

Laws and regulations related to animal experiments in Japan

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The fundamental principle of lab. animal welfare

“3Rs”

Replacement

Substitution for conscious living higher animals of insentient material (tissue/cell culture (*in vitro*), computer simulation (*in silico*) e.t.c.)

Reduction

Reduction in the numbers of animals
(solid plan, proper selection of animals, high-precision *in vivo* imaging)

Refinement

Any decrease in the incidence or severity of inhumane procedures
(appropriate anesthesia/analgesic, sophistication in handling)

W.M.S. Russell and R.L. Burch

The Principles of Humane Experimental Technique, 1959



Framework for the development of laws

INTERNATIONAL GUIDING PRINCIPLES FOR BIOMEDICAL RESEARCH INVOLVING ANIMALS (1985)*

Council for International Organizations of Medical Sciences (CIOMS)

* : revised version (2012) is available at <http://www.cioms.ch/images/stories/CIOMS/IGP2012.pdf>

- I. The advancement of biological knowledge and the development of improved means for the protection of the health and well-being both of man and of animals require recourse to experimentation on intact live animals of a wide variety of species.
- II. Methods such as mathematical models, computer simulation and *in vitro* biological systems should be used wherever appropriate.
- III. Animal experiments should be undertaken only after due consideration of their relevance for human or animal health and the advancement of biological knowledge.
- IV. The animals selected for an experiment should be of an appropriate species and quality, and the minimum number required to obtain scientifically valid results.
- V. Investigators and other personnel should never fail to treat animals as sentient, and should regard their proper care and use and the avoidance or minimization of discomfort, distress, or pain as ethical imperatives.
- VI. Investigators should assume that procedures that would cause pain in human beings cause pain in other vertebrate species, although more needs to be known about the perception of pain in animals.

Framework for the development of laws

- vii. Procedures with animals that may cause more than momentary or minimal pain or distress should be performed with appropriate sedation, analgesia, or anesthesia in accordance with accepted veterinary practice. Surgical or other painful procedures should not be performed on unanesthetized animals paralysed by chemical agents.
- viii. Where waivers are required in relation to the provisions of article VII, the decisions should not rest solely with the investigators directly concerned but should be made, with due regard to the provisions of articles IV, V, and VI, by a suitably constituted review body. Such waivers should not be made solely for the purposes of teaching or demonstration.
- ix. At the end of, or, when appropriate, during an experiment, animals that would otherwise suffer severe or chronic pain, distress, discomfort, or disablement that cannot be relieved should be painlessly killed.
- x. The best possible living conditions should be maintained for animals kept for biomedical purposes. Normally the care of animals should be under the supervision of veterinarians having experience in laboratory animal science. In any case, veterinary care should be available as required.
- xi. It is the responsibility of the director of an institute or department using animals to ensure that investigators and personnel have appropriate qualifications or experience for conducting procedures on animals. Adequate opportunities shall be provided for in-service training, including the proper and humane concern for the animals under their care.

For putting 3Rs into practice

▪ Self-management

eg. Japan, USA

Reviewer of project: IACUC (Institutional Animal Care and Use Committee)

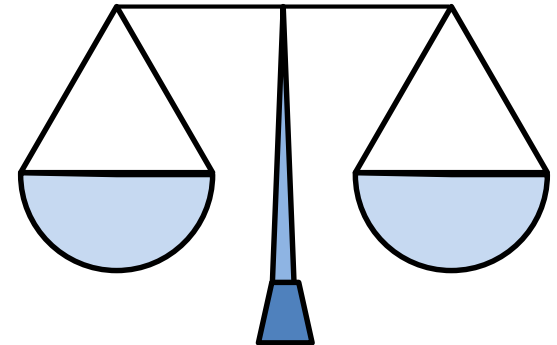
Approver of experiment: Director of research institution

▪ Legal-control

eg. UK, Germany, Switzerland, France

Authorization (personnel, facility, project) and inspection by regulatory agency

Approver of experiment: Home Minister (UK), Ministre de l'Agriculture (France) etc.



Laws and regulations related to animal experiments

Act on Welfare and Management of Animals

- Basic principles of lab. animals and animal experiments
- Welfare & management of lab. animals
- Consideration for animal experiments

Welfare & management of lab. animals

MOE : Standards relating to the care and management, etc. of experimental animals

Animal experiment

MEXT : Fundamental guidelines for proper conduct of animal experiment and related activities in academic research institutions
MHLW
MAFF

Regulations for Animal Experiments

of The Jikei University School of Medicine

Act on Welfare and Management of Animals

Act No. 105 of October 1, 1973

Act No. 38 of June 12, 2012 (revised)

Article 1 (Purpose)

The purpose of this Act is to engender a spirit for animal welfare among citizens and contribute to the development of a respect for life and sentiments of amity and peace by providing for the prevention of cruelty to animals, the proper handling of animals and other matters concerning animal welfare, as well as to prevent animals from causing an infringement on the life, body or property of humans by providing for matters concerning the management of animals.

Article 2 (Fundamental Principle)

In light of the fact that animals are living beings, no person shall kill, injure, or inflict cruelty on animals without due cause, and every person shall treat animals properly by taking into account their natural habits and giving consideration to the symbiosis between humans and animals.

Act on Welfare and Management of Animals

Article 40

(Method to Be Applied in the Case of Destroying Animals)

(1) In the case where an animal must be destroyed, a method that minimizes as much as possible the pain and distress to the animal shall be used.

(2) The Minister of the Environment may, after consultation with the heads of the relevant administrative organs, provide necessary matters with regard to the method set forth in the preceding paragraph.

Act on Welfare and Management of Animals

Article 41

(Method to Be Applied, Subsequent Measures, etc. in the Case of Providing Animals for Scientific Use)

: Animal experiment

(1) When providing animals for use in education, testing and research or the manufacture of biological preparations, or for any other scientific use, consideration shall be given to the appropriate use of such animals by such means as using alternative methods to that of the use of animals as much as possible and reducing the number of animals provided for such use as much as possible, within the extent that the purpose of the scientific use can be attained.

(2) In the case where an animal is provided for a scientific use, a method that minimizes the pain and distress to the animal as much as possible shall be used, within the limit necessary for such use.

(3) In the case where an animal has fallen into a state from which recovery is unlikely after being provided for a scientific use, the person who provided the animal for such scientific use shall immediately dispose of said animal by a method that minimizes pain and distress as much as possible.

(4) The Minister of the Environment may, after consultation with the heads of the relevant administrative organs, prescribe the standards to be complied with regarding the method set forth in paragraph (2) and the measures set forth in the preceding paragraph.

Act on Welfare and Management of Animals

Chapter VI Penal Provisions

Article 44

(1) A person who has destroyed or injured, without reason, a protected animal shall be punished by imprisonment with work for not more than two year or a fine of not more than two million yen.

(2) A person who has committed on a protected animal such cruelty as causing debilitation by discontinuing feeding and/or watering without reason shall be punished by a fine of not more than one million yen.

(3) A person who has abandoned a protected animal shall be punished by a fine of not more than one million yen.

Specific examples of abuse (notified in being revised in 2012)

- Tethering a protected animal in the place where is not suitable for maintaining its health and/or safety
- Leaving an affected and/or injured animal without proper care
- Feeding a protected animals in facilities where excrement is piled up and/or bodies of other protected animals are left uncontrolled
- Any other abusive behaviors

Act on Welfare and Management of Animals

Article 44 (continued)

(4) The term "protected animal" as used in the preceding three paragraphs shall be the animals listed in the following items:

(i) Cattle, horses, pigs, sheep, goats, dogs, cats, domestic rabbits, chickens, domestic pigeons, and domestic ducks

(ii) Animals in the possession of persons where such animals are categorized as mammals, birds or reptiles, other than those listed in the preceding item

Article 48

When the representative person of a juridical person, or an agent, employee or any other worker of a juridical person or individual has committed an act in violation of the provisions from Article 44 to the preceding Article with regard to the business of said juridical person or individual, not only the offender shall be punished but also said juridical person or individual shall be punished by a fine prescribed in the respective Articles.

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

Ministry of Education, Culture, Sports, Science and Technology, Notice No. 71 of June 1, 2006

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.

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

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.

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

(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 equipment for animal experiment and related activities

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

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

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.

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

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.

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

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.

Standards relating to the care and management, etc. of experimental animals

Notification No.6, March 27, 1980 of the Prime Minister's Office

General Principles

Persons in charge, etc. should understand the physiology, ecology and habits etc of experimental animals and should care for them with affection, and ensure that they be used for scientific purposes; persons in charge, etc. should also care for experimental animals responsibly and prevent them from doing harm to human life, body or property, and polluting or damaging the living environment.

- **Considerations when Bringing in Experimental Animals**
- **Maintenance of the Health and safety of Experimental Animals**
- **Matters to Be Considered in the Performance of Experiments, etc. of, and Measures to Be Taken after Experiments, etc.**
- **Prevention of Damage**
- **Conservation of the Living Environment**
- **Measures to Be Taken by Breeders of Experimental Animals**