

# International Christian University Regulations Governing Animal Experimentation

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## Preamble

Research in life sciences, conducted at universities and other such organizations, that involves animal experimentation is a means necessary for not only the development of human health, welfare, and advanced medicine but also the advancement of research fields such as in animal health promotion. These regulations prescribe the establishment of a management and operation system concerning the care and keeping of laboratory animals and establish the methods in which experiments, etc. using animals (hereinafter referred to as “animal experiments, etc.”) shall be conducted, from the perspectives of science, animal protection, environmental conservation, and the safety of faculty, staff, students, etc. who conduct animal experiments, etc., based on the Act on Welfare and Management of Animals (Act No.105 of 1973) (hereinafter referred to as the “Japanese law”), Standards relating to the Care and Keeping and Reducing Pain of Laboratory Animals (Public Notice of the Ministry of the Environment No.88 of 2006) (hereinafter referred to as the “MOEJ’s standards on care and keeping of animals”), and Ministry of Education, Culture, Sports, Science and Technology’s Fundamental Guidelines for Proper Conduct of Animal Experiment and Related Activities in Academic Research Institutions under the jurisdiction of the Ministry of Education, Culture, Sports, Science and Technology (Public Notice of the Ministry of Education, Culture, Sports, Science and Technology No. 71 of 2006) (hereinafter referred to as the “MEXT’s fundamental guidelines”), and using as a reference the Science Council of Japan’s Guidelines for Proper Conduct of Animal Experiments (June 2006)” (hereinafter referred to as the “SCJ’s guidelines”).

## Chapter I: General Provisions

### (Objectives and Basic Principles)

- Article 1. These regulations shall establish matters necessary for the proper conduct of animal experiments, etc. and care and keeping, etc. of laboratory animals at School Juridical Person International Christian University, including the responsibilities of the President, the establishment of the Committee on the Use of Animals in Experimentation, procedures for the approval of animal experiment plans, and the care and keeping of laboratory animals.
2. Animal experiments, etc. shall be governed by these regulations, in addition to the Japanese law, MOEJ’s standards on care and keeping of animals, MEXT’s fundamental guidelines, Basic Rule for Abandoned Animals and Killing Animals (Public Notice of the Prime Minister’s Office No. 40 of 1995), other laws, ordinances, etc.
  3. Animal experiments, etc. must be conducted properly, in line with the Japanese law and MOEJ’s standards on care and keeping of animals, and based on the principles of the 3Rs, namely, Replacement (using technologies or approaches that directly replace or avoid the use of animals in experiments where they would otherwise have been used, to the extent that the scientific purposes of the use are achieved), Reduction (giving consideration to the proper use of laboratory animals by such means as minimizing the number of animals used per experiment, to the extent that the scientific purposes of the use are achieved), and Refinement (using methods that minimize pain and distress, suffering, or lasting harm that laboratory animals may experience, to the extent necessary for the scientific use).
  4. In the care and keeping of laboratory animals, the Five Freedoms (freedom from hunger and thirst, freedom from physical discomfort, pain, and distress, freedom from injury and disease, freedom from fear and mental pain and distress, and freedom to express normal patterns of behavior), which is the basic philosophy of animal welfare, shall be taken into consideration and implemented to the extent that the scientific purposes of the use are achieved.

### (Definition of Terms)

Article 2. As used in these regulations, the following terms shall have the following respective meanings:

- (1) Animal experiments, etc.: any use of laboratory animals specified in item (5) of this article for education, research and development, manufacture of biological preparations, or other scientific purposes
- (2) Animal care and keeping facility (facilities): any facility used for the caring and keeping of laboratory animals constantly, or for conducting animal experiments, etc.
- (3) Laboratory (laboratories): any animal laboratory used for performing experimental procedures on laboratory animals (including the temporary keeping of such laboratory animals for a period of 48 hours or less)
- (4) Facility, etc. (facilities, etc.): animal care and keeping facilities and laboratories
- (5) Laboratory animals: mammals, birds, and reptiles cared for or kept at facilities, etc. for use in animal experiments, etc. (including such animals in transit to be introduced into facilities, etc.)
- (6) Animal experiment plan(s): plan(s) for the conducting of animal experiments, etc.
- (7) Researcher(s): individuals who conduct animal experiments, etc.
- (8) Lead researcher(s): individuals among researchers who oversee the conducting of animal experiments, etc.
- (9) Manager(s): individuals who are responsible for the overall management of laboratory animals and facilities, etc. under the President's order
- (10) Laboratory animal manager(s): individuals (e.g., full-time academic staff) who have knowledge of and experience with laboratory animals, assist managers in animal care and keeping facilities, and are responsible for the management of laboratory animals
- (11) Caretaker(s): individuals who serve under laboratory animal managers or researchers to engage in the care and/or keeping of laboratory animals
- (12) Management: the President, managers, laboratory animal managers, researchers, and caretakers
- (13) Guidelines, etc.: the MEXT's fundamental guidelines and fundamental guidelines on the implementation of animal experiments, etc. given by the Ministry of Health, Labour and Welfare or the Ministry of Agriculture, Forestry and Fisheries, as well as the SCJ's guidelines

