

国立大学法人東北大学における動物実験等に関する規程

(英語第2版)

**Regulations for Animal Experiments and
Related Activities at Tohoku University**

June 27th, 2007

Regulation No 122

(English version two)

[Only the original Japanese texts of regulations have legal effect, and the translations are to be used solely as reference material to aid in the understanding of Japanese regulations.]

Index

Chapter 1. General Provisions (Articles 1–4)

Chapter 2. Institutional Animal Care and Use Committee (Article 5)

Chapter 3. Center for Laboratory Animal Research (Article 6)

Chapter 4. System of Management (Articles 7–11)

Chapter 5. Animal Experiment Protocol and Education Protocol (Articles 12–15)

Chapter 6. Facilities (Articles 16–18)

Chapter 7. Conduct of Animal Experiments and Related Activities (Articles 19, 20)

Chapter 8. Care and Management of Laboratory Animals (Articles 21–27)

Chapter 9. Safety Management (Articles 28–30)

Chapter 10. Education and Training (Article 31)

Chapter 11. Self-inspection, Assessment, and Verification (Article 32)

Chapter 12. Public Disclosure of Information (Article 33)

Chapter 13. Miscellaneous Provisions (Articles 34, 35)

Additional Provisions

Chapter 1. General Provisions

(Basis)

Article 1

This Regulation covers the proper performance of animal experiments and related

activities in Tohoku University (“the University”) from the standpoints of science, animal welfare, environmental conservation, and the safety of staff and students performing animal experiments and related activities. It is based on the Fundamental Guidelines for Proper Conduct of Animal Experiment and Related Activities in Academic Research Institutions (Notice No. 71 of the Ministry of Education, Culture, Sports, Science and Technology, 2006; “the Fundamental Guidelines”).

(Definitions)

Article 2

The following terms used in this Regulation are defined below:

- (i) **Animal Experiment**
Use of animals mentioned in Item iv for testing, research and development, manufacture of biological products, or other scientific purposes.
- (ii) **Education**
Use of animals mentioned in Item iv for education of students or others.
- (iii) **Animal experiments and related activities**
Term that indicates “Animal Experiment” and “Education.”
- (iv) **Laboratory animal**
Animal of mammalian, avian, or reptilian species cared for or managed in Facilities mentioned in Item vii, for use in animal experiments and related activities (including animals in transport to or from Facilities mentioned in Item vii).
- (v) **Facility for care and management**
Facility used to constantly care for or manage laboratory animals and to perform animal experiments and related activities (excluding Laboratory, mentioned in the next item).
- (vi) **Laboratory**
Room used to perform experimental procedures on laboratory animals (including temporary management, up to 48 h).
- (vii) **Facilities**
Term that indicates “Facility for care and management” and “Laboratory.”
- (viii) **Animal Experiment Protocol**
Protocol for the conduct of an animal experiment.
- (ix) **Education Protocol**

Protocol for the conduct of education.

(x) Animal Experiment Researcher

Person performing animal experiments or related activities.

(xi) Animal Technician

Person in charge of care and management of laboratory animals.

(xii) Manager, *etc.*

Term that indicates “manager,” defined in Article 6; “assistant manager,” defined in Article 7; “laboratory animal manager,” defined in Article 8; “animal experiment researcher”; and “animal technician.”

(xiii) Laboratory Animal Manager, *etc.*

Term that indicates “laboratory animal manager,” “animal experiment researcher,” and “animal technician.”

(Relationship to other laws and ordinances)

Article 3

Animal experiments and related activities are regulated by the provisions of the Law for the Humane Treatment and Management of Animals (Law No. 105, 1973; “the Law”), Standards Relating to the Care and Management of Laboratory Animals and Relief of Pain (Notice No. 88 of the Ministry of Environment, 2006; “Care and Management Standards”), the Fundamental Guidelines, Basic Rules for Abandoned Animals and Killing Animals (Notice No. 40 of the Prime Minister’s Office, 1995), Guidelines for Proper Conduct of Animal Experiments (Science Council of Japan, June 1, 2006), and other laws and ordinances (“Related Ordinances”), as well as this Regulation.

(Responsibilities of the Manager, *etc.*)

Article 4

When conducting animal experiment and related activities, the Manager, *etc.* shall take account of Paragraphs 1 and 2 of Article 41 in the Law to conduct them properly. The Manager, *etc.* shall consider the application of alternative methods that do not require the use of animals within limits that allow scientific objectives to be achieved, the use of as few animals as possible within limits that allow scientific objectives to be achieved, and the application of methods that do not distress the animals or subject them to pain within limits required for use.

