and Training)
Article 24:

1. Division Directors shall provide education and training on the following matters to Laboratory Animal Managers, Animal Experiment Researchers and Animal Technicians:
2. Applicable Laws and relevant regulations of the University
3. Basic matters concerning methods of Animal Experiments
4. Basic matters concerning care and management of Laboratory Animals
5. Matters concerning security measures and safety management
6. Other matters concerning appropriate implementation of Animal Experiments
7. Division Directors shall retain records on the dates and contents of education and training, and the names of instructors and persons attending.

(Self-Inspection/Evaluation and Verification)

Article 25:

1. To ensure the transparency of Animal Experiments, Division Directors shall have the respective Divisional Committees conduct a self-inspection/evaluation and notify the President of the results thereof.
2. Upon receipt of the results stated in the preceding Paragraph, the President shall have the Committee conduct an evaluation on compliance with the Applicable Laws.
3. The Committee may require Division Directors to submit materials for self-inspection/evaluation.
4. The President shall endeavor to have an external party verify the results of the self-inspection/evaluation conducted by the Committee.

(Information Disclosure)
Article 26:

Information on Animal Experiments conducted at the University, including but not limited to information on regulations on Animal Experiments, conditions of care and management of Laboratory Animals, and method of disclosing the results of self-inspection/evaluation and verification, shall be disclosed around once a year.

(Mutatis Mutandis Application)

Article 27:

These Regulations shall be applied mutatis mutandis to Animal Experiments using animals other than Laboratory Animals defined in Item (6) of Article 2.

(Miscellaneous Provision)

Article 28:

Matters concerning Animal Experiments not specified herein shall be set forth separately.

Supplementary Provision

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

2. Osaka University Guidelines on Animal Experiments (dated April 20, 1988) and Osaka University Regulations on Animal Experiment Committee (dated April 20, 1988) shall be abolished.

3. Notwithstanding the provisions of Articles 8 and 10, a Laboratory Animal Manager who has set up an Animal Care and Management Facility as of the effective date of these Regulations may provide care and management of Laboratory Animals or conduct an Animal Experiment at said Animal Care and Management Facility for the period up to six (6) months following the effective date hereof.

4. An Animal Experiment Plan approved under Paragraph 2 of Article 5 of the Osaka University Regulations on Animal Experiment Committee stated in Paragraph 2 of Supplementary Provisions prior to the effective date of these Regulations shall be deemed to have been approved under Paragraph 3 of Article 8 hereof.

Supplementary Provision

These Regulations as amended shall come into effect on October 1, 2007.

Supplementary Provision

These Regulations as amended shall come into effect on November 17, 2009.

Supplementary Provision

These Regulations as amended shall come into effect on April 1, 2016.

Supplementary Provision

These Regulations as amended shall come into effect on April 1, 2018.