## Chapter II: Scope of Application

Article 3. These regulations shall apply to all animal experiments, etc. conducted at International Christian University (hereinafter referred to as the "University") using live mammals, birds, and reptiles.

2. Where animal experiments, etc. are commissioned, etc. to an outside organization, the lead researcher(s) shall ensure that such animal experiments, etc. are conducted properly at the commissioned organization, etc. based on the guidelines, etc.

## Chapter III: Organization

Article 4. As the individual who is ultimately responsible, the President shall oversee the proper conduct of animal experiments, etc. and the care and keeping of laboratory animals at the University.

2. The President shall bear responsibility for approving animal experiment plans; understanding the status of their implementation and results and taking measures for improvement based on the results; establishing animal care and keeping facilities and approving animal care and keeping facilities and laboratories; safety management concerning animal experiments, etc.; education and training; self-inspections and evaluations; inspections by external experts; information disclosure; and other measures necessary for the proper conduct of animal experiments, etc.
3. The President shall establish the Committee on the Use of Animals in Experimentation (hereinafter referred to as the "committee") provided for in Chapter IV as a body that gives reports or advice to fulfill the responsibilities set forth in the preceding paragraph.

## Chapter IV: Committee on the Use of Animals in Experimentation

### (Role of the Committee)

Article 5. The committee shall screen or investigate the following matters and report to or advise the President in response to consultations from the President:

- (1) Screening whether animal experiment plans are in compliance with laws and ordinances concerning animal experiments, etc., the MOEJ's standards on care and keeping of animals, the MEXT's fundamental guidelines, etc., and these regulations
  - (2) Matters pertaining to the status and results of animal experiment plans
  - (3) Matters pertaining to the facilities, etc., and the status of care and keeping of laboratory animals
  - (4) Matters pertaining to the contents or systems of education and training pertaining to the proper handling of animal experiments and laboratory animals, as well as relevant laws, ordinances, etc.
  - (5) Matters pertaining to self-inspections and evaluations, inspections by external experts, and information disclosure
  - (6) Other matters necessary for the proper conduct of animal experiments, etc.
2. The committee shall endeavor to engage in mutual provision of necessary information, etc. with committees, etc. related to animal experiments requiring attention for safety management as necessary.

### (Composition of the Committee)

Article 6. The committee shall consist of the following members, who are appointed by the President:

- (1) Vice President for Academic Affairs
- (2) Managers (as defined in Article 2, item (9))
- (3) Laboratory animal managers (as defined in Article 2, item (10))
- (4) Full-time academic staff not engaged in animal experiments
- (5) A small number of other individuals deemed necessary by the President

### (Committee Chair)

Article 7. The chair shall be selected by mutual vote from among the committee members.

2. The chair shall convene and preside over the meetings of the committee.

### (Term of Service of Committee Members)

Article 8. With the exception of the Vice President for Academic Affairs, the members of the committee shall serve a term of two years.

2. Committee members may be reappointed.
3. Whenever any vacancy occurs, it shall be filled promptly by appointment of the President. A member appointed to fill a vacancy shall serve the remaining term of the predecessor.

### (Administrative Matters for the Committee)

Article 9. The Center for Research Planning and Support shall manage the administrative matters for the committee.

2. The Center for Research Planning and Support shall be responsible for matters including the preparing of the minutes, etc. pertaining to the committee meetings and retaining of relevant documents, etc.

