



INTERNATIONAL GUIDING PRINCIPLES

FOR

BIOMEDICAL RESEARCH INVOLVING ANIMALS

DECEMBER 2012



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PREAMBLE

The *International Guiding Principles for Biomedical Research Involving Animals* has been the framework for the development of laws, policies, and guidelines for over 25 years. When the *Guiding Principles* were written in 1985, the profession of laboratory animal medicine and science was still establishing best practices and standards of care. Over the years, many of these practices and standards have become ingrained in the oversight structure of numerous countries. Since the publication of the original *Guiding Principles*, the scope of animal research has expanded significantly, numerous technological advancements have occurred, and societal attention to the welfare of research animals has increased. This evolution has prompted an update and expansion of the focus of the *Guiding Principles* to address contemporary issues facing scientists when animals are used for research and education.

The revised *International Guiding Principles for Biomedical Research Involving Animals* is the result of a partnership between the Council for International Organizations for Medical Science (CIOMS) and the International Council for Laboratory Animal Science (ICLAS) formed to update the *Guiding Principles*. These international organizations have a common mission of advancing international collaboration in biomedical sciences. The revised document is the outcome of an international collaboration of scientists, veterinarians, and other experts whose ideas and suggestions were gathered from more than 10 different meetings held in conjunction with several scientific conferences around the world over a period of more than 3 years. Discussions were based on the Statements of Principles for the Use of Animals from over 30 professional societies, organizations, and countries. The working group had an international and interdisciplinary membership representing several pivotal stakeholder professional organizations.

The revised *International Guiding Principles for Biomedical Research Involving Animals* reflect congruence with the more specific guidance offered by other national and international agencies. These *Guiding Principles* will be a touchstone for countries with emerging research and teaching programs that use animals in developing a framework of responsibility and oversight to ensure the appropriate use of animals. They may also serve as an international benchmark for countries with well-developed animal-based research programs. As noted in 1985, there are varying approaches in different countries to the use of animals for research, testing and teaching purposes. By applying these *Guiding Principles* and other documents with more specific standards of care, each country can develop a detailed system of guidelines or regulations that is commensurate with national customs and social practices.

The use of animals in research, education and testing is an essential component of the advancement of our understanding about human and animal function. This knowledge is important for advancing human and animal health and welfare through disease prevention and cures, new treatments, and drug and device development. The scientific community, understanding that using animals is a privilege entrusted by society, remains committed to ensuring the health and welfare of animals as an integral consideration when animals are used for these purposes.



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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 improvement of human and animal health and welfare, conservation of the environment, and the good of society. Animals play a vital role in these scientific activities and good 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 moral obligations and responsibilities 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 individuals working with animals willingly, deliberately, and consistently act in an ethical, humane and compliant way. Institutions and individuals using 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 be used only when necessary and only when their use is scientifically and ethically justified. The principles of the Three Rs – Replacement, Reduction and Refinement – should be incorporated into the design and conduct of scientific and/or educational activities that involve animals. Scientifically sound results and avoidance of unnecessary duplication of animal-based activities 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, or other non-animal (adjunct) 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. Cost and convenience must not take precedence over these principles.
- IV. Animals selected for the activity should be suitable for the purpose and of an appropriate species and genetic background to ensure scientific validity and reproducibility. The nutritional, microbiological, and general health status as well as the physiological and behavioral characteristics of the animals should be appropriate to the planned use as determined by scientific and veterinary medical experts and/or the scientific literature.
- V. The health and welfare of animals should be primary considerations in decisions regarding the program of veterinary medical care to include animal acquisition and/or production, transportation, husbandry and management, housing, restraint, and final disposition of animals, whether euthanasia, rehoming, or release. Measures should be taken to ensure that the animals' environment and management are appropriate for the species and contribute to the animals' well-being.
- VI. The welfare, care, and use of animals should be under the supervision of a veterinarian or scientist trained and experienced in the health, welfare, proper handling, and use of the species being maintained or studied. The individual or team responsible for animal welfare, care and use should be involved in the development and maintenance of all aspects of the program. Animal health and welfare should be continuously monitored and assessed with measures to ensure that indicators of potential suffering are promptly detected and managed. Appropriate veterinary care should always be available and provided as necessary by a veterinarian.



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- VII. Investigators should assume that procedures that would cause pain or distress in human beings cause pain or distress in animals, unless there is evidence to the contrary. Thus, there is a moral imperative to prevent or minimize stress, distress, discomfort, and pain in animals, consistent with sound scientific or veterinary medical 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 by refinement of experimental techniques and/or appropriate sedation, analgesia, anesthesia, non-pharmacological interventions, and/or other palliative measures developed in consultation with a qualified veterinarian or scientist. Surgical or other painful procedures should not be performed on unanesthetized animals.
- 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 prevent, ameliorate, 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 removed from the study and/or 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 and competent through training and experience for the procedures they perform. Adequate opportunities should be provided for on-going training and education in the humane and responsible treatment of animals. Institutions also are responsible for supervision of personnel to ensure proficiency and the use of appropriate procedures.
- X. While implementation of these Principles may vary from country to country according to cultural, economic, religious, and social factors, a system of animal use oversight that verifies commitment to the Principles should be implemented in each country. 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 harm-benefit analysis for animal use, balancing the benefits derived from the research or educational activity with the potential for pain and/or distress experienced by the animal. Accurate records should be maintained to document a system of sound program management, research oversight, and adequate veterinary medical care.

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