

Good Scientific Practice

Ethics in Science and Research

Guidelines developed by the Medical University of Vienna

Defined by the study group, Arbeitskreis Wissenschaftsethik der Arbeitsgruppe Strategische Planung der Medizinischen Universität Wien, in the years 1999 to 2001

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Adopted by the Fakultätskollegium der medizinischen Fakultät as from 12 October 2001.

All person-related references are applicable equally to male and female individuals.

Introduction

The Medical Faculty of the University of Vienna adheres to the highest values and standards of scientific ethics, which include truth, accuracy, and honesty in disseminated information and publications, reliability, free expression of opinion on scientific questions, and the exchange of ideas. The following guidelines have been drawn up to preserve and uphold these values in a complex research environment and to give each individual staff member a better understanding of our standards and mission.

Mission Statement

1. Adopt generally applicable and mandatory guidelines to be followed by scientific members of the Medical University of Vienna.
2. Determine evaluation mechanisms for quality management.
3. Define the process in cases of suspected scientific misconduct.

Existing legal guidelines take precedence over what is regulated by this text.

Implementation

The guidelines are mandatory for all members involved in research activities on the Medical Faculty of the University of Vienna. All members shall make a written commitment signifying their acceptance of these guidelines.

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1. Guidelines

1.1 General

- 1.1.1 The guidelines for strictly ethical behaviour in science shall apply to any scientific work, its conduct, documentation, and publication.
- 1.1.2 The Medical University of Vienna welcomes innovative scientific research of high quality through good teamwork. Project-oriented or target-oriented teams are, to the extent necessary, multi-disciplinary in order to benefit from the intellectual expertise and the material resources supplied by various clinics, hospitals, departments, and institutes.
- 1.1.3 Teamwork draws on available expertise and also serves to orient and integrate new generation of academics. Responsibility for orientation or education of the new generation of academics shall preferably be undertaken by experienced scientists. For each project, a responsible investigator or project leader shall be named. He or she shall be responsible for the integrity of the scientific research project appointed.
- 1.1.4 Within the framework of research, the investigator or project leader actively guides and mentors the next generation of academics and is ultimately responsible for providing directions for projects, which academic and non-academic personnel follow and carry out. The investigator or project leader is also responsible for the experimental design, the acquisition of information, the data analysis and its documentation, the selection of statistical analytical techniques, the writing of a manuscript and its publication, and for compliance with the guidelines that define strictly ethical behaviour.
- 1.1.5 Freedom of research is a general core principle; however, the use of institutional resources (personnel, instruments, devices, funds) requires prior approval from the head of the participating body (institute, clinic, hospital, department).

1.2 Scientific Design: Outlining the Table of Contents of a Study Plan

1.2.1 General

Each defined scientific project shall be documented in a study plan. The study plan shall be designed before commencing the study and be made available at the institute, the clinic, the hospital, the clinical department (ideally at a documentation centre for studies), and to all members involved in the study. Papers shall be complete before they are submitted to the Ethical Review Board for authorization and the copyright of the idea for a scientific project should be documented.

1.2.2 Table of contents: a complete study plan shall contain

1.2.2.1 Synopsis

- Cover page (dated and signed)
- Summary
- Table of contents
- List of members of the project team
- Index of authors (ideally listed in order of importance)

1.2.2.2 Scientific and Medical Section

- Introduction
- Object and hypotheses of study
- Preliminary information/pilot studies
- Study design or test record
- Basic principles and discussion of study design
- Details of sample test
- Number of patients or healthy volunteers (for clinical studies), number of experimental animals, number of in vitro observations
- Inclusion and exclusion criteria (for clinical studies)
- Treatment, intervention
- Representation of variable outcomes
- Methods of evaluation
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1.3 Guidelines for Review by the Ethical Review Board

1.3.1 General

The Ethical Review Board of the Medical Faculty of the University of Vienna and the Vienna General Hospital (Ethik-Kommission der Medizinischen Universität Wien und des Allgemeinen Krankenhauses AKH der Stadt Wien) was established according to the relevant provisions of the Declaration of Helsinki, the EC GCP Note for Guidance, the Austrian Pharmaceuticals Act (Arzneimittelgesetz), the Austrian Act on Medical Devices (Medizinproduktegesetz), the Vienna Hospital Act (Wiener Krankenanstaltengesetz), and the Austrian Federal Hospital Act (Bundeskrankenanstaltengesetz). The Board reviews clinical research projects conducted at the Medical Faculty of the University of Vienna and the Vienna General Hospital.

1.3.2 Research projects involving human subjects to be submitted to the Ethical Review Board

According to the Austrian laws at present in force and international guidelines, all research projects involving human subjects shall, as a general principle, be submitted to an Ethical Review Board. This includes all procedures or tests on patients or healthy volunteers for knowledge purposes only, which are not designed to treat an individual. Also included, without differentiation, are new drugs or medical devices or any other research protocol.

1.3.3 Research projects involving human subjects *not* to be submitted to the Ethical Review Board

Medical actions taken exclusively in the interest of the individual patient are not required to be submitted to the Ethical Review Board. That is to say that the object of the procedure is not to gain knowledge and/or to use the data for study reasons. Such medical actions shall not be characterized as research projects and therefore, require no ethical review, even if the treatment of the patient involves, for example, the administration of a drug that is not registered in Austria (see §12 of the Austrian Pharmaceuticals Act which states that a drug can be used without being registered, provided that a practitioner qualified in the Austrian health sector on a self-employed basis states that the drug is necessary to protect the life of an individual and that no other registered drug is available:

Arzneispezialitäten bedürfen keiner Zulassung, wenn 2. ein zur selbständigen Berufsausübung im Inland berechtigter Arzt ... bescheinigt, daß die Arzneispezialität zur Abwehr einer Lebensbedrohung oder schweren gesundheitlichen Schädigung dringend benötigt wird und dieser Erfolg mit einer zugelassenen und verfügbaren Arzneispezialität nach dem Stand der Wissenschaft voraussichtlich nicht erzielt werden kann ...).

A therapy that has no research purpose shall not be reviewed by an Ethical Review Board, but is the sole responsibility of the attending physician.

Post-marketing observational studies of already authorized drugs shall not be submitted to the Ethical Review Board.

1.3.4 Opinion of the Ethical Review Board on clinical research projects of inadequate scientific quality (extract from the decision of 12 April 1999)

The Ethical Review Board recognizes that clinical research projects involving human subjects are essential to the development of medical science and society.

In line with the Declaration of Helsinki, the Ethical Review Board approves studies involving human subjects only if they are designed to discover comprehensible and objective answers to a clearly formulated research question.

The Ethical Review Board therefore considers it its legal duty both to review the ethical issues in each proposed study (in particular with regard to risk to the patient) and to evaluate its medical scientific quality. The Ethical Review Board is of the opinion that poor science is, ipso facto, unethical. Incorrect information in a scientific study causes more damage to the progress of medical scientific investigation and the care of patients than a study that has never been performed; this applies in particular to disputed therapies of special economic interest. The Ethical Review Board does not approve research projects if a precise conclusion of the results cannot reasonably be expected, even if the risk to the patient is negligible; in, for example, uncontrolled or open studies, where, respectively, random controls and double-blind studies would be preferable.

Accurate collection, maintenance, and statistical analysis of information are a prerequisite to gain knowledge. The Ethical Review Board therefore does not approve research projects in which these standards are not met.

The Ethical Review Board is aware of the fact that some clinical departments, clinics or institutes may have difficulties in conducting research projects with a sufficient number of patients and therefore encourages inter-institutional and multi-centre research.

1.4 Guidelines for Projects Involving Animal Experiments

1.4.1 Legislation

In Austria, live animal experiments are regulated by the Animal Experiments Act (Tierversuchsgesetz TGV, Federal Law Gazette on live animal experiments No. 501/1989 in the 27 September 1989 version, last amended in Federal Law Gazette I No. 169/1999). Furthermore, two regulations implementing Directive 86/609/EEC were made: the Regulation on animals used for experimental purposes (Tierversuchsordnung, 198th regulation of 30 June 2000, CELEX No. 386L0609) by the Federal Ministry of Education, Science and Culture BMfBWK defines the keeping, accommodation, care, breeding and supplying establishments, and individual identification mark of experimental animals; the Regulation on statistics on animals used for experimental purposes (199th regulation of 30 June 2000, CELEX No. 386L0609) defines the statistical records of experimental animals.

Animal experiments involving genetic modification or biological agents are, in addition to the aforementioned regulations, subject to the Austrian Gene Technology Act (Gentechnikgesetz GTG, Federal Law Gazette of 12 July 1994) and the Ordinance on Biological Agents (Verordnung über biologische Arbeitsstoffe VbA of 23 July 1998). The Animal Infectious Disease Act (Tierseuchengesetz, Federal Law Gazette No. 177/1909, last amended in Federal Law Gazette I No. 66/1988) and the Ordinance on the Disposal of TSE-infected Animal Tissue (TSE-Tiermaterial-Beseitigungsverordnung, 330th Ordinance of 12 October 2000, CELEX No. 300D0418) shall apply generally.

In addition, reference shall be made to the existing EU law outlined in Directive 86/609/EEC on the use of experimental animals (Gazette No. L358 of 18 December 1986) and in the „European Convention for the protection of vertebrate animals used for experimental and other scientific purposes“ (ETS No. 123).

1.4.2 Current Procedure at the Medical Faculty of Vienna

According to the Animal Experiments Act 1998 (version 1999), all animal experiments undertaken at universities require the authorization (or notification) of the competent Federal Minister of Education, Science, and Culture; the application or notification shall be done through official channels and the competent dean.

