

Regulations for Animal Experiments

Central Institute for Experimental Animals

[Chapter 1: General Rules]

(Purpose and Basic Principles)

- Article 1** These Regulations specify the items required for proper conduct of animal experiments from the scientific, animal welfare and environmental safety aspects and the aspect of safety assurance of researchers conducting the animal experiments by the Central Institute for Experimental Animals (CIEA) based on Basic Policies on Animal Experiments conducted in Research Institutions. (Basic Policies) (Notice No. 71 of the Ministry of Education, Culture, Sports, Science and Technology, June 2006).
2. The regulations for handling laboratory animals in animal experiments are specified in the Standards Relating to the Care and Management of Laboratory Animals and Relief of Pain (Care and Management Standards) (Notice No. 88, Ministry of the Environment, April 2006) based on the Law for the Humane Treatment and Management of Animals.
 3. When animal experiments are performed, consideration must be given to the 3R-Principle for humane experimental technique (Replacement: use of methods to replace living whole animals, Reduction: decrease in the number of animals used and Refinement: reduction of pain in the animals) within the range of achieving the scientific purpose of utilization in all cases.
 4. Researchers performing animal experiments in CIEA must comply with these Regulations.

(Definitions)

- Article 2** In these Regulations, the definitions of terms are as specified below.
- (1) **Animal experiments:** These refer to provision of animals for use in education, experimental research, collection of biological samples or other scientific purposes. The utilization of animals for maintenance of strains, production or testing is included.
 - (2) **Facilities:** These refer to facilities and equipment for the conduct of animal experiments.
 - (3) **Laboratory animals:** These refer to mammals, birds or reptiles bred or maintained for use in animal experiments (including those during transport to facilities).
 - (4) **Animal experiment protocols:** These are protocols for performing animal experiments.
 - (5) **Researchers performing animal experiments:** These are persons who perform animal experiments.
 - (6) **Principal investigators:** Among the researchers performing animal experiments, the investigator is the researcher in charge of the animal experiment.
 - (7) **Manager:** This is the person who supervises the laboratory animals and facilities as an assistant to the director.
 - (8) **Laboratory animal manager:** This is the person in charge of the laboratory animals and facilities in each facility as an assistant to the manager.
 - (9) **Animal technicians:** These are persons who undertake care and management or maintenance of laboratory animals under the laboratory animal manager or researchers performing animal experiments.

(10) Manager, etc.: This refers to the manager, laboratory animal manager, researchers performing animal experiments and animal technicians.

[Chapter 2: Range of Application]

Article 3 These Regulations apply to all animal experiments performed in CIEA.

2. When CIEA contracts animal experiments to outside institutions, it confirms that the animal experiments are performed appropriately by the contract research facility based on the Basic Policies or policies on animal experiments specified by other Ministries.
3. When CIEA receives contracts to perform animal experiments from outside institutions, it explains to the contracting institution that all animal experiments in CIEA are performed appropriately in compliance with the Basic Policies and based on regulations of CIEA specified on the basis of the Basic Policies.

[Chapter 3: Organization]

(Responsibilities of the Director)

Article 4 The Director bears final responsibility for conduct of all animal experiments in CIEA.

2. The Director establishes the Institutional Animal Care and Use Committee (IACUC) and requires IACUC to review animal experiment protocols.
3. The Director either gives or denies approval based on the report of IACUC.
4. After completion of the animal experiment, the Director verifies the results obtained in the animal experiment and points out improvements to the principal investigator or the manager based on the advice of IACUC.
5. The Director retains the animal experiment protocols, the results obtained in the animal experiments, minutes of IACUC meetings, application for approval of establishment of animal facilities.
6. The Director takes particular care to ensure the safety and maintain the health of managers, etc. in animal experiments that handle physical or chemical materials or pathogens, in animal experiments that might affect human safety or health, and in animal experiments that might affect the proximate environment.
7. Within the range that does not hinder research activities as well as to protect individual and research information, the Director shall publish the results of research and projects.
8. The Director shall provide education and training to improve the quality of managers, etc.
9. The Director shall be able to transfer authority specified in Item 3 of this Article to the manager.

[Chapter 4: Institutional Animal Care and Use Committee (IACUC)]

(Role of IACUC)

Article 5 IACUC receives inquiries from the Director and undertakes the following tasks.

- (1) IACUC conducts reviews on whether or not the animal experiment protocol submitted by the principal investigator complies with the Basic Policies and these Regulations, and reports the results to the Director.