## Chapter V: Conducting Animal Experiments, Etc.

### (Drawing Up Animal Experiment Plans, Their Screening, and Procedures)

Article 10. From the standpoint of ensuring the reliability of data obtained through animal experiments, etc., lead researchers shall draw up animal experiment plans by taking into account the following points, and apply to the President in the

prescribed format:

- (1) Objectives, significance, and necessity of the research
  - (2) Proper use of laboratory animals in consideration of the principle of Replacement
  - (3) Consideration of the following, in order to reduce the number of laboratory animals used: selection of laboratory animal species appropriate for the objectives of animal experiments, etc.; the number of laboratory animals that determines the accuracy and repeatability of the results of animal experiments; genetic and microbiological qualities; and conditions under which laboratory animals are cared for
  - (4) Proper conduct of animal experiments, etc. through the reduction of pain and distress
  - (5) Consideration given at the planning stage to setting humane endpoints (points at which an experiment is stopped in order to release laboratory animals from intense pain and distress) in cases where the animal experiments, etc. involve toxicity test, infection and irradiation experiments that may be fatal to laboratory animals, or otherwise cause severe pain and distress
2. The President shall have lead researchers make the application in the preceding paragraph before the start of the animal experiments, etc., determine approval or disapproval after review by the committee, and inform the lead researchers of the results of the review.
  3. Lead researchers may not conduct any experiments until after the President has approved their animal experiment plans.
  4. When changing animal experiment plans that have been approved, lead researchers must obtain approval for the application for the change in the same manner as paragraph 1.

(Experimental Procedures)

Article 11. When conducting animal experiments, etc., researchers shall comply with laws and ordinances concerning animal experiments, etc., the MOEJ's standards on care and keeping of animals, and guidelines, etc., and, in particular, shall also observe the following matters:

- (1) Researchers shall conduct animal experiments, etc. at properly maintained facilities, etc.
  - (2) Researchers shall observe the matters stated in the animal experiment plan and matters set forth in the following items:
    - (a) Appropriate use of anesthetics, analgesics, etc.
    - (b) Consideration of the timing to end an experiment (including humane endpoints)
    - (c) Appropriate post-operative management
    - (d) Selection of an appropriate method of euthanasia
  - (3) Researchers shall comply with relevant laws, ordinances, etc. and relevant University regulations, etc. in conducting experiments that require particular attention to safety management (experiments involving the use of physically and chemically hazardous materials, pathogens, genetically modified animals, etc.).
  - (4) Researchers shall secure appropriate facilities and equipment for conducting animal experiments, etc. involving the use of physically and chemically hazardous materials, pathogens, etc. safely.
  - (5) Researchers shall seek to learn the necessary experimental techniques, etc. before conducting an experiment.
  - (6) When performing highly invasive, major surgical procedures on living animals, researchers shall do so under the supervision of a person with experience in such procedures.
2. After the completion of an animal experiment, etc., the President shall have the lead researcher(s) report the results of the implementation of the animal experiment plan including the number of animals used, whether there were any deviations from the approved plan, and outcomes, using the prescribed form. The President shall receive advice from the committee and implement improvement measures for the proper conduct of animal experiments, etc. if necessary.

(Establishment of Animal Care and Keeping Facilities)

- Article 12. When establishing an animal care and keeping facility or making a change thereto, managers shall submit the prescribed Request for Approval to Establish Animal Care and Keeping Facilities and receive the approval of the President.
2. The President shall have the committee investigate animal care and keeping facilities for which applications have been submitted and shall determine approval or disapproval based on advice from the committee and inform the managers in question of the results.
  3. Laboratory animal managers, researchers, and caretakers may not care for or keep laboratory animals or conduct animal experiments, etc. unless the animal care and keeping facility has received approval from the President.
  4. The President shall have managers and laboratory animal managers report the status of the care and keeping of laboratory animals, and shall receive advice from the committee and instruct improvement if necessary.

(Requirements for Animal Care and Keeping Facilities)

Article 13. An animal care and keeping facility shall satisfy the following requirements:

- (1) It has a structure, etc. that is capable of maintaining a suitable temperature, humidity, ventilation, light, etc.
- (2) It has equipment for caring appropriate to the species, physiology, ecology, behavior, etc. of the laboratory animals and the number being cared for or kept.
- (3) It has a structure that allows for the floors, walls, etc. to be easily cleaned and sanitized and sanitation equipment for the cleaning, sanitizing, etc. of fixtures.
- (4) It has a structure and strength that prevents laboratory animals from escaping.
- (5) It has measures in place to prevent harmful effects on the surrounding environments caused by smells, noise, waste, etc.
- (6) It has been assigned laboratory animal managers.

(Establishment of Laboratories)

- Article 14. When establishing a laboratory or making a change thereto outside of animal care and keeping facilities, managers shall submit the prescribed Request for Approval to Establish Laboratory and receive the approval of the President.
2. The President shall have the committee investigate laboratories for which applications have been submitted, determine approval or disapproval based on advice from the committee, and inform the managers in question of the results.
  3. Laboratory animal managers, researchers, and caretakers may not conduct animal experiments, etc. (including the temporary keeping of such laboratory animals for a period of 48 hours or fewer) unless the laboratory has received approval from the President.

(Requirements for Laboratories)

Article 15. A laboratory shall satisfy the following requirements:

- (1) It has a structure and strength that prevents laboratory animals from escaping, and an environment is maintained such that it is easy to capture laboratory animals even if they escape inside the laboratory.
- (2) It has a structure that allows for the easy cleaning and sanitization of any contamination from animal waste, blood, etc.
- (3) It is kept clean at all times, and has measures in place to prevent harmful effects on the surrounding environments caused by smells, noise, waste, etc.

(Maintenance, Management, and Improvement of Facilities, Etc.)

Article 16. Managers shall endeavor to maintain, manage, and improve the facilities, etc. as necessary to manage laboratory animals appropriately and conduct animal experiments, etc.

2. Managers shall ensure an environment for the care and keeping of laboratory animals that takes into consideration the species, physiology, ecology, behavior, etc. of the laboratory animals.

(Dismantling Facilities, Etc.)

Article 17. Based on the prescribed Notification on Dismantling of Facilities, Etc. submitted by a manager, the President shall approve the dismantling after investigation of the facilities, etc. by the committee.

2. Managers shall, as necessary, endeavor to work together with lead researchers to ensure that any laboratory animals being cared for or kept at the facility, etc. are transferred to another animal care and keeping facility.

## Chapter VII: Caring for and Keeping of Laboratory Animals

(Preparation and Dissemination of the Manual (Standard Operating Procedures))

Article 18. Managers and laboratory animal managers shall establish a manual on the caring and keeping of animals, make the manual known to researchers and caretakers, and ensure that researchers and caretakers observe the manual.

(Maintaining Health and Safety of Laboratory Animals)

Article 19. Laboratory animal managers, researchers, and caretakers shall observe the MOEJ's standards on care and keeping of animals and endeavor to maintain the health and safety of laboratory animals.

(Bringing in Laboratory Animals)

Article 20. Managers shall bring in laboratory animals only from organizations that are managed properly in accordance with relevant laws and ordinances and the guidelines, etc.

2. When bringing in laboratory animals, laboratory animal managers shall conduct appropriate quarantine isolation, etc.

3. Laboratory animal managers shall take necessary measures to acclimate and adapt the laboratory animals to the care environments.

(Food and Water)

Article 21. Laboratory animal managers, researchers, and caretakers shall provide food and water appropriate to the laboratory animals' species, physiology, ecology, behavior, etc.

2. Laboratory animal managers shall ensure that the number and condition of laboratory animals cared for or kept are checked through day-to-day management, maintenance, and inspection, and regular rounds, etc. of animal care and keeping facilities.

(Maintenance of Health)

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

2. In cases of injury or illness that occurs outside the objectives of experiments, laboratory animal managers, researchers, and caretakers shall provide appropriate medical treatment, etc. for laboratory animals.

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

Article 23. When caring for or keeping multiple laboratory animals and/or laboratory animals of different species in the same facility, laboratory animal managers, researchers, and caretakers shall determine the housing arrangements accordingly.

(Maintaining Records and Reporting)

Article 24. Management shall maintain records on laboratory animals, including where they were acquired, history of care, and medical records, and shall keep them for 10 years in principle.

2. Managers shall report annually to the President information on the species, numbers, etc. of laboratory animals cared for or kept.

(Provision of Information at the Time of Transferring, etc. of Laboratory Animals)

Article 25. When transferring laboratory animals, management shall provide information on the laboratory animals being transferred, including their distinguishing characteristics, method of care or keeping, and infectious diseases.

(Transportation)

Article 26. When transporting laboratory animals, management shall observe the MOEJ's standards on care and keeping of animals, and endeavor to secure the health and safety of the laboratory animals and prevent harm to humans.

## Chapter VIII: Safety Management

(Harm Prevention)

Article 27. Managers shall determine in advance the means of capturing, etc. of escaped laboratory animals.

2. When laboratory animals with a risk such as causing harm to humans escape from a facility, etc., the managers shall contact relevant organizations promptly.
3. Managers shall take measures necessary to prevent laboratory animal managers, researchers, and caretakers from contracting infectious diseases of laboratory-animal origin, allergic diseases, etc., to prevent bites, etc. caused by laboratory animals, and to respond to such incidents when they do occur.
4. When caring for or keeping poisonous animals (e.g., poisonous snakes), managers shall separately determine matters necessary for preventing harm to humans based on the MOEJ's standards on care and keeping of animals.
5. Management shall endeavor to implement identification measures to the extent technologically possible for laboratory animals with a risk of causing harm to humans, etc. such as the fitting of name tags, leg banding, microchips, etc.
6. Laboratory animal managers, researchers, and caretakers shall endeavor to mutually provide necessary information to prevent the occurrence of harm caused by laboratory animals, etc.
7. Management shall take measures necessary to prevent individuals not involved in the care or keeping of laboratory animals or the conducting of animal experiments, etc. from coming in contact with laboratory animals, etc.

(Emergency Response)

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

2. In the event of an emergency, management shall endeavor to protect laboratory animals, prevent harm to humans caused by the escaping of laboratory animals, and prevent the arising of environmental conservation issues, etc.

(Response to Zoonotic Infectious Diseases)

Article 29. Laboratory animal managers, researchers, and caretakers shall endeavor to acquire sufficient knowledge and collect information on zoonotic infectious diseases.

2. Managers, laboratory animal managers, and researchers shall endeavor to establish a contact framework with public health institutions, etc. such that necessary measures may be implemented promptly when zoonotic infectious diseases occur.

## Chapter IX: Education and Training

Article 30. Prior to the start of experiments, the President shall have laboratory animal managers, researchers, and caretakers receive the prescribed education and training pertaining to the matters listed below at an appropriate time:

- (1) Laws and ordinances concerning animal experiments, etc., the guidelines, etc., and University regulations, etc.
  - (2) Basic matters pertaining to the methods of animal experiments, etc.
  - (3) Basic matters pertaining to the care or keeping of laboratory animals
  - (4) Matters pertaining to securing and maintaining safety
  - (5) Matters pertaining to zoonotic infectious diseases
  - (6) Other matters pertaining to the proper conduct of animal experiments, etc.
2. The President shall retain records on education and training including the dates, details, and names of instructors and trainees for 10 years in principle.
  3. The President shall endeavor to ensure that necessary education and training is given according to the categories of laboratory animal manager, researcher, and caretaker.

#### Chapter X: Self-Inspection, Evaluation, Verification

- Article 31. The President shall have the committee conduct self-inspections and evaluations every year with respect to compliance with the MEXT's fundamental guidelines and the state of compliance with the MOEJ's standards on care and keeping of animals.
2. The committee must conduct self-inspections and evaluations on the status, etc. of animal experiments, etc. and the status of care and keeping of animals and report the results to the President.
  3. The committee may request managers, laboratory animal managers, lead researchers, and caretakers, etc. to submit materials for self-inspections and evaluations.
  4. The President shall regularly conduct inspections by external experts of the results of self-inspections and evaluation.

#### Chapter XI: Disclosure of Information

- Article 32. The President shall disclose information on animal experiments, etc. conducted at the University (including regulations pertaining to animal experiments, etc., the status of care or keeping of laboratory animals, self-inspections and evaluations, the results of the inspections by external experts, etc., and information on the Committee on the Use of Animals in Experimentation such as its composition) approximately once every year.

#### Chapter XII: Auxiliary Provisions

##### (Application)

- Article 33. For any animal experiments, etc. that involve the use of animals other than the laboratory animals prescribed in Article 2, item (5), efforts shall be made to conduct them in accordance with the purposes of the MOEJ's standards on care and keeping of animals.

##### (Miscellaneous Provisions)

- Article 34. Beyond what is provided for in these regulations, necessary matters shall be determined separately by the President.

##### (Revision and Abolition)

- Article 35. Revision or abolition of these regulations shall be conducted after deliberation by the Senate.

Supplementary Provisions:

These regulations shall come into effect as of October 13, 2011.

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