

Ministry of Education, Culture, Sports, Science and Technology, Notice No. 71

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 are provided as follows.

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Preamble

A scientific understanding of the biological activities of living organisms on the planet is essential for the solution of many issues, including human welfare, and conservation and restoration of the environment. Animal experiments and related activities are necessary and unavoidable for gaining scientific insights into the biological activities of living organisms, but they must be performed properly taking into consideration the welfare of the animals.

To ensure the appropriateness of animal experiments, efforts have been made in academic research institutions to establish and implement institutional guidelines on animal experimentation, through establishment of institutional animal experiment committees which conform to the Notice of “Animal Experimentation in Universities and Similar Institutions.” (Director General, Science and International Affairs Bureau, Ministry of Education, May 25, 1987). In the future, animal experiments and related activities are expected to continue, in order to facilitate advancement of the life sciences and the development of medical treatments and other technologies.

Since then, the Law for Partial Amendment of the Law for the Humane Treatment and Management of Animals (Law No. 68, 2005) was promulgated in June 2005. In this Law, in addition to the provision of Refinement (*i.e.*, techniques to reduce pain and distress to animals used, while still allowing attainment of the scientific objective) of the so-called 3R principles of animal experiment and related activities, the provisions of Replacement (*i.e.*, substituting animals with non-animal research methods, while still allowing attainment of the scientific objective) and Reduction (*i.e.*, minimizing the number of animals used, while still allowing attainment of the scientific objective) were included.

With these changes in the circumstances surrounding animal experiment and related activities, it is important for Academic Research Institutions to perform properly animal experiment and related activities not just out of scientific necessity, but also with consideration of both the scientific rationale and the welfare of the animal, pursuant to the provisions of the Law for the Humane Treatment and Management of Animals (Law No. 105, 1973; “the Law” hereinafter), as well as Standards Relating to the Care and Management of Laboratory Animals and Relief of Pain (Notice No.88 of the Ministry of the Environment dated April 28, 2006; “Care and Management Standards” hereinafter).

On the basis of the current state of affairs, these Fundamental Guidelines for Proper Conduct of Animal Experiment and Related Activities in Academic Research Institutions (“the Fundamental Guidelines” hereinafter) are provided to ensure proper conduct of animal experiments and related activities.

Article 1 Definitions

The following terms used in the Fundamental Guidelines are defined below:

(1)Animal experiments and related activities

Utilization of animals for education, testing, research and development, manufacture of biological products, or other scientific purposes.

(2)Laboratory animals

Animals of mammalian, avian or reptilian species, reared or maintained in facilities of academic research institutions, for use in animal experiments and related activities.

(3)Academic Research Institutions

Any of the following institutions where testing, research or development are performed, in science, technology, or for academic research:

(i) Universities

(ii) Inter-University Research Institute Corporation

(iii) Colleges of Technology

(iv) Facilities and institutions under the jurisdiction of the Ministry of Education, Culture, Sports, Science and Technology

(v) Independent Administrative Institutes (limited to those under the jurisdiction of the Ministry of Education, Culture, Sports, Science and Technology; excluding the Independent Administrative Corporation Institute of National Colleges of Technology)

(vi) Corporations established pursuant to the provisions of Article 34 of the Civil

Code (Law No. 89 1896) (limited to those under the jurisdiction of the Ministry of Education, Culture, Sports, Science and Technology)

(4) Animal experiment protocol

Protocol for conduct of animal experiment or related activities.

(5) Animal experiment researcher

Individual performing the animal experiment or related activities.

(6) Principal investigator

The animal experiment researcher who is responsible for all activities concerning the animal experiment and related activities.

Article 2 Responsibilities of the director of the academic research institution

1. Responsibilities of the director of the academic research institution

The director of the academic research institution bears ultimate responsibility for conduct of animal experiments and related activities in the institution. The director shall establish the institutional animal experiment committee, establish the institutional regulations specified in Item 2 below, approve the animal experiment protocols, comprehend the results of the animal experiments performed based on the protocol, and implement any other necessary measures required for proper conduct of animal experiments and related activities.

2. Establishment of institutional regulations

The director of the academic research institution shall establish the institutional regulations (“Institutional regulations” hereinafter) specifying methods for the maintenance and management of animal experimentation facilities, as well as methods for proper conduct of animal experiments and related activities, pursuant to the provisions of the Law, Care and Management Standards, the Fundamental Guidelines, and other laws and ordinances (including notices, the same hereinafter) concerning animal experiments and related activities.

3. Approval of animal experiment protocols

The director of the academic research institution shall have the principal investigator submit the animal experiment protocol prior to the start of the animal experiment and related activities, and shall approve or reject the submitted animal experiment protocol after a review by the Institutional Animal Experiment Committee.

4. Comprehension of the results of the animal experiment and related activities.

After completion of the experiment, the director of the academic research institution shall receive the report of results of the experiment performed according to the animal experiment protocol, and shall implement whatever measures are necessary for improvement in the proper conduct of the animal experiment and related activities, as required.

Article 3 Institutional Animal Experiment Committee

1. Establishment of the Institutional Animal Experiment Committee

The director of the academic research institution shall establish the Institutional Animal Experiment Committee.

