

Meiji Holdings Co., Ltd. Ethical Guidelines for Judgments on Animal Testing

1. Background and purpose

Meiji Holdings Co., Ltd. (hereinafter, Meiji HD) seeks to create new health value through research activities conducted in accordance with sound ethical principles.

International efforts to minimize and adopt alternative methods to animal testing have been intensifying.

In our research activities, Meiji HD adopts the approach of not positioning animal testing as our first choice. Instead, we prioritize alternative methods that do not involve the use of animals. However, in pursuit of the Meiji HD mission of expanding our knowledge of the life sciences and promoting human health, there are cases in which animal testing is essential and the only option for testing. Such cases require the option to use animal testing. The implementation of animal testing by Meiji HD is based on the following: 1) Compliance with the Act on Welfare and Management of Animals and 2) adherence to the 3R Principle. The 3R Principle is based on the concept of (1) Replacement (use alternative methods), (2) Reduction (reduce the number of animals used), and (3) Refinement (pain mitigation). This Principle serves as the foundation for regulations set forth by various administrative authorities as well as the Ethical Rules for Animal Testing formulated by Meiji HD Wellness Science Labs. The 3R Principle, and rules and regulations based on the 3R Principle, outline the requirement for maintaining a balance between scientific necessity and animal welfare.

These ethical guidelines were formulated to clarify the criteria for decisions made concerning the use of animal testing in Meiji HD research activities and in research activities conducted by Meiji HD in collaboration with external entities.

2. Scope of applicability

"Animal testing" shall refer to the use of animals for the purpose of maintaining and improving human health, medical research, or other scientific advancements. Applicable animal testing shall be that which involves the use of animals classified as mammals.

These Ethical Guidelines shall be applied to Meiji HD research activities and research activities conducted by Meiji HD in collaboration with external entities.



3. Meiji HD animal testing policy

Research conducted by Meiji HD is based on themes set with the goal of resolving issues related to society and health. As such, it is a prerequisite that research activities be conducted based on high ethical standards. Meiji HD has established the Meiji HD Ethics Committee for Proper Animal Testing as an internal entity for evaluating the decisions made concerning the use of animal testing as well as the adequacy of external disclosure of research results resulting from animal testing.

At Meiji HD, our basic policy is to minimize animal testing. To this end, we proactively promote the exploration and adoption of alternative methods such as in vitro and in silico.

However, in carrying out research activities aimed at expanding our knowledge of the life sciences and promoting human health, there are cases in which animal testing is essential and the only option for testing. Such cases do require the option to use animal testing. In the following cases, judgments on the use of animal testing must be made following a strict internal process (review by the Meiji HD Ethics Committee for Appropriate Animal Testing) to confirm the absolute necessity for animal testing.

Animal testing conducted in accordance with laws and regulations or a request from an administrative authority or national government

- · Animal testing conducted to validate the safety and quality of an ingredient where it is necessary to fulfill a public duty of accountability
- · Research related to the development of a pharmaceutical product or a medical device
- Research related to the safety, efficacy, or mechanism of an ingredient for which non-clinical validation via animal testing is essential for persons requiring special considerations*1
- Research concerning the understanding of biological phenomena or research*2 concerning safety, physiological effects, or mechanisms of an ingredient for which a systemic or multiorgan interaction is assumed as the mechanism of action, and for which no adequate alternative method exists at the time of application*3
- *1: Persons requiring special consideration include pregnant women, nursing mothers, newborns, infants, toddlers, young children, the elderly, patients, etc.
- *2: This does not include animal testing for the purpose of validating health claims related to food product development
- *3: Refers to the time of application for a review by the Meiji HD Ethics Committee for Appropriate Animal Testing



4. Evaluation structure for external disclosure concerning the use of animal testing and results

Animal testing planned by Meiji HD and animal testing conducted by Meiji HD in collaboration with an external entity is subject to a judgment on the use of animal testing. This judgment shall be made by the Meiji HD Ethics Committee for Appropriate Animal Testing in accordance with these Ethical Guidelines. Animal testing approved by the Meiji HD Ethics Committee for Appropriate Animal Testing shall require the submission of a testing plan, which must be formulated in compliance with the separately outlined Ethical Rules for Animal Testing. After an ethics inspection by the Meiji HD Committee on Animal Testing and the receipt of approval from the head of the research body, animal testing must be conducted in accordance with the approved plan. The external disclosure of the results resulting from animal testing must be content that corresponds to the testing plan created in accordance with these Ethical Guidelines and approved by the Meiji HD Ethics Committee for Appropriate Animal Testing.

The Meiji HD Ethics Committee for Appropriate Animal Testing shall conduct monitoring to obtain retrospective confirmation that the animal testing and the external disclosure of results gained through animal testing have been conducted appropriately in accordance with these Ethical Guidelines.

5. Revisions to these Ethical Guidelines

Meiji HD understands the importance of animal protection and welfare. We will continue working to minimize animal testing and, as necessary, may make revisions to these Ethical Guidelines.

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