

A Publication Ethics and Publication Malpractice Statement

(These guidelines are based on COPE's Best Practice Guidelines for Journal Editors)

The Medical Journal "Acta Medica Medianae"

Ethical guidelines for journal publication

The publication of an article in the peer-reviewed journal "Acta Medica Medianae" is a process of permanent knowledge improvement. It is a direct reflection of the quality of the work of the authors and the institutions that support them. Peer-reviewed articles support and embody the scientific method. It is therefore important to agree upon standards of expected ethical behaviour for all parties involved in the act of publishing: the author, the journal editor, the peer reviewer, the publisher and the society of society-owned or sponsored journals.

Publishers of the journal Acta Medica Medianae, Faculty of Medicine, University of Niš, Serbia, and Serbian Medical Society take its duties of guardianship over all stages of publishing extremely seriously and we recognise our ethical and other responsibilities.

We are committed to ensuring that advertising, reprint or other commercial revenue has no impact or influence on editorial decisions. In addition, Editorial Board will assist in communications with other journals and/or publishers where this is useful to editors.

Duties of authors

- **Reporting standards**

Authors of reports of original research should present an accurate account of the work performed as well as an objective discussion of its significance. Underlying data should be represented accurately in the paper. A paper should contain sufficient detail and references to permit others to replicate the work. Fraudulent or knowingly inaccurate statements constitute unethical behavior and are unacceptable. Review and professional publication articles should also be accurate and objective, and editorial 'opinion' works should be clearly identified as such.

- **Data access and retention**

Authors may be asked to provide the raw data in connection with a paper for editorial review, and should in any event be prepared to retain such data for a reasonable time after publication.

- **Originality and plagiarism**

The authors should ensure that they have written entirely original works, and if the authors have used the work and/or words of others, that this has been appropriately cited or quoted. Plagiarism takes many forms, from 'passing off' another's paper as the author's own paper, to copying or paraphrasing substantial parts of another's paper (without attribution), to claiming results from research conducted by others. Plagiarism in all its forms constitutes unethical publishing behavior and is unacceptable.

- **Multiple, redundant or concurrent publication**

An author should not in general publish manuscripts describing essentially the same research in more than one journal or primary publication. Submitting the same manuscript to more than one journal concurrently constitutes unethical publishing behavior and is unacceptable.

In general, an author should not submit for consideration in another journal a previously published paper.

- **Acknowledgement of sources**

Proper acknowledgment of the work of others must always be given. Authors should cite publications that have been influential in determining the nature of the reported work. Information obtained privately, as in conversation, correspondence, or discussion with third parties, must not be used or reported without explicit, written permission from the source. Information obtained in the course of confidential services, such as refereeing manuscripts or grant applications, must not be used without the explicit written permission of the author of the work involved in these services.

- **Authorship of the paper**

Authorship should be limited to those who have made a significant contribution to the conception, design, execution, or interpretation of the reported study. All those who have made significant contributions should be listed as co-authors. Where there are others who have participated in certain substantive aspects of the research project, they should be acknowledged or listed as contributors. The corresponding author should ensure that all co-authors have seen and approved the final version of the paper and have agreed to its submission for publication.

- **Hazards and human or animal subjects**

If the work involves chemicals, procedures or equipment that have any unusual hazards inherent in their use, the author must clearly identify these in the manuscript. If the work involves the use of animal or human subjects, the author should ensure that the manuscript contains a statement that all procedures were performed in compliance with relevant laws and institutional guidelines and that the appropriate institutional committee(s) has approved them. Authors should include a statement in the manuscript that informed consent was obtained for experimentation with human subjects. The privacy rights of human subjects must always be observed.

- **Disclosure and conflicts of interest**

All authors should disclose in their manuscript any financial or other substantive conflict of interest that might be construed to influence the results or interpretation of their manuscript. All sources of financial support for the project should be disclosed.

Examples of potential conflicts of interest which should be disclosed include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding. Potential conflicts of interest should be disclosed at the earliest stage possible.

- **Fundamental errors in published works**

When an author discovers a significant error or inaccuracy in his/her own published work, it is the author's obligation to promptly notify the journal editor or publisher and cooperate with the editor to retract or correct the paper. If the editor or the publisher learns from a third party that a published work contains a significant error, it is the obligation of the author to promptly retract or correct the paper or provide evidence to the editor of the correctness of the original paper.

