mediford
A Member of PHC Group

Mediford Corporation
36-1 Shimizu-cho, Itabashi-ku
Tokyo 174-0053, Japan
www.mediford.com

Guidelines for Animal Experiments

Mediford Corporation

1. Purpose

The Guidelines for Animal Experiment (hereinafter Guideline) is for Mediford Corporation (hereinafter Mediford) to conduct animal experiments appropriately as recommended by AAALAC International. Moreover, the Guideline aims to promote appropriate conduct of animal experiments from the viewpoint of animal protection and welfare as well as scientific aspects by stipulating basic matters to be observed based on laws, standards, and guidelines.

2. Applicable Scope

This Guideline applies to all animal experiments for research, testing, and education purposes operated at the Kashima and Kumamoto Laboratories (hereinafter institution) of Mediford. This Guideline is also applicable to the case of transportation as well as handling of animals in outsourced studies conducted at external facilities.

3. Definition

The terms used in this Guideline shall be defined as follows:

Animal experiment:
: Use of animals for testing, research, or manufacture of biological products and education

Laboratory animal:
: Animals housed or kept at the institution for use in animal experiments (including transportation to and between facilities)

Facility :
: Facilities to conduct housing or management of laboratory animals or animal experiments

Director of institution:
: Person with overall responsibility in the institution as Institutional Official (IO) for conduct of animal experiments and management of facilities

Attending Veterinarian (AV):
: Person responsible for the health and well-being of all animals used at the institution, and provides guidance and supervision on veterinary care to comply with this Guideline.

Veterinarian appointed by AV:
: Veterinarians appointed by AV have the same responsibility as AV for the instructions.

Study Director (SD):

Person responsible for all duties related to the study.
SD can act as the principal investigator (PI) when the institution corresponds to the test site of a multisite study.

Manager : A collective name of managers such as AV designated by IO and GLP managers (animal care manager, facility maintenance manager) designated by facility manager

SOP : Standard operating procedures used at the institution

AAALAC International:
Association for Assessment and Accreditation of Laboratory Animal Care International

4. Responsibilities of Institutional Official (IO)

IO bears the final responsibility for all animal experiments conducted at the institution.

(1) Formulation of the Guideline and verification of compatibility
(2) Establishment of IACUC and appointment of IACUC members and AV
(3) Approval of animal experiment protocols and amendments
(4) Overall comprehension of the results of animal experiments from experiment completion reports
(5) Provision of education and training to IACUC members and all personnel involved in the care and use of animals
(6) Implementation of self-inspection and evaluation, and program review by AAALAC international
(7) Information disclosure

5. Responsibility of Institutional Animal Care and Use Committee (IACUC)

IO establishes IACUC for proper conduct of animal experiments. IACUC consists of (1) AV, (2) those who have excellent insights regarding animal experiments, (3) those who have excellent insights regarding laboratory animals, (4) those who have other academic experience, and (5) those who do not have biological or chemical duties, and (6) representatives of the general public (external committee members) who are not involved in animal experiments. In addition, IO appoints an IACUC chair and secretariat. No particular term of office is set. IACUC carries out the following tasks after being consulted by IO.

(1) Reviewing of animal experiment protocols submitted from SDs based on the relevant guidelines and reporting of the results to IO.
(2) Provision of advice to IO on the results of animal experiments as necessary
(3) Holding IACUC meeting for supervision and evaluation of the program
(4) Monitoring of active projects (post approval monitoring [PAM]) to confirm that the research is being conducted as approved and animal well-being is not compromised.
(5) Self-inspection/evaluation and verification concerning compatibility to the

Guideline and reporting to IO

(6) Confirmation of appropriateness of the Guideline and reporting to IO

6. Responsibility of Attending Veterinarian (AV)

AV is responsible for the health and well-being of all animals used at the institution, and shall provide guidance and supervision of all elements associated with animal care and use (animal maintenance and housing). In addition, AV shall guarantee that the program of the institution is in accordance with the Guide for the Care and Use of Laboratory Animals.

7. Planning experiments

Animal experiments must be designed and carried out in accordance with 3Rs, which are the international principles of animal experiments based on scientific rationale and stipulated in laws, standards, and guidelines.