- (2) IACUC receives reports on the results of execution of the animal experiment protocol from the Director and offers advice as required.
- (3) IACUC checks the facilities, performs surveys as required and reports the results to the Director.
- (4) IACUC determines the status of education and training related to animal experiments and participates in the planning as required.
- (5) IACUC reviews all items required for the proper conduct of animal experiments.

(IACUC Membership)

Article 6 IACUC shall be composed of the following members appointed by the Director.

- (1) Two or more persons with excellent knowledge related to animal experiments.
- (2) Two or more persons with excellent knowledge related to laboratory animals.
- (3) One or more persons with other knowledge and experience
- (4) An IACUC chair elected from among the members.

(Term of Office of IACUC Members)

Article 7 The term of office of IACUC members shall be one year and they may be reelected.

2. The period of office for IACUC members who are appointed when a vacancy on IACUC arises shall be the remainder of the term of the former member.
3. The members in Item 2 above can be reelected.

(IACUC Meetings)

Article 8 IACUC meetings shall be held when at least two thirds of the members are present.

2. The agenda shall be decided by at least two thirds of the members who are present.
3. IACUC chair shall lead the IACUC meetings.

(Obligation of Secrecy)

Article 9 IACUC members shall not disclose to outside parties any information on animal experiments obtained in IACUC meetings.

(Office)

Article 10 The Office of IACUC shall be established in the General Affairs Department.

2. The Office shall arrange the schedule for holding IACUC meetings and shall record the minutes of the meetings.

(Miscellaneous Provisions)

Article 11 In addition to the specifications in these Regulations, the items required for reviews by the IACUC meetings are as specified in the "Guidelines for Review of Animal Experiment Protocols" specified by IACUC.

[Chapter 5: Conduct of Animal Experiments]

(Drafting of Animal Experiment Protocols)

Article 12 The principal investigator drafts the animal experiment protocol based on the following items from the standpoint of assurance

of the reliability of data obtained from animal experiments and performs the animal experiment properly.

- (1) Objective and significance of the animal experiment.
- (2) Investigation on the use of alternatives: When animal experiments are performed, the method shall be replaced by an alternative as much as possible within the range of achieving the scientific purpose of utilization.
- (3) Rational selection of laboratory animals: When animal experiments are performed, the number of animals used must be as few as possible within the range of achieving the scientific purpose of utilization. In such cases, the animal experiment protocol must be drafted in consideration of selection of the species, etc. of laboratory animals that comply with the objective of the animal experiment; selection of the number of laboratory animals based on the expected accuracy and reproducibility of the results of the animal experiments; genetic and microbiological quality; and rearing conditions.
- (4) Measures to predict and to minimize the severity of pain applied to laboratory animals: When animal experiments are performed, methods must be used that do not inflict pain on the animals as much as possible within the range of achieving the scientific purpose of utilization.
- (5) Final disposal method of laboratory animals.
- (6) For lethal experiments in carcinogenicity studies, infection studies and studies using radiation, humane endpoints must be considered.

(Submission of Animal Experiment Protocols)

Article 13 The principal investigator must submit to the Director beforehand the draft animal experiment protocol when an animal experiment is planned. The results of the debate by other committees (Genetic Recombinant Safety Committee, etc.) must be confirmed as required.

(Changes in Animal Experiment Protocols)

Article 14 When approved animal experiment protocols are changed, the necessary procedures as specified in the Guidelines for Review of Animal Experiment Protocols must be taken.

(Experimental Procedures)

Article 15 The principal investigator must instruct the researchers performing the animal experiment and the animal technicians involved that the animal experiment must be performed in accordance with the approved animal experiment protocol.

- (1) When surgical procedures are performed, anesthetics and analgesics must be administered based on the animal experiment protocol and appropriate postoperative management of pain, heat retention, etc. is required.
- (2) Application of humane endpoints must be considered to relieve laboratory animals from pain resulting from irreversible damage due to disease or experimental procedures.
- (3) When laboratory animal managers, researchers performing animal experiments or animal technicians undertake disposal of laboratory animals used in experiments that have been completed or discontinued or laboratory animals subjected to irreversible damage due to diseases, they shall use chemical or physical methods such as administration of anesthetics at higher than the lethal dose, cervical

dislocation or exsanguination under anesthesia based on the "Care and Management Standards."