Duties of editors

- **Publication decisions**

The editor of a peer-reviewed journal is responsible for deciding which of the articles submitted to the journal should be published, often working in conjunction with the relevant society (for society-owned or sponsored journals). The validation of the work in question and its importance to researchers and readers must always drive such decisions. The editor may be guided by the policies of the journal's editorial board and constrained by such legal requirements as shall then be in force regarding libel, copyright infringement and plagiarism. The editor may confer with other editors or reviewers (or society officers) in making this decision.

- **Fair play**

An editor should evaluate manuscripts for their intellectual content without regard to race, gender, sexual orientation, religious belief, ethnic origin, citizenship, or political philosophy of the authors.

- **Confidentiality**

The editor and any editorial staff must not disclose any information about a submitted manuscript to anyone other than the corresponding author, reviewers, potential reviewers, other editorial advisers, and the publisher, as appropriate.

- **Disclosure and conflicts of interest**

Unpublished materials disclosed in a submitted manuscript must not be used in an editor's own research without the express written consent of the author.

Privileged information or ideas obtained through peer review must be kept confidential and not used for personal advantage.

Editors should recuse themselves (i.e. should ask a co-editor, associate editor or other member of the editorial board instead to review and consider) from considering manuscripts in which they have conflicts of interest resulting from competitive, collaborative, or other relationships or connections with any of the authors, companies, or (possibly) institutions connected to the papers. Editors should require all contributors to disclose relevant competing interests and publish corrections if competing interests are revealed after publication. If needed, other appropriate action should be taken, such as the publication of a retraction or expression of concern.

It should be ensured that the peer-review process for sponsored supplements is the same as that used for the main journal. Items in sponsored supplements should be accepted solely on the basis of academic merit and interest to readers and not be influenced by commercial considerations. Non-peer reviewed sections of their journal should be clearly identified.

- **Involvement and cooperation in investigations**

An editor should take reasonably responsive measures when ethical complaints have been presented concerning a submitted manuscript or published paper, in conjunction with the publisher (or society). Such measures will generally include contacting the author of the manuscript or paper and giving due consideration of the respective complaint or claims made, but may also include further communications to the relevant institutions and research bodies, and if the complaint is upheld, the publication of a correction, retraction, expression of concern, or other note, as may be relevant. Every reported act of unethical publishing behavior must be looked into, even if it is discovered years after publication. For editors who require details on recommended actions for particular types of ethics complaints, please consult our Publishing Ethics Resource Kit (PERK)

Duties of reviewers

- **Contribution to editorial decisions**

Peer review assists the editor in making editorial decisions and through the editorial communications with the author may also assist the author in improving the paper. Peer review is an essential component of formal scholarly communication, and lies at the heart of the scientific method. Acta Medica Medianae shares the view of many that all scholars who wish to contribute to publications have an obligation to do a fair share of reviewing.

- **Promptness**

Any selected referee who feels unqualified to review the research reported in a manuscript or knows that its prompt review will be impossible should notify the editor and excuse himself from the review process.

- **Confidentiality**

Any manuscripts received for review must be treated as confidential documents. They must not be shown to or discussed with others except as authorized by the editor.

- **Standards of objectivity**

Reviews should be conducted objectively. Personal criticism of the author is inappropriate. Referees should express their views clearly with supporting arguments.

- **Acknowledgement of sources**

Reviewers should identify relevant published work that has not been cited by the authors. Any statement that an observation, derivation, or argument had been previously reported should be accompanied by the relevant citation. A reviewer should also call to the editor's attention any substantial similarity or overlap between the manuscript under consideration and any other published paper of which they have personal knowledge.

- **Disclosure and conflict of interest**

Unpublished materials disclosed in a submitted manuscript must not be used in a reviewer's own research without the express written consent of the author. Privileged information or ideas obtained through peer review must be kept confidential and not used for personal advantage. Reviewers should not consider manuscripts in which they have conflicts of interest resulting from competitive, collaborative, or other relationships or connections with any of the authors, companies, or institutions connected to the papers.

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). 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: