



## Policy for the Care and Use of Laboratory Animals

### Introduction

At Chugai, our mission is to research and develop pharmaceutical products and new medical technologies that will contribute to better human health and medical care worldwide. Although we are actively pioneering and implementing experimental methods that do not use animals, it is not yet technologically possible to accurately recreate complicated physiological phenomenon outside of a living body, therefore testing in animals remains necessary to provide new safe and effective medicines to the world.

Animal experiments must be precise and reproducible, but we must always bear in mind that this can require the sacrifice of animals. For this reason, the “3 Rs” has been adopted worldwide. Defined by Russell and Barch, the 3 Rs consist of Replacement (replacing animal experiments with other methods), Reduction (reducing the overall use of animals), and Refinement (avoiding the suffering of animals). In Japan, several laws and guidelines have been established: the "Animal Care and Management Law" (instituted in 1973, revised in 1999), the "Standards Relating to the Care and Management of Experimental Animals" (instituted in 1980), the "Guidelines for Properly Conducting Animal Experiments" (Science Council of Japan, instituted in 2006), and the "Ministry of Health, Labour and Welfare's Fundamental Guidelines for Conducting Animal Experiments" (MHLW, instituted in 2006). As stipulated by these guidelines, when using laboratory animals, it is our responsibility to consider the scientific necessity of such experiments, to respect the lives of the animals, and to minimize their suffering as much as possible. Furthermore, the use of laboratory animals can also pose health and injury risks to personnel involved in their handling, so occupational safeguards must be carefully implemented. At Chugai, we crafted our policy not just to satisfy our legal requirements, but because we believe strongly in the underlying principles.

All personnel involved with laboratory animals must understand this policy fully and must strive to improve both the welfare of animals and the quality of research.

1. **Aims**

These rules are intended to encourage the proper care and use of laboratory animals, not only from a scientific perspective, but also for the welfare of animals and safety of employees. This policy stipulates the steps that must always be taken when conducting animal experiments.
2. **Scope**

This policy applies to all activities involving laboratory animals in Chugai and to all the personnel involved. In addition, it is also applied to all Contract Research Organizations that conduct animal research on Chugai's behalf. That means that whenever we outsource animal experiments, we must confirm that all these guidelines will be strictly implemented at the external facilities.
3. **Responsibility of the General Manager of the Research Division**

The General Manager of the Research Division has final responsibility for the care and use of laboratory animals in the Chugai Group as an Institutional Official. He or she ensures that all the measures specified in this policy are taken, as well as any other measures necessary to ensure animal welfare.
4. **Establishment of a committee to ensure the proper application of this policy.**

To ensure the proper implementation of these rules, the General Manager of Research Division shall establish an Institutional Animal Care and Use Committee (IACUC) that will supervise and guide the care and use of laboratory animals.
5. **Preparation of study protocols**

When drafting study protocols, the researchers must consider the 3 Rs when selecting experimental methods. They must try to reduce the number of animals used and avoid inflicting stress or pain. They must carefully consider which animal species will be suitable to the experimental purpose, the appropriate number of animals needed, their genetic characteristics, microbiological quality, and housing conditions. If any experimental method involves severe pain, every measure must be taken to animal suffering using sedatives, analgesics, and anesthetics. Study protocols must be approved by the IACUC.
6. **Education, training, and qualifications of personnel involved in the care and use of laboratory animals**

The care and use of laboratory animals can only be undertaken by personnel who can be demonstrated to have sufficient scientific knowledge about laboratory animals and who have had sufficient experience with the relevant techniques. Therefore, such personnel must undergo education and training, and regular

efforts must also be made to maintain and improve their knowledge and technical abilities.

7. **Occupational health and safety**

Efforts must be made to ensure the health and safety of personnel involved in animal research. Therefore, we will monitor the health of such personnel. We will also identify and acknowledge any risks associated with the care and use of laboratory animals and take measures to avoid these risks. It is essential to ensure sufficient safety, especially in animal experiments that could pose a physical, chemical, or biological risk to personnel.

8. **Husbandry of laboratory animals**

For the purpose of animal welfare, and in order to ensure the reliability of the study results, the husbandry environment must be appropriate to the animal species. All aspects of husbandry, including the provision of food and drinking water, changes in bedding, and the cleaning and disinfection of cages, racks, and animal rooms, must be appropriate in terms of both animal welfare and scientific requirements.

9. **Environmental enrichment**

Environmental enrichment refers to altering the physical and/or social environment so that it resembles a natural habitat in which the animals are more likely to feel comfortable. Environmental enrichment is essential for animal welfare. The optimum environment must be selected based on a variety of factors.

10. **Veterinary care**

All laboratory animals must be handled and managed in an ethical manner to ensure their health and welfare. Therefore, all disease management, surgical procedures, pain control, and euthanasia must be carried out under the direction of a veterinarian with sufficient experience in dealing with laboratory animals.

11. **Inspection of laboratory animals upon arrival**

When animals are transported to animal facilities, care must be taken to reduce the stress of travel. Inspections are conducted upon arrival to confirm that the animals match the order and to check their health and shipment conditions.

12. **Acclimatization of laboratory animals**

An acclimatization period must be provided to animals to alleviate transportation-related stress and allow them time to adjust to their new environment.

13. **Facilities and equipment**

To carry out of laboratory animal examinations with consideration for animal welfare and the occupational health and safety of personnel, facilities and equipment must be installed and maintained based on scientific principles relevant to the use of laboratory animals.

14. **Self-inspections, evaluation and verification**

Periodically, we will conduct internal inspections to confirm compliance with these policies, and the results of these internal inspections will be verified and certified by an independent third-party institution.

15. **Public disclosure**

Inspection results obtained as described in "14. Self-inspection, evaluation and verification" must be disclosed to the public in a transparent manner.

16. **Additional provisions**

- 1) Any revision of this policy will be handled by the Research Support Department and approved by the General Manager of the Research Division.
- 2) This policy will be effective from March 1, 2022.