Replacement : Replace the use of animals to the extent possible to achieve the purpose of the research

Reduction : Reduce the use of animals to the extent possible to achieve the purpose of the research

Refinement : Refine the use of animals by selecting methods that would not cause pain to the animals to the extent possible to achieve the purpose of the research

The 3Rs principles are not only the ideology of animal experiments but also the ideology of handling laboratory animals. Therefore, animal experiments should be appropriately planned by SDs in consideration of the 3Rs principles to the extent possible to achieve the purpose of the research.

8. Responsibility of Study Director (SD)

SDs have the following responsibilities in implementation of studies.

(1) Preparation of experiment design, submission of animal experiment protocol, and acquisition of approval from IO

(2) Administration and oversight of approved protocol in practice

(3) Reporting to AV when there is any concern in animal health condition

(4) Reporting of study results to IO at completion of study

9. Application for animal experiment

(1) Animal experiment protocol

When conducting an animal experiment, SD shall prepare an experiment protocol and submit it through the animal experiment application system. The animal experiment protocol submitted is reviewed by IACUC in the animal experiment application system, and the result is reported to IO. IO notifies the results of review to the SD.

(2) Amendment to animal experiment protocol

When there is an amendment to the animal experiment protocol, SD shall prepare an animal experiment protocol amendment and submit it through the animal experiment application system. The animal experiment protocol amendment submitted is reviewed by IACUC in the animal experiment application system, and the result is reported to IO. IO notifies the results of review to the SD.

(3) Reporting of results at completion of animal experiment

At completion of the approved animal experiment, SD shall promptly report the study results to IO through the animal experiment application system. IO notifies the results of review to the SD.

10. Experiment operations

In conducting animal experiments, the pain caused to laboratory animals should be reduced to the extent possible in scientific use and be controlled in conformity to the relevant laws and standards. SDs shall determine the contents of experiments in consideration of the elements listed below.

(1) Physical retention
(2) Feeding and water supply restriction
(3) Surgical procedures
(4) Pain treatment, anesthesia, and postoperative management
(5) Humanitarian endpoint
(6) Euthanasia
(7) Safety management

11. Housing and management of laboratory animals

In consideration of animal welfare, in order to ensure the safety of personnel while increasing the scientific reliability of animal experiment data, SDs, AV, animal care manager, quarantine manager, and facility maintenance manager shall cooperate to properly house and maintain laboratory animals under the guidance of IO.

12. Animal housing environment

All personnel involved in care and use of animals must follow the standards specified in SOP for the items listed below in order to provide appropriate housing conditions for laboratory animals.

(1) Social housing and enrichment
(2) Housing space
(3) Environmental temperature and humidity
(4) Ventilation
(5) Lighting
(6) Feed and drinking water
(7) Bedding and flooring

(1) Noise and vibration

13. Healthcare of laboratory animals

Personnel involved in care and use of animals shall provide necessary healthcare to prevent laboratory animals from being injured or getting sick due to any cause unrelated to the purpose of animal experiments. When laboratory animals are injured or get sick, appropriate treatment or prompt measures shall be provided to the extent it does not interfere with the achievement of the purpose of animal experiments.

14. Facilities

IO shall construct and operate facilities under the guidance of the person in charge of facility maintenance, while paying special attention to the requirements for research execution, animal physiology, ecology, habits, and requirements for hygiene management.

15. Safety management

Under the direction of IO, the person in charge of safety management shall endeavor to ensure the safety and health of personnel at the institution based on relevant laws and regulations.

16. Implementation of education and training

IO shall provide necessary education and training to all personnel involved in care and use of animals. Education and training must be carried out before engaging in animal experiments, and it is desirable to be continued as necessary thereafter.

From the viewpoint of conducting proper animal experiments, the following items shall be included as items for education and training.

(1) Matters concerning related laws, ordinances, guidelines, and regulations
(2) Matters concerning animal experiments and handling of laboratory animals
(3) Matters concerning care and management of laboratory animals
(4) Matters related to ensuring safety

17. Self-inspection/Evaluation and verification regarding compatibility to the Guideline

In order to ensure transparency regarding the implementation of animal experiments, IACUC shall perform self-inspection and evaluation regarding compatibility to the Guideline every 6 months at the institution and report to IO.

18. Information disclosure

IO shall publish information on animal experiments (e.g., self-inspection results, verification results by AAALAC International, etc.) about once every year on the website of Mediford.

19. Memorial service

In principle, IO shall hold an animal memorial service once every year with the attendance of personnel involved in animal experiments in order to deepen the interest and understanding of protection and proper care of animals, and to memorialize the animals that have contributed to the prosperity and welfare of humankind.

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