

ICU Regulations on Animal Experimentation

Preamble

Research in life sciences at universities and other such organizations that is conducted using animals in experimentation is a necessary means of research not only for the development of human health, welfare and new medical treatments but also for the development of research fields where the health of animals is promoted.

These regulations determine the manner in which experiments using animals are to be conducted and are based on “Laws Pertaining to the Protection and Management of Animals (act no. 105, 1973)” (herein referred to as “Japanese law”), “Standards Pertaining to Laboratory Animals’ Breeding, Care and Reduction of Pain and Distress (directive 88 from the Ministry of the Environment, 2006)” (herein referred to as “the Ministry of the Environment’s standards on animal breeding and care”), and MEXT’s “Basic Principles on Animal Experimentation at Research Organizations and Other Such Bodies (June 2006)” (herein referred to as “the basic principles”); they use as a point of reference the Science Council of Japan’s “Guidelines for the Proper Use of Animals in Experimentation (June 2006)” (herein referred to as “the SCJ’s guidelines”); and take into consideration scientific and environmental perspectives, perspectives on animal breeding, and perspectives on securing the safety of students and educational and general staff who conduct experiments using animals.

Chapter 1 General Provisions

(Objectives and Basic Principles)

Article 1. These regulations determine the establishment of a Committee on the Use of Animals in Experimentation, procedures for approval of plans for animal experimentation, and other matters necessary for the proper conducting of animal experimentation at the School Juridical Person International Christian University.

2. Animal experimentation is to be based on these regulations as well as on Japanese law, the Ministry of the Environment’s standards on animal breeding and care, the basic principles, the Cabinet Office’s directive “Policies on Disposal of Animals,” and other laws and ordinances.
3. Animal experimentation must be conducted in line with Japanese law and the Ministry of the Environment’s standards on animal breeding and care. At the same time, it must also be properly conducted based on the “3-Rs” principle of Replacement (to the extent that it is possible to satisfy comparable scientific objectives, animals are replaced as much as possible with methods that can stand in place of animal experimentation), Reduction (to the extent that it is possible to satisfy comparable scientific objectives, consideration is given to the suitable use of laboratory animals by such means as reducing as much as possible the number of animals), and Refinement (in cases in which animal experimentation is unavoidable, such experimentation must use methods that causes no pain or distress to animals).

(Definition of Terms)

Article 2. Within these regulations, the below terms are to be defined as follows.

- (1) Animal experimentation: any use of “laboratory animals” (as defined in point 5, below) for

education or research purposes

- (2) Animal breeding and care facility (facilities): any facility that constantly breeds laboratory animals, keeps such animals, or conducts animal experimentation
- (3) Laboratory (laboratories): any laboratory that conducts experiments with laboratory animals (including temporary maintenance of such experiments for periods of 48 hours or fewer)
- (4) Facility (facilities): animal breeding and care facilities as well as laboratories
- (5) Laboratory animals: mammals, birds and reptilians bred or cared for at facilities and which are for use in animal experimentation (including such animals in transit in order to be introduced into facilities)
- (6) Animal experimentation plan(s): plan(s) on the conducting of animal experimentation
- (7) Researcher(s): individual(s) conducting experiments using animals
- (8) Lead researcher(s): individual(s) among researchers who oversee the conducting of animal experimentation
- (9) Manager(s): individual(s) receiving orders from the President and who manage(s) laboratory animals and facilities
- (10) Laboratory animal manager(s): individual(s) (e.g., full-time educational staff) who assist managers, has/have knowledge of/experience with laboratory animals, and is/are responsible for laboratory animals
- (11) Breeder(s): individual(s) serving under manager(s) and laboratory animal manager(s) and who is/are engaged in the breeding and care of laboratory animals
- (12) Management: includes the President, manager(s), laboratory animal manager(s), researcher(s) and breeder(s)
- (13) Guidelines: Basic principles and guidelines determined by administrative bodies pertaining to animal experimentation

Chapter 2 Extent of Regulations' Authority

Article 3. These regulations shall be enforced for all animal experimentation at ICU using live mammals, birds and reptilians.

2. If an outside organization is asked to conduct animal experimentation, lead researcher(s) are to confirm that the organization conducts animal experimentation based on the MEXT's basic principles and the basic principles related to animal experimentation as determined by other government ministries and agencies.