Chapter 2. Institutional Animal Care and Use Committee

Article 5

The Institutional Animal Care and Use Committee (“the Committee”) of the Tohoku University Environmental & Safety Committee is in charge of the management, supervision, and coordination of the proper conduct of animal experiments and related activities, based on the regulations of Tohoku University Environmental & Safety Committee.

2 The Committee reports the results of its examinations and deliberations to the President and offers advice, as required.

3 The Committee may have Manager, *etc.* report to it as required.

Chapter 3. Center for Laboratory Animal Research

Article 6

The Center for Laboratory Animal Research supports the activities of the Committee, which conducts the management, supervision, and coordination for keeping the legitimacy and promoting the safety management of animal experiments and related activities in the University.

Chapter 4. System of management

(Manager)

Article 7

A Manager is appointed by the President to manage laboratory animals and Facilities.

2 The Manager shall be a Dean of a Faculty, *etc.*, which has the laboratory animals or Facilities as a concern (“the Faculty, *etc.*”).

(Assistant Manager)

Article 8

The Manager may appoint an Assistant Manager if there is a need for assistance.

(Laboratory Animal Manager)

Article 9

A Laboratory Animal Manager is appointed by the Manager of the Faculty, *etc.* to assist

the Manager in the management of laboratory animals.

2 The Laboratory Animal Manager shall be a member of staff of the Faculty, *etc.* with knowledge and experience related to laboratory animals.

(Principal Investigator and Principal Instructor)

Article 10

A Principal Investigator or Principal Instructor shall be appointed and shall be responsible for each animal experiment or education.

2 The Principal Investigator or Principal Instructor shall be an animal experiment researcher who is engaged in the animal experiment or the education concerned.

(Person in charge of Establishing Facilities)

Article 11

A Person in charge of Establishing Facilities shall be appointed for being responsible for management and maintenance of the facilities concerned.

Chapter 5. Animal Experiment Protocol and Education Protocol

(Review and approval of animal experiment protocol or education protocol)

Article 12

When conducting animal experiments and related activities, the Principal Investigator or the Principal Instructor shall draft an animal experiment protocol or education protocol, submit the protocol to the President through the Manager, and receive approval before beginning the animal experiment or related activity.

2 The President shall request that the Committee reviews the protocol and then approve or deny the animal experiment protocol or education protocol concerned.

3 The President shall inform the Principal Investigator or Principal Instructor concerned of the decision through the Manager.

4 An animal experiment protocol or education protocol approved by the Committee shall be valid within three academic years.

(Change of animal experiment protocol or education protocol)

Article 13

The provisions of the previous Article apply in cases where changes are made to an

animal experiment protocol or education protocol.

(Report for cancellation or completion of animal experiment and related activities)

Article 14

The Principal Investigator or Principal Instructor shall report the cancellation or completion of animal experiments and related activities to the President through the Manager on the designated form.

(Recommendation for cancellation of animal experiments and related activities)

Article 15

The Committee can examine the situation regarding an animal experiment protocol or education protocol approved in compliance with the second paragraph of Article 12 and report or provide advice to the President, as required.

2 The President may recommend cancellation of the animal experiments and related activities concerned in cases where a decision to conduct them is inappropriate, based on the report or advice referred to in the preceding paragraph.

Chapter 6. Facilities

(Application and approval for establishing Facilities)

Article 16

The Manager shall submit an application with the designated form for an establishment and shall request the approval of the President for establishing or changing a Facility for the care and management or Laboratory.

2 The President shall ask the Committee to review the application and then the President shall approve or deny the establishment or change of Facility for care and management or Laboratory concerned.

3 The President shall inform the Manager of the decision.

4 A Facility for the care and management or Laboratory approved in compliance with this Article is valid for a time period decided by the President.

(Maintenance and improvement of Facilities)

Article 17

The Manager shall implement maintenance and improvements of Facilities for the

proper management of laboratory animals and for conducting animal experiments and related activities.

(Notification of closing Facilities)

Article 18

In the event that Facilities are closed, the Manager shall submit an application with a designated form for closing in advance.

2 The Manager shall endeavor to transfer the animals present to other facilities for care and management, in cooperation with the Principal Investigator, as required.

