

Ethical Principles and Guidelines for Experiments on Animals

(3rd edition 2005)

Preamble

These Principles and Guidelines are based on the recognition that in their need to resolve their problems, human beings cannot dispense with experimentation on live animals, on the one hand, while the ethical principles of “respect for life” and respect for the “dignity of creation” demand that they protect animals, on the other. These Ethical Principles and Guidelines are based on the conviction that, as responsible people, scientists should themselves define, implement and monitor the measures necessary to attain the best possible resolution of this conflict .

These Ethical Principles and Guidelines for Experiments on Animals were formulated jointly by the Swiss Academy of Medical Sciences (SAMS) and the Swiss Academy of Sciences (SCNAT). They were adopted at the meetings of their Senates in spring of 1983 and declared binding as a code of conduct for all researchers and their scientific collaborators practising in Switzerland. The Ethics Committee for Animal Experimentation of both Academies revised the Ethical Principles and Guidelines for Animal Testing in the light of recent experience and insights in 1993 and 2005. This version of the Ethical Principles and Guidelines for Experiments on Animals was approved by the Senate of the Academy of Medical Sciences on 24 November 2005 and by the Central Committee of the Swiss Academy of Sciences on 16 December 2005 and replaces the previous version of 1995.

1. Legal Bases

1.1 The Federal Constitution of the Swiss Confederation stipulates that “The Confederation shall legislate on the protection of animals. It shall regulate in particular: a) the keeping and care of animals; b) experiments and intervention on live animals; c) the use of animals; d) the importation of animals and animal products; e) trade in animals and transportation of animals; f) the slaughter of animals” (Art. 80 Swiss Federal Constitution).

The Federal Constitution also stipulates that “The Confederation shall legislate on the use of the reproductive and genetic material of animals, plants, and other organisms. In doing so it shall take into account the dignity of creation and the safety and security of man, the animal and environment, and shall protect the genetic diversity of animal and vegetal species” (Art. 120 Swiss Federal Constitution).

1.2 The Swiss Federal Law on Animal Protection of 9 March 1978 (*Tierschutzgesetz (TSchG)*, SR 455), the Ordinance on Animal Protection of 27 May 1981 (*Tierschutzverordnung (TSchV)*, SR 455.1), the Ordinance on the Acquisition of the Certificate of Competency for Animal Guardians of 22 August 1986 (*Verordnung über den Erwerb des Fähigkeitsausweises für Tierpfleger (VTpf)*, SR 455.12) and the Ordinance on the Education and Training of Specialized Staff for Animal Experiments of 12 October 1998 (*Verordnung über die Aus- und Weiterbildung des Fachpersonals für Tierversuche*, SR 455.171.2) regulate the area of experiments on animals, i.e. specify requirements for the implementation of experiments on animals, the keeping of laboratory animals, the training of qualified personnel and the special obligations of researchers and authorities (bes. Art. 12-19a TSchG, Art. 58-64b TSchV). Various guidelines issued by the Swiss Federal Veterinary Office (www.bvet.admin.ch) provide assistance in the interpretation of the various legal requirements.

The basic principle for the treatment of animals whereby “no person shall inflict unjustified pain, suffering or injury on an animal or cause it to experience fear” (Art. 2 TSchG) is enshrined in the Federal Law on Animal Protection. “Experiments on animals that cause pain, suffering or injury, or extreme anxiety to the animal, or that could considerably impair its general health must be restricted to the unavoidable minimum.” Such animal experiments “are subject to authorization” (Art. 13 and 13a TSchG).

1.3 Persons involved in experiments on animals are obliged to act in accordance with the Federal Law on the Protection of Animals, the Federal Ordinance on the Protection of Animals and the guidelines of the Swiss Confederation.

However, considerable discretionary powers remain, the scope of which is defined by the authorizing bodies and the judicial organs, on the one hand, and the researchers themselves, on the other. In the context of these discretionary powers and based on their individual responsibility, persons who are involved in animal experiments are bound over to take ethically-based decisions founded on these Principles and Guidelines.

2. Ethical Considerations and Ethical Balancing

2.1 Human existence gives rise to problems, the resolution of which requires the extension and consolidation of knowledge. Animal research is often crucial to the understanding of living phenomena. It represents a way of using animals with the aim of availing of the insights gained for the promotion of human welfare and health and the alleviation of human suffering. Research carried out in the area of veterinary medicine and organismic biology (e.g. ecology, evolutionary and behavioural biology) often serves the purposes of animal welfare and the protection of species and ecosystems. The protection of life and alleviation of severe suffering of humans and animals are requirements which humans are not only authorized, but obliged to meet.