Chapter 3 Organization

Article 4. A "Committee on the Use of Animals in Experimentation" (herein referred to as "the committee") shall be established as described in section 4 as a body to report to and advise the President on matters related to the proper conducting of animal experimentation, including approval of animal experimentation plans at ICU, maintaining an understanding of the status and results of such experimentation, approval of laboratories and animal breeding and care facilities, conducting self-inspections/evaluations, and making information on animal experimentation available to the public.

Chapter 4 Committee on the Use of Animals in Experimentation

(Role of the Committee)

Article 5. The committee shall deliberate on and investigate the following matters as well as report to and advise the President on these matters.

- (1) Deliberation on matters relating to conformity of animal experimentation plans with various principles and these regulations
- (2) Matters pertaining to the status and results of animal experimentation plans
- (3) Matters pertaining to facilities as well as the breeding and care of laboratory animals
- (4) Matters pertaining to contents and systems of education and training related to proper handling of animal experimentation and laboratory animals as well as related laws, ordinances, etc.
- (5) Matters pertaining to self-inspections and self-evaluations
- (6) Other matters necessary for the proper conducting of animal experimentation

(Committee Members)

Article 6. The committee shall be composed of the following members. Members are to be appointed by the President.

- (1) Vice President for Academic Affairs
- (2) Manager(s) (as defined in article 2, clause 9)
- (3) Laboratory animal manager(s) (as defined in article 2, clause 10)
- (4) Full-time educational staff not involved in the conducting of animal experimentation
- (5) A small number other individuals deemed necessary by the President

(Committee Chair)

Article 7. The committee will select the chair from among its members.

2. The chair will convene meetings of the committee and preside over the meetings' proceedings.

(Committee Members' Term of Appointment)

Article 8. With the exception of the Vice President for Academic Affairs, the members of the committee shall serve 2-year terms of appointment.

2. Committee members may not be reappointed.

3. When a committee member resigns mid-term, the president shall make an appointment as soon as possible. The individual taking over the resigned committee member's seat shall serve the remainder of the term of that seat.

(Committee Secretariat)

Article 9. The committee's secretariat shall be the Center for Research Planning and Support.

2. The Center for Research Planning and Support must prepare the agenda for committee meetings and maintain records of relevant documents.

Chapter 5 Conducting Animal Experimentation

(Drawing Up Animal Experimentation Plans, Their Screening and Procedures)

Article 10. From the standpoint of securing the reliability of data gathered through animal experimentation, lead researchers are to draw up animal experimentation plans based on the following points and submit the necessary documentation on animal experimentation plans to the President.

- (1) Objectives, significance and necessity of the research
- (2) Proper use of laboratory animals and consideration of alternate research methods
- (3) Consideration of the following in order to reduce the number of laboratory animals used:

selection of type of laboratory animal appropriate for objectives of animal experimentation;
number of laboratory animals that can control the precision and reproducibility of results of
animal experimentation; genetic and microbiological prerequisites in terms of quality and
breeding/care

- (4) Proper conducting of animal experimentation through the reduction of pain and distress
 - (5) Consideration given at planning stages of the setting of a humane endpoint (point at which
an experiment is stopped in order to free laboratory animals from intense pain or distress) in
case the animal experimentation involves lethal poisons, infectious diseases, radiation, or
otherwise causes a high degree of pain or distress
2. When receiving documents on animal experimentation plans from lead researchers, the
President is to ask the committee to screen the plans and inform the lead researcher of the results
of the committee's findings.
 3. Lead researchers may not conduct experiments until after the President has given approval of
their animal experimentation plans.

(Experiment Procedures)

Article 11. When conducting animal experimentation, researchers must conform to Japanese law,
the Ministry of the Environment's standards on animal breeding and care, the various principles,
and, in particular, also comply without fail to the following.

- (1) Animal experimentation must be conducted in properly maintained facilities.
 - (2) Experiments must comply with points outlined in documents on animal experimentation as
well as the following.
 - ① Proper use of anesthetics and analgesics
 - ② Consideration of timing to end experiment (including humane endpoint)
 - ③ Proper management after operations
 - ④ Selection of proper euthanasia
 - (3) In experiments in which especial care must be taken for safety management (experiments
using hazardous materials or chemicals, pathogens, genetically modified animals, etc.) related
laws and ordinances as well related ICU regulations must be obeyed.
 - (4) Proper facilities and equipment must be secured for safety reasons when animal
experimentation deals with hazardous materials or chemicals, pathogens, etc.
 - (5) Any necessary technical training is to be carried out before the start of experimentation.
 - (6) When highly invasive major surgical procedures are performed on living animals, they
must be performed under the guidance of someone with experience in the procedure.
2. After carrying out an animal experimentation plan, lead researchers must report to the
President such matters as the number of animals used, whether there were any deviations from
the approved plan, and the experiment's results. The report is to be made using the prescribed
format.