Chapter 7. Conduct of Animal Experiments and Related Activities

Article 19

When conducting animal experiments and related activities, animal experiment researchers shall observe the items below, in addition to Related Ordinances.

- (i) Conducting animal experiments and related activities in Facilities maintained appropriately.
- (ii) Observing items below, so as not to subject laboratory animals to unnecessary pain, and observing items mentioned in the protocol.
 - a) Use of appropriate anesthetics and analgesics.
 - b) Proper postoperative management after surgical procedures.
 - c) Consideration of the timing of the termination of an experiment with pain, based on a humane endpoint.
- (iii) Conducting genetic engineering experiments; animal experiments using radioactive materials or radiation; experiments using poisons, deleterious substances, or psychotropic drugs; and animal experiments using pathogenic agents or hazardous chemicals in compliance with the Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Law No. 97, 2003) and related laws and ordinances, the regulations for safety management of genetic engineering experiments in Tohoku University (Regulation No. 38, 1981), and related regulations of the University.
- (iv) Making an effort to acquire the skills required for the experiment in advance.
- (v) Conducting highly invasive, major surgery under the guidance of a specialist with

relevant experience.

2 An animal experiment researcher shall take the items below into consideration for canceling or completing an experiment.

- (i) Selecting proper procedure of euthanasia, to cause as little pain as possible and not to cause distress to other animals in the laboratory.
- (ii) Taking proper measures with carcasses of laboratory animals, so as not to have any adverse influence on human health or the environment.

(Entrustment of operations)

Article 20

In cases where the conduct of animal experiments and related activities is entrusted to other institutions, the Principal Investigator shall ensure that the animal experiment and related activities are performed at the institution concerned in accordance with the Fundamental Guidelines and guidelines for animal experiment and related activities enacted by other government ministries and agencies.

Chapter 8. Care and Management of Laboratory Animals

(Preparation of a manual)

Article 21

The Manager and Laboratory Animal Manager shall prepare a manual on the care and management of laboratory animals and make it available to animal experiment researchers and animal technicians.

(Introduction of laboratory animals)

Article 22

The Laboratory Animal Manager shall require a Principal Investigator to obtain laboratory animals exclusively from institutions managed properly, based on Related Ordinances.

2 The Laboratory Animal Manager shall institute appropriate quarantine measures and isolation in the introduction of laboratory animals.

3 The Laboratory Animal Manager shall take measures for the acclimatization of laboratory animals to the conditions of care and management, as required.

(Care and management of laboratory animals)

Article 23

The Laboratory Animal Manager, *etc.* shall supply the animals with food and water, as appropriate to the physiology, ecology, and behavior of the animals.

2 When caring for and managing different animal species or numerous laboratory animals in the same facilities, the Laboratory Animal Manager, *etc.* shall accommodate animals taking into consideration this combination.

(Preservation of the health and safety of laboratory animals)

Article 24

The Laboratory Animal Manager, *etc.* shall observe the standards of care and management and endeavor to preserve the health and safety of laboratory animals.

2 The Laboratory Animal Manager, *etc.* shall conduct necessary health management to prevent laboratory animals suffering injuries unrelated to the objective of an animal experiment or from contracting a disease.

3 The Laboratory Animal Manager, *etc.* shall provide animals with appropriate treatment in the event of injury or disease unrelated to the objective of an animal experiment.

(Retention and report of records)

Article 25

The Manager, *etc.* shall prepare and retain record books related to laboratory animal sources, rearing history, history of disease, and rearing environment.

2 The Manager shall submit a report annually about the conditions of care and management of laboratory animals to the President.

(Provision of information on transferring of laboratory animals)

Article 26

In cases of the transfer of laboratory animals, the Manager, *etc.* shall provide information concerning the animals' characteristics, care and management methods for the animals, and infectious diseases to the transferee.

2 In cases of the transfer of genetically modified laboratory animals, the Manager, *etc.*

shall provide information to the transferee based on the “Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms.”

(Transport)

Article 27

In cases of transporting laboratory animals, the Manager, *etc.* shall observe the standards of care and management and endeavor to take care of both the health and safety of the laboratory animals, preventing any hazard to humans.

Chapter 9. Safety Management

(Prevention of hazard to humans from laboratory animals)

Article 28

In cases of animal experiments involving materials that may pose a physical or chemical risk or that involve pathogens, the animal experiment researcher shall secure appropriate facilities or equipment necessary for safety.

2 The Manager shall implement measures for the prevention of infection or bites by laboratory animals and shall implement necessary measures at the time of any accident. An emergency medical system enabling prompt emergency measures by a physician in the case of accidents shall be established.

3 In cases of care and management of poisonous animals, such as poisonous snakes, the Manager shall establish necessary provisions for the prevention of injury or harm to humans based on standards of care and management.

4 The Manager shall implement appropriate measures to prevent people not involved in the care and management of laboratory animals or in animal experiments from coming into contact with laboratory animals.

(Measures when laboratory animals escape)

Article 29

The Manager shall establish methods and equipment for the recapture of any laboratory animals that escape.

2 In cases in which the escape or theft of laboratory animals is discovered, the animal experiment researcher and animal technician shall endeavor to search for and

recapture the animals. If the laboratory animals are genetically modified animals or animals that might injure or cause harm to humans, the animal experiment researcher and animal technician shall inform the Manager through the Principal Investigator or Laboratory Animal Manager as soon as possible.

3 If the Manager receives such a notification, the Manager shall take necessary measures, promptly report the matter to the President, and contact the relevant authorities.

(Dealing with emergencies)

Article 30

The Manager shall draw up plans beforehand related to measures to be implemented in the event of an emergency such as an earthquake or fire and shall familiarize relevant persons with them.

2 In an emergency situation, the Manager shall endeavor to protect laboratory animals and to prevent injury or harm to humans due to the escape of laboratory animals.

Chapter 10. Education and Training

Article 31

The President requests that the Committee provides education and training about the items mentioned below for Laboratory Animal Manager, *etc.*

- (i) Related Ordinances and regulations established by the University.
- (ii) Basic items related to methods for animal experiments and related activities.
- (iii) Basic items related to the care and management of laboratory animals.
- (iv) Items related to safety assurance and safety management.
- (v) Items related to the proper conduct of animal experiments and related activities.

2 The Committee shall record the dates of instruction, educational content, and the names of the instructor and those receiving instruction, and shall retain such records.

Chapter 11. Self-inspection, Assessment, and Verification

Article 32

The President requires that the Committee periodically conducts inspections and assessments (“self-inspections and assessments”) to determine whether the situation regarding the animal experiments and related activities in the University complies with

Related Ordinances and this Regulation.

2 The Committee shall implement self-inspections and assessments and shall report its findings to the President. The Committee may require the Manager to present data on the situation regarding animal experiments and related activities.

3 The President shall endeavor to have the results of self-inspections and assessments verified by persons or agencies outside the University.

Chapter 12. Public Disclosure of Information

Article 33

The President shall publicly disclose information on the conduct of animal experiments and related activities at the University every academic year.

Chapter 13. Miscellaneous Provisions

(Animal experiments and related activities on animals except mammalian, avian or reptilian species)

Article 34

In cases of animal experiments and related activities on animals except mammalian, avian, or reptilian species being cared or managed at the University, the Manager shall ensure the proper conduct of animal experiments and related activities based on this Regulation.

(Miscellaneous provisions)

Article 35

The President shall provide necessary rules regarding the proper conduct of animal experiments and related activities not covered by provisions in this Regulation.

Additional Provisions

1. The Regulation (the first version) shall come into force on October 1, 2007.

The Regulation (the second version) shall come into force on April 1, 2011.

2. The provisions of Article 12 shall be applied to animal experiments and related activities conducted after such date.

3. Animal experiment protocol or education protocol related to animal experiments and related activities conducted on the preceding day of the effective date of this Regulation (“the effective date”) and continued on or after the effective date shall be deemed to have been applied under the provision of the Paragraph 1 of Article 12 and have been approved under the provisions of the Paragraph 2 of the same Article. In this case, the valid period of the animal experiment protocol or education protocol that is deemed to have been approved (“deemed approved plan”) is until March 31, 2008, notwithstanding the provision of Paragraph 4 of Article 12, and report for the cancellation or completion of the animal experiments and related activities or education concerned is not required, notwithstanding the provision of Article 14.

4. Facilities established on the day preceding the effective date may continue from the effective date to March 31, 2008, without the approval based on the provisions of Article 16.

Supplementary provisions:

The regulations were revised on March 31st, 2011.

The regulations were revised on May 8th, 2012.

(Translated by Terada, Okano and Kasai on July 2009)