2.2 Due to their capacity for reason and reflection, human beings are answerable for their actions. Therefore, they are obliged to take the welfare of all stakeholders into account in their actions. Thus, in the context of animal experiments, they cannot evade the ethical conflict that arises between the desire for new insights and the basic ethical position of "respect for life". This conflict is unavoidable and can only be resolved responsibly by ethically balancing the human and animal values and goods involved.

2.3 Animal experiments must be justified on the basis of prevailing values and interests. Researchers are obliged to demonstrate the need for and tenability of all experiments on animals and to carefully verify their ethical justifiability through ethical balancing.

2.4 The balancing of the ethical issues involved in all animal experiments is the responsibility of the individual researcher and must be justifiable to the consulting cantonal commission for animal experimentation, the authorizing bodies, the ethical committees for animal experimentation, animal welfare officers and the general public.

2.5 Based on the principle of "respect for life", human beings are obliged to protect animals as sentient fellow creatures. This respect and the obligation to avoid pain where possible necessitate that animal experiments be limited to the minimum .

The basis of this approach is provided by the "3 R" principles (replacement, reduction, refinement):

- the avoidance of animal experiments through the use of replacement methods,
- the reduction of the number of animals involved in experiments,
- the refinement of methods for the alleviation of the suffering of animals during experiments and in the context of animal keeping and breeding.

2.6 Furthermore, animals have the right to the respect of their dignity and, hence, the respect of their species-specific characteristics, needs and behaviours. Any animal experiment that causes pain or stress to the animal basically represents an attack on the dignity of the animal and must, therefore, be justified through the balancing of the ethical concerns involved. If human beings fail to respect the acknowledged dignity of animals, they abuse their freedom and fail to respect their own dignity.

3. Ethical Requirements for the Admissibility of Animal Experiments

3.1 The more essential and significant the knowledge to be gained from an animal experiment from the human perspective, the easier it is to justify the experiment.

3.2 The more severe or lasting the potential suffering of the animal, the more pressing the question as to the reasonableness and acceptability of an experiment.

3.3 Research tests on animals must conform to the established principles and precepts of science. In particular, the targeted results must lie clearly beyond the limits of current knowledge, the hypothesis to be tested must be reasonable and the selected procedures must be promising and consistent with the relevant status of research.

3.4 Experiments on animals are fundamentally ethically acceptable if this has been demonstrated through the balancing of ethical concerns for each individual experiment; these include, in particular,:

- experiments on animals which visibly enhance the life and health of human beings and animals or the protection of the environment; i.e. experiments with prophylactic, diagnostic and therapeutic objectives in the fields of medicine and veterinary medicine;
- experiments on animals which – even in the absence of directly identifiable benefits for life and health – serve the quest for new knowledge as they are very likely to lead to a significant gain in knowledge in relation to the structure, function and behaviour of living organisms;
- experiments on animals carried out in the context of education and training in which no other possibility exists for achieving the necessary learning targets; such targets include the gaining of a better understanding of living phenomena and the imparting of the necessary skills for the implementation of experiments on animals and operating on human beings.

3.5 Certain experimental set-ups can be expected to cause such severe suffering for animals that the weighing up of ethical concerns will always fall in favour of the animals. If it is not possible to find less harmful and more ethically acceptable test arrangements by changing the research hypothesis, it will be necessary to refrain from carrying out the experiment and to forgo the expected gain in knowledge.

3.6 Experiments on animals whose sole objective is the research and development of luxury consumer goods must not be carried out.

4. Ethical Requirements for the Conduct of Experiments on Animals

4.1 Responsibility must be assumed for the conduct of an animal experiment throughout the entire duration of the experiment which involves the following phases:

- definition of objectives, selection of animals (species, breed, strain), ethical balancing, test plan, application for authorization, acquisition and keeping of the animals, preparation of the animals for the intervention and treatment;
- conduct of the experiment, intervention and treatment, monitoring of the animals, documentation of all intervention and treatment, measurements and observations;
- conclusion of the final experiment followed by restoration of the welfare of the animals or killing of the animals;
- evaluation of the research findings, publication, reporting to the relevant authorities.

4.2 The ethical approach of respect for life requires that the maximum gain in knowledge is achieved using the minimum possible number of laboratory animals and the limitation of their suffering to the essential minimum.

If the suffering of individual animals can be reduced significantly through the use of a larger number of animals, the reduction of individual suffering shall take priority over the reduction of the number of animals used in the experiment.

4.3 All persons involved in animal experiments are obliged to support the welfare and minimum possible suffering of the laboratory animal.

4.4 Experiments on animals shall be carried out in accordance with the latest developments. Known prophylactic, diagnostic and therapeutic processes shall be taken into account and the scientific guidelines provided by international expert bodies shall be observed.

4.5 If pain, suffering or stress are inevitable concomitants of an experiment, their duration and intensity must be limited to the minimum. To this end, the animals shall be monitored by specially trained personnel in accordance with predefined criteria and at predefined times and measures necessary to alleviate suffering shall be taken insofar as this is compatible with the objective of the experiment. The

animal must be able to express its sensations and where possible avoid painful stimuli. Hence, the use of substances that induce paralysis without loss of consciousness and analgesic effects is unauthorized.

4.6 In all experiments that give rise to long or chronic suffering or necessitate repeated intervention, all possible measures must be undertaken to alleviate suffering and dispel fear and anxiety. The professional care of the animals, before, during and after the experiment are particularly important in this context.

4.7 Continuous physical restraint may only be resorted to if other processes have been considered and deemed unsuitable. All possible measures must be taken to alleviate fear and anxiety, in particular the careful and protective familiarization of the animal with the test conditions.

4.8 If distressing measures, such as the restriction of food or water or the withholding of other important environmental factors or administration of pain stimuli are unavoidable, they must be recorded in detail in the test protocol. To ensure that the distress caused does not exceed an acceptable level, the effects of these measures on the animal shall be monitored through the collection of the relevant data.

4.9 To avoid unnecessary suffering, clearly defined termination criteria must be established for all animal experiments. Animals which experience serious suffering must be killed as quickly as possible using a pain-free method.

4.10 If possible, animals on which experiments are carried out should be obtained from authorized laboratory-animal breeding units. Animals of unknown origin must not be used in experiments. Particular restraint should be exercised in relation to the use animals from species that live in the wild. Even if they cause little pain or distress, experiments on species threatened with extinction are only justifiable if they contribute to the conservation of the species in question.

4.11 Laboratory animals should be sheltered and cared for in accordance with the principles of proper animal guardianship. Every effort must be made to ensure that pens and cages are well made and generously sized and that the animals have adequate opportunities for activity and social contact. The legal regulations concerning the keeping of such animals merely constitute minimum requirements. If they have been overtaken by new information and insights, keeping practices that exceed the legal requirements should be selected.

4.12 Animals with genetic diseases and defects or behavioural disorders may only be bred if their use is deemed essential following careful ethical balancing. In the case of the breeding of genetically modified animals, the risk of the development of defects, suffering or pain must be particularly thoroughly evaluated. To avoid unnecessary suffering, clearly-defined criteria must be defined, according to which animals shall be killed as soon as possible and stocks shall not be developed further.

4.13 If the breeding of animals with diseases, defects, or behavioural disorders is unavoidable, it should only be done for a short time and the numbers produced should be strictly tailored to requirements. The animals should be introduced into the experiment as quickly as possible and immediately killed when the test results have been obtained. If the conservation of breeds associated with such suffering is necessary, conservation processes other than maintenance breeding should be sought.

5. Responsibilities

5.1 The main requirements of persons involved in all animal experiments are professional competency and a declared willingness to assume responsibility in relation to the use of laboratory animals and to comply with the relevant legal requirements.

Investigators bear the moral, scientific and legal responsibility for the planning, justification (through ethical balancing) and implementation of experiments on animals. This responsibility is shared by all other persons involved in such experiments; they must, therefore, have full right of expression and have the right to refuse to participate in experiments without negative consequences.

5.2 Researchers employed in Switzerland shall refrain from carrying out experiments on animals abroad that contravene the Swiss animal welfare legislation and cannot be justified on the basis of these Ethical Principles and Guidelines and from participating in their implementation abroad.

They shall also refrain from procuring laboratory animals from abroad if their breeding, keeping and treatment cannot be justified in accordance with these Ethical Principles and Guidelines.

The conditions should be strived for in relation to the procurement of foreign products created using animal testing.

5.3 Persons involved in research are obliged to take and support all possible measures to limit painful and stressful experiments on animals.

Persons involved in research are obliged to subject the suitability of all established and officially promoted animal testing methods to regular critical assessment.

They are also obliged to promote the exchange of information about the results of experiments on animals so as to avoid unnecessary experiments and, where applicable, to support the updating of regulations and methods.

5.4 Persons involved in scientific research are obliged to do further training in animal welfare and to support the development of alternative research methods.

5.5 Where possible, scientists shall actively promote the open dissemination of information to the public and the media about the importance, necessity, methodology and results of experiments on animals. They shall also work towards the critical evaluation of society's demand for well-being and safety generated through experiments on animals.

They shall make every effort to ensure maximum transparency in the dissemination of information about experiments on animals and shall be willing to provide access to interested parties to their experiments and animal keeping within the scope of the available technical, personnel and data protection facilities.

6. Recommendations for Institutions

6.1 Institutions which carry out experiments on animals are urged to create independent institutions for ethical concerns relating to animal testing for staff involved in experiments.