Chapter 6 Facilities

(Establishment of Animal Breeding and Care Facilities)

Article 12. If animal breeding and care facilities are to be established or changes are to be made
to an existing animal breeding and care facility, managers must submit the prescribed document
("Request for Approval to Establish Animal Breeding and Care Facilities") and receive the

approval of the President.

2. Managers of animal breeding and care facilities may breed or care for animals or otherwise conduct animal experimentation at no other breeding and care facility than that for which the President's approval has been received.
3. The President will have the committee investigate animal breeding and care facilities for which requests are received. The President will approve or deny requests based on the committee's advice.

(Requirements for Animal Breeding and Care Facilities)

Article 13. Animal breeding and care facilities must satisfy the following requirements.

- (1) Must be a structure that is capable of maintaining suitable temperature, humidity, ventilation, light, etc.
- (2) Must have breeding equipment suitable for the species and number of animals.
- (3) Must be of a construction such that floors, walls, etc. can be easily cleaned and sanitized; must have sanitation equipment for cleaning and sanitizing fixtures.
- (4) Must be of a construction and strength such that laboratory animals cannot escape.
- (5) Must take measures to prevent adverse effects on the surrounding area caused by smells, noise, waste, etc.
- (6) Must have laboratory animal manager(s) on site.

(Establishment of Laboratories)

Article 14. If laboratories other than those at animal breeding and care facilities are to be established or changes are to be made to an existing laboratory, managers must submit the prescribed document ("Request for Approval to Establish Laboratory") and receive the approval of the President.

2. The President will have the committee investigate laboratories for which requests are received. The President will approve or deny requests based on the committee's advice.
3. Managers of laboratories may conduct animal experimentation (including temporary maintenance of such experiments for periods of 48 hours or fewer) at no other laboratory than that for which the President's approval has been received.

(Requirements for Laboratories)

Article 15. Laboratories must satisfy the following requirements.

- (1) Must be of a construction and strength such that laboratory animals cannot escape. Must prevent laboratory animals from escaping outside even if they do escape within the laboratory.
- (2) Must be of a construction such that cleaning and sanitization can be easily performed to prevent contamination from animal waste, blood, etc.
- (3) Must be a structure that can be kept clean at all times and is capable of maintaining suitable temperature, humidity, ventilation, light, etc.

(Laboratory Maintenance and Improvement)

Article 16. Managers must make efforts to maintain and improve facilities to meet the needs dictated by proper management of laboratory animals and the conducting of animal experimentation.

(Dismantling Facilities)

Article 17. When facilities are dismantled, the manager must submit the prescribed notification (“Notification on Dismantling of Facilities”) to the President.

2. As necessary, managers must work together with lead researchers and make efforts to transfer any animals being bred or cared for at that time to another breeding and care facility.

Chapter 7 Breeding and Care of Laboratory Animals

(Creation and Dissemination of Manual on Standard Operating Procedures)

Article 18. Managers and laboratory animal managers are to determine agreements on the breeding and care of animals and make these known to researchers and breeders.

(Maintaining Health and Safety of Laboratory Animals)

Article 19. Laboratory animal managers, researchers and breeders must strictly abide by animal breeding and care standards and make efforts to maintain the health and safety of laboratory animals.

(Bringing in Laboratory Animals)

Article 20. When bringing in laboratory animals, managers are to introduce animals from organizations that are properly managed in accordance with related laws and ordinances and various principles.

2. When bringing in laboratory animals, laboratory animal managers are to check the animals against the terms of the order for irregularities or deaths and conduct quarantine procedures.
3. Laboratory animal managers are to take necessary measures to plan for adapting the breeding and care environments of laboratory animals.

(Food and Water)

Article 21. Laboratory animal managers, researchers and breeders are to provide food and water appropriate to laboratory animals’ physiology, ecology, behavior, etc.

(Maintenance of Health)

Article 22. Laboratory animal managers, researchers and breeders are to provide the necessary maintenance of health for laboratory animals in order to prevent injury or illness occurring outside the objectives of experimentation.

