

## CIOMS principles 2011年改訂最終案

### 改訂 2011 医学生物学領域の動物実験に関する国際原則(案)

原文

THE REVISED 2011 INTERNATIONAL GUIDING PRINCIPLES FOR BIOMEDICAL RESEARCH INVOLVING ANIMALS.

The following Principles should be used by the international scientific community to guide the responsible use of vertebrate animals in scientific and/or educational activities.

- I. The advancement of scientific knowledge is important for the improvement of human and animal health and welfare, conserving the environment, and the good of society. Animals serve a vital role in these scientific activities and animal welfare is integral to achieving scientific and educational goals. Decisions regarding the welfare, care, and use of animals should be guided by scientific knowledge and professional judgment, reflect ethical and societal values, and consider the potential benefits and the impact on the well-being of the animals involved.
- II. The use of animals for scientific and/or educational purposes is a privilege that carries with it a moral obligation and ethical responsibility for institutions and individuals to ensure the welfare of these animals to the greatest extent possible. This is best achieved in an institution with a culture of care and conscience in which they willingly, deliberately, and consistently act in an ethical, humane and compliant way. Individuals working with animals have an obligation to demonstrate respect for animals, to be responsible and accountable for their decisions and actions pertaining to animal welfare, care and use, and to ensure that the highest standards of scientific integrity prevail.
- III. Animals should only be used when necessary and only when their use is scientifically and ethically justified. The tenets of the Three Rs – Replacement, Reduction and Refinement – should be incorporated in the design and conduct of scientific and/or educational activities that involve animals. Scientifically sound results and avoidance of unnecessary duplication of animal-based research are achieved through study and understanding of the scientific literature and proper

experimental design. When no alternative methods, such as mathematical models, computer simulation, *in vitro* biological systems, and other non-animal approaches, are available to replace the use of live animals, the minimum number of animals should be used to achieve the scientific or educational goals, and the animal's experience of pain and distress should be avoided or minimized. Cost and convenience must not take precedence over these tenets.

- IV. The animals selected for the research or educational purpose should be suitable for the purpose, of an appropriate species and genetic background, and of a nutritional, microbiological, and general health status to ensure scientific validity and reproducibility. The physiological, immunological, and behavioral characteristics of the animal also should be appropriate to the planned use.
  
- V. The health and welfare of animals should be primary considerations in decisions regarding the program of veterinary medical care, animal production, transportation, husbandry and management, housing, restraint, and final disposition of animals. Measures should be taken to ensure that the animals' environment and management are appropriate for the species, contribute to the animals' well-being and do not result in unnecessary use of animals by adversely affecting the scientific or educational outcomes through the introduction of confounding variables.
  
- VI. The welfare, care, and use of animals should be under the supervision of a veterinarian, scientist, or other person trained and experienced in the health, welfare, and proper handling and use of the species being maintained or studied. The individual or team responsible for animal care should be involved in the development and maintenance of all aspects of the program. If the program is directed by a scientist, veterinary care should be available as necessary.

- VII. Investigators should assume that procedures that would cause pain in human beings cause pain in other animals, unless there is evidence to the contrary. Thus it is a moral imperative to minimize stress, distress, discomfort, and pain in animals, consistent with sound scientific practice. Taking into account the research and educational goals, more than momentary or minimal pain and/or distress in animals should be managed and mitigated with refinement of experimental techniques and/or appropriate sedation, analgesia, anesthesia, and/or non-pharmacological therapies developed in consultation with a qualified veterinarian. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.
- VIII. Endpoints and timely interventions should be established for both humane and experimental reasons. Humane endpoints and/or interventions should be established before animal use begins, should be assessed throughout the course of the study, and should be applied as early as possible to avoid, eliminate, or minimize unnecessary and/or unintended pain and/or distress. Animals that would otherwise suffer severe or chronic pain, distress, or discomfort that cannot be relieved and is not part of the experimental design, should be euthanized using a procedure appropriate for the species and condition of the animal.
- IX. It is the responsibility of the institution to ensure that personnel responsible for the welfare, care, and use of animals are appropriately qualified through relevant training and experience for the procedures they perform. Adequate opportunities should be provided for on-the-job training and continuing education in the humane and responsible treatment of animals.
- X. A system of animal use oversight that verifies commitment to these Principles should be implemented in each country, varying from country to country according to cultural, economic, religious, and social factors. This system should include a mechanism for authorization (such as licensing or registering of institutions, scientist, and/or projects) and oversight which may be assessed at the institutional, regional, and/or national level. The oversight framework should encompass both ethical review of animal use as well as considerations related to animal welfare and

care. It should promote a risk-benefit analysis for animal use, balancing the benefits derived from the research and/or educational activity with the potential for pain and/or distress experienced by the animal.

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