6.2 Institutions which carry out experiments must constantly promote the training of those involved in experiments on animals and monitor their knowledge and skills in a suitable way.

It is particularly important that people who will be authorized to carry out experiments on animals in the future be made aware of the moral principles involved in the treatment of animals in the context of their third-level education.

6.3 Institutions for the advancement of science must not support animal testing that contravenes these Ethical Principles and Guidelines. The academic boards of scientific journals and reviewers of publications shall refuse to accept publications based on studies that contravene these Ethical Principles and Guidelines.

6.4 The Swiss Academy of Medical Sciences and the Swiss Academy of Sciences consider it their permanent duty to review the suitability and validity of the relevant legal texts and provisions and their own Ethical Principles and Guidelines in the light of current scientific knowledge and, where appropriate, to support their alteration.

The Ethical Principles and Guidelines for Experiments on Animals are available on the internet in German, French and English (www.samw.ch -> Ethics -> Guidelines; and www.scnat.ch). They can also be obtained from the secretariats of the SAMS and SCNAT:

Swiss Academy of Medical Sciences (SAMS)
Petersplatz 13, CH 4051 Basel (mail@samw.ch)

Swiss Academy of Sciences (SCNAT)
Schwarztorstr. 9, CH 3007 Bern (info@scnat.ch)

In addition to these Principles and Guidelines the Ethics Committee for Animal Experimentation of the SAMS and SCNAT has compiled the following documents:

- *“Prozessflussdiagramm für die Planung und Durchführung von Tierversuchen“* (“Flowchart for the planification and execution of experiments in animals”) (2002): the diagram is intended to assist researchers in completing applications for the authorization of animal testing and, in particular, for training based on assessment criteria for ethical balancing in the planning and implementation of experiments and on completion of animal testing by all persons and instances involved in animal testing.
- *“Ethische Güterabwägung bei Tierversuchen“* (“Ethical assessment of intangible items in animal experimentation”) (2005): this template for ethical balancing is intended to act as a model for critical self-assessment and for use in education and further training.

These two documents are available in German and French and the diagram is also available in English. They can be downloaded from the SAMW website: www.samw.ch -> Ethics -> Ethics Committee for Animal Studies.

Other publications of the SAMS/SCNAT's Ethics Committee for Animal Experimentation:

- *Menschliche Gene oder Menschengene?*, 2002, Schweizerische Ärztezeitung 83, 574-577.
- *Beitrag zur ethischen Beurteilung der Xenotransplantation in Hinblick auf den Schutz der Würde der Tiere*, 2000, Schweizerische Ärztezeitung 81, 36-37, und Altex, 2000, 1/00, 24-26.
- *Stellungnahme zum Begriff “Würde des Tieres“*, 1997, Schweizerische Ärztezeitung 78, 1299-1302.

Members of the Ethics Committee for Animal Experimentation which revised the Ethical Principles and Guidelines: Professor A Steiger, Division of Animal Housing and Welfare, Vetsuisse Faculty, University of Bern (Chair); Dr C Aus der Au, Department of Systematic Theology, University of Basel; Professor B Baertschi, Interfaculty Centre for Bioethics and Human Medical Sciences, University of Geneva; Professor H-U Bertschinger, Pfäffikon (University of Zurich to 2002); Professor A Bondolfi, Centre Lémanique d'éthique, University of Lausanne; Professor K Bürki, Institute for Laboratory Animal Studies, University of Zurich; Professor H Durrer, Oberwil (professor emeritus, Faculty of Medicine, University of Basel); Dr A Gutzwiller, Eidgenössische Forschungsanstalt für Nutztiere, Posieux (since 2003); Professor M-C Hepp-Reymond, Institute of Neuroinformatics, University of Zurich and Swiss Federal Institute of Technology Zurich (to 2002); Professor E Hummler, Institute of Pharmacology and Toxicology, University of Lausanne; Professor Beatrice Lanzrein, Institute for Cellular Biology, University of Bern (since 2005); Dr M Leuthold, General Secretary SAMW, Basel; Dr B E Matter, Olsberg (previously Novartis Pharma AG Basel); PD K-P. Rippe, Ethics in Discourse, University of Zurich; Professor E Rouiller, Department of Physiology, University of Fribourg (2003 - 2004); Dr H Sigg, Cantonal Veterinary Office Zurich (to 2002); Professor B M Stadler, Institute for Immunology, University of Bern; lic. iur. M. Tinner, staff member, Advocate for Animal Welfare Criminal Cases of the Canton of Zurich (since 2003); Dr Thierry Wannier, Institute of Physiology, University of Fribourg (since 2005); Professor E. van der Zypen, Institute of Anatomy, University of Bern (to 2004).