2. In case of injury or illness occurring outside the objectives of experimentation, laboratory animal managers, researchers and breeders are to provide appropriate medical treatment for laboratory animals.

(Caring for Multiple Laboratory Animals and/or Laboratory Animals of Different Species)

Article 23. When multiple laboratory animals and/or laboratory animals of different species are bred and/or cared for within the same facility, laboratory animal managers, researchers and breeders are to accommodate the animals in consideration of these animals being brought together within the single facility.

(Maintaining and Reporting Records)

Article 24. Managers are to maintain records on laboratory animals, including where they were acquired, a history on their care, medical records, etc. Records are to be kept for three years.

2. Every year managers are to report to the President information on the species and numbers of laboratory animals kept and cared for.

(Provision of Information When Transferring Laboratory Animals)

Article 25. When transferring laboratory animals, management is to provide information on their distinguishing characteristics, method of breeding and care, infectious diseases, etc.

(Transportation)

Article 26. When transporting laboratory animals, management is to strictly abide standards for breeding and care and make efforts to secure the health and safety of the laboratory animals and prevent harm to humans.

Chapter 8 Safety Management

(Harm Prevention)

Article 27. Managers are to determine in advance the means of capturing escaped laboratory animals.

2. If laboratory animals for which there is a concern of causing harm to humans escape a given facility, the managers are to contact relevant organizations immediately.
3. Managers are to take measures necessary to prevent infection or injury of laboratory animal managers, researchers and breeders caused by laboratory animals. Managers are to take the necessary measures in the event that such infection or injury occurs.
4. If poisonous animals (e.g., poisonous snakes) are cared for or kept, managers are to determine separately matters based on animal breeding and care standards that are necessary in order to prevent harm to humans.
5. Managers are to take measures necessary to prevent individuals with no connection to the care of laboratory animals or the conducting of animal experimentation from coming in direct contact with laboratory animals.

(Emergency Response)

Article 28. Managers must draw up in advance plans outlining measures to be taken in the event of an emergency (e.g., earthquake, fire) and make those plans known to interested parties.

2. In the event of an emergency, managers must make efforts to protect laboratory animals and prevent harm caused by escaped laboratory animals.

Chapter 9 Education and Training

Article 29. Before the start of experiments, lead researchers, researchers and breeders must at an appropriate time receive the prescribed education and training related to the following.

- (1) Regulations determined in related laws and ordinances, various principles, and ICU regulations
 - (2) Basic matters related to methods of animal experimentation
 - (3) Basic matters related to the breeding and care of laboratory animals
 - (4) Matters related to securing and maintaining safety
 - (5) Other matters related to the proper conducting of animal experimentation
2. Records on training (dates, content of instruction, instructor, trainees) are to be kept for three years.

Chapter 10 Self-Inspection/Evaluation/Verification

Article 30. The President must have the committee conduct self-inspections and evaluations with respect to compliance with the basic principles.

2. The committee must conduct self-inspections and evaluations on the status of animal experimentation and report the results to the President.

3. In order to conduct self-inspections and evaluations, the committee may request documents to be submitted by managers, researchers, lead researchers, laboratory animal managers and breeders.
4. The President must make efforts to receive outside verification of the self-inspection and evaluation.

Chapter 11 Public Availability of Information

Article 31. Information on animal experimentation (regulations on animal experimentation, status of breeding and care of laboratory animals, method by which results of self-inspections, evaluations and verifications are to be made public, etc.) is to be released approximately once each year.

Chapter 12 Supplementary Regulations

(Application)

Article 32. In cases in which animal experimentation keeps animals other than those laboratory animals determined in article 2, clause 5, efforts must be made so that this is done in accordance with the main points of the Ministry of the Environment's standards on animal breeding and care.

(Exceptions)

Article 33. These regulations are not to be applied in cases of: education or test-based research on the breeding and management of farm animals; breeding or care of laboratory animals (in general limited to animal species considered to be domesticated animals) with the objective of improving breeds of farm animals; or, breeding or care of laboratory animals with the objective of habitat observation.

(Miscellaneous)

Article 34. Other than those matters determined herein, necessary matters are to be determined separately by the President.

(Revision and Abolition)

Article 35. Revision or abolition of these documents is to be conducted by the President after such matters are deliberated on in the Senate.

Supplementary Provisions:

These regulations shall be effective from October 13, 2011.