(4) When highly invasive major surgery is performed, it must be supervised by persons with sufficient experience and knowledge who have been trained in the experimental techniques to perform these procedures.

(5) When animal experiments are performed that might affect the ecosystem, such as animal experiments using genetically modified animals, care must be taken to prevent escape of the genetically modified animals.

(Reporting of Results)

Article 16 Principal investigators shall report the number of laboratory animals used and results of animal experiments to the Director on completion of the experiments (when continued, at the end of the year) using the forms for animal experiment reports after completion of the animal experiment and retain the raw data .

[Chapter 6: Facilities]

(Establishment of Facilities)

Article 17 When facilities are established, the Department Head submits to the Director via the Division Head an "Animal Facility Establishment Application Form" with the cooperation of the Manager. After IACUC completes a status survey and review, approval of the Director is obtained.

(Requirements for Facilities)

Article 18 The facilities shall have the following requirements.

(1) The facilities must have equipment and structures for rearing, sanitation and prevention of escape based on the species of laboratory animals concerned.

(2) Consideration must be given to odor, noise, handling of waste materials, etc. so that there will be no adverse effects on local residents or the proximate environment of the facilities.

(3) A laboratory animal manager must be appointed.

(Maintenance Control of Facilities)

Article 19 The manager must endeavor to maintain the facilities so that the laboratory animals are not injured by contamination of the rearing environment, and also maintain the facilities required for proper management of the laboratory animals and the conduct of animal experiments.

(Handling of closure of the facilities)

Article 20 When facilities are closed, the Department Head shall submit to the Director via the Division Head an "Animal Facility Closure Application Form" and obtain approval.

2. When facilities are closed, efforts shall be made to transfer laboratory animals that are bred and maintained in the closed facilities to other facilities either in or outside of CIEA in cooperation with the manger. When the animals must be sacrificed, efforts must be made to comply with the provisions of "Policies for Disposal of Animals" (Notice No. 40 of the Prime Minister's Office, July 1995).

[Chapter 7: Care and Management of Laboratory Animals]

Article 21 The manager specifies operating procedures related to animal care and management and conduct of experiments to maintain the laboratory animals in good health and safety, and informs the laboratory animal manager, researchers performing animal experiments and animal technicians of these specifications.

2. The manager gives consideration to maintaining the health of the laboratory animals by performing quarantine as required, as well as microbiologic monitoring or periodic health checks.
3. Facilities shall be provided with the structure and strength to prevent escape of laboratory animals based on the "Care and Management Standards." Measures to be taken when animals escape or in emergencies shall be specified beforehand and efforts shall be made to prevent problems related to danger to humans and maintenance of the environment.
4. The manager shall take the necessary measures to prevent the laboratory animal manager, researchers performing animal experiments and animal technicians from contracting diseases originating from laboratory animals (zoonoses).
5. The manager must endeavor to specify measures for emergencies to take in cases of major disasters such as earthquakes, fires and typhoons to prevent danger caused by the laboratory animals and protect the laboratory animals.
6. The manager must take the required measures to prevent persons not related to the rearing of the laboratory animals or conducting animal experiments from coming into contact with the laboratory animals.
7. The manager shall endeavor to maintain proper records related to laboratory animals including receipt of the animals, rearing and disease histories, and record books related to the rearing environment, to aid in the care and management of laboratory animals in the facilities.

[Chapter 8: Education and Training]

Article 22 The Director shall endeavor to ensure the education and training required for the manager, etc. The education and training must be undertaken before the managers, etc. take part in animal experiments and regular education and training courses must be conducted thereafter as required.

2. When education and training are performed, records of the dates, contents, names of instructors and trainees must be kept and retained as specified in the Regulations.

[Chapter 9: Self-inspections, Evaluations and Validation]

Article 23 The Director shall periodically undertake inspections and evaluations related to the responsibilities of the Director, role of IACUC, etc. specified in these Regulations at the request of the Compliance Committee of CIEA to assure social transparency in the conduct of animal experiments.

[Chapter 10: Publishing of Information]

Article 24 The Director shall publish information related to animal experiments in CIEA (examples: related regulations; results of inspections and evaluations of animal experiments; conditions of care and management of laboratory animals) once a year in a research and project report, on a webpage or by another appropriate method.

[Amendment or Abolition of These Regulations]

These Regulations shall be amended or abolished via deliberation by the "Executive Board."

[Additional Provision]

These Regulations shall come into effect from December 11, 2006.