2. Roles of the Institutional Animal Experiment Committee

The Institutional Animal Experiment Committee shall have the following duties.

(i) Upon a request from the director of the academic research institution, the Committee shall review the animal experiment protocol submitted by the principal investigator to determine whether it complies with the Law, Care and Management Standards, the Fundamental Guidelines concerning animal experiment and related activities, and the Institutional regulations, and shall report the results of the findings to the director of the institution.

(ii) The Committee receives a report from the director of the academic research institution of the results of the animal experiments performed according to the animal experiment protocol, and shall give advice as required.

3. Membership of the Institutional Animal Experiment Committee

The Institutional Animal Experiment Committee shall consist of members who are appointed from the following individuals by the director of the academic research institution, with consideration given to achieve appropriately the roles of the Committee.

(i) Individuals with excellent knowledge and experience regarding animal experiments and related activities.

(ii) Individuals with excellent knowledge and experience regarding laboratory animals.

(iii) Individuals with scholarship and experience.

Article 4 Conduct of animal experiments and related activities

1 Assurance of scientific rationale

The principal investigator shall prepare the animal experiment protocol and shall

properly perform the animal experiment and related activities, based on the following items, from the standpoint of assuring the reliability of data obtained from the animal experiment and related activities.

(1) Selection of proper methods for the animal experiment and related activities

The animal experiment and related activities shall be performed by selecting the proper methods based on the following items.

(i) Use of alternative methods (Replacement)

In the animal experiments and related activities, consideration must be given to the proper use of laboratory animals by replacing laboratory animals with other research materials where possible, while still allowing attainment of the scientific objective.

(ii) Selection of laboratory animals (Reduction)

In the animal experiments and related activities, consideration must be given to the appropriate use of laboratory animals by reducing the number of animals used to as few as possible, while still allowing attainment of the scientific objective. In these cases, it is necessary to consider the selection of laboratory animal species appropriate for the purpose of the animal experiment and related activities, the number of laboratory animals which will determine the accuracy and reproducibility of the results of the animal experiment, the genetic and microbiological quality, and the rearing conditions.

(iii) Reduction of pain (Refinement)

In the animal experiments and related activities, methods must be employed which cause as little pain and distress as possible to the laboratory animals, while still allowing attainment of the scientific objective, based on the Law and Care and Management Standards.

(2) Facilities and equipments for animal experiment and related activities

Animal experiments and related activities shall be conducted using appropriately maintained and managed facilities and equipment.

2. Animal experiments and related activities that require special attention concerning safety management

The director of the academic research institution shall consider the following items when animal experiments and related activities are to be performed which require special attention concerning safety management.

(i) When animal experiments and related activities are to be conducted which involve physical or chemical agents or pathogens, or which may affect the safety or health of humans or the surrounding environment, special attention to assurance of safety and maintenance of the health of the animal experiment researchers must be paid, while still properly maintaining facilities and equipment in the

academic research institution.

(ii) The facilities and equipment shall be maintained so that the laboratory animals are not harmed by contamination of the rearing environment, while consideration shall also be given to maintenance of the health of the laboratory animals by implementing quarantine or other measures as required.

(iii) When animal experiment and related activities that might affect the ecosystem are to be performed, such as animal experiments or related activities using genetically modified animals, special attention shall be given to prevention of escape or other undesirable events of the genetically modified animals, while facilities and equipment in the academic research institution shall be managed properly.

Article 5 Rearing and maintenance of laboratory animals

Rearing and maintenance of laboratory animals in the animal experiment and related activities shall be performed properly from the standpoints of both scientific rationale and animal welfare, based on the Law and Care and Management Standards.

Article 6 Miscellaneous Provisions

1. Conduct of education and training

The director of the academic research institution shall ensure that education and training are provided to animal experiment researchers and workers who engage in the rearing and maintenance of laboratory animals (“animal experiment researchers and workers” hereinafter), with the aim of guaranteeing that animal experiment researchers and workers shall acquire the basic knowledge required for the proper conduct of animal experiments and other activities, and for the proper rearing and maintenance of laboratory animals. The director shall also implement any other necessary measures to improve the level of skills and professionalism of animal experiment researchers and workers.

2. Self-inspections, evaluation and verification of compliance with the Fundamental Guidelines

To assure transparency concerning the conduct of animal experiments and related activities, the director of the academic research institution shall periodically implement self-inspections and evaluations of compliance with the Fundamental Guidelines for the animal experiments and related activities in the institution. Furthermore, the director shall endeavor to have the results of these self-inspections and evaluations verified by a third party, independent of the research institution

concerned.

3. Public disclosure of information

The director of the academic research institution shall publicly disclose information regarding the animal experiments and related activities in the institution (*e.g.*, Institutional regulations, self-inspections and evaluations regarding animal experiments and related activities, results of verification by a third party independent of the institution concerned, and conditions of rearing and maintenance of laboratory animals) through the Internet, distribution of annual reports or by other appropriate means, approximately once a year.

Supplementary Provision

The Fundamental Guidelines shall come into effect beginning June 1, 2006.

(Research Promotion Bureau, Life Sciences Divisions)