In 1987, the Medical Faculty of Vienna, to evaluate and offer advice about the scientific, ethical, and legal issues involving the use of faculty resources, introduced a committee to assess research projects involving animal experiments, in line with the University Organization Act (Universitätsgesetz UOG). With the implementation of UOG 93, the aforementioned Faculty Committee had to be dissolved and replaced by a committee acting in an advisory role to the dean. The committee itself shall not be competent to take decisions and shall therefore transmit its informed and ethical reviews of the project applications to the dean. The committee shall remain a joint body (6:3:3:1) and shall consist primarily of members who are technically qualified in their field.

1.4.3 Ethical Guidelines

The position that poor science is, *ipso facto*, unethical, shall apply; thus, the research projects involving animal experiments, performed under the auspices of the University of Vienna, as well as with clinical studies, shall be subject to good scientific practice.

1.4.3.1 Preamble

All persons and institutions involved in animal experiments must comply with the recommendations published by the World Health Organization (WHO) and with the regulations of the Austrian Animal Experiments Act of 1974, the Animal Protection Act of the respective Federal State, and the following ethical considerations. In addition, all other legal requirements relating to, for example, purchase, trade, transport, and import of animals, and the international rules on biodiversity, shall be followed: it is the project leader's responsibility to ensure that these regulations are adhered to when undertaking animal experiments.

1.4.3.2 Ethical Considerations

- 1.4.3.2.1 In general, respect for life shall be a first principle for all living beings; the human being is particularly obligated to care for and protect all animals that are part of his or her life.
- 1.4.3.2.2 The question of whether animal life may be used for human purposes by human beings requires ethical consideration of the principle of respect for life and must be a balanced consideration of the respect for human life and the respect for animal life.
- 1.4.3.2.3 A form of use of animal life is the examination of animals – animal experiments – that help to understand biological processes and their influences. The results serve the protection and preservation of human life and animal life, allow the prevention of diseases and the healing or relief of pain, and contribute to the protection and improvement of the environment.
- 1.4.3.2.4 The preservation and protection of human life is an obligation that includes the need for animal experiments in basic and applied research.

1.4.3.3 Admissibility of Animal Experiments

- 1.4.3.3.1 It is the duty of the scientist to justify the necessity for and adequacy of a proposed animal experiment and to weigh the value of the study against the distress of the experimental animal.
- 1.4.3.3.2 Animal experiments shall comply with the principles of natural scientific research, the matter and the procedure chosen shall be justifiable, and state-of-the-art science shall be taken into account.
- 1.4.3.3.3 An animal experiment shall not be allowed if another convincing and acknowledged method of obtaining the knowledge sought is available. The professionally skilled conducting of animal experiments may only be repeated upon substantiated justification. Control experiments shall be admissible if standard results are needed to evaluate the test results.

1.4.3.4 Conducting Animal Experiments

- 1.4.3.4.1 The respect for life ethical approach requires us to use the minimum possible number of experimental animals and limiting their suffering to the essential minimum to achieve the maximum gain in knowledge. This requires a detailed research design, preparation, and professional conduct. All persons involved in animal experiments are obligated to support, in a responsible manner, the welfare of experimental animals and to minimize any possible suffering of the experimental animal. Only persons with the required expertise will be entrusted with the conduct of animal experiments and the care of animals.
- 1.4.3.4.2 The living conditions of experimental animals shall be appropriate to their species; the animals shall be taken care of and carefully familiarized with the test conditions.
- 1.4.3.4.3 The experimental animal shall be conscious and mobile, when possible, because this is the only way to determine whether the animal is in distress so that appropriate countermeasures can be taken. Only if no other technique is available is immobilization ethically reasonable.
- 1.4.3.4.4 Intervention or manipulation that is likely to cause pain in the animals shall be carried out under general or local anaesthesia, provided such action is compatible with the object of the experiment. If pain, suffering, distress, or fear are inevitable concomitants of an experiment, their duration and intensity shall be limited to a level that is necessary. Experimentation that leads to permanent damage or repeated intervention and manipulation requires special diligence and attention by the persons involved. If an animal is seriously injured in animal experiments and if a precise conclusion or use of the results cannot be reasonably expected, the animals shall be immediately killed by a humane method.
- 1.4.3.4.5 The acquisition of animals for use in experiments shall be clearly verifiable and controllable. Animals of unknown origin shall not be used in experiments.

1.4.3.5 Duties and Responsibilities

- 1.4.3.5.1 In general, all persons who take part in animal experiments bear the ethical and scientific responsibility for their actions. Furthermore, justification, planning, and conduct of animal experiments are the legal responsibilities of the investigator.
- 1.4.3.5.2 The scientist is obligated to avoid unnecessary animal experiments, and shall consider the international knowledge base with regard to animal experimentation, and, to the extent possible and as necessary, shall promote knowledge exchange and scientific cooperation. Furthermore, he or she must always critically evaluate the applicability of animal experiments and their results in accordance with the latest developments.
- 1.4.3.5.3 Scientists are encouraged to use the knowledge about behavioural research and experimental animal science as well as new methods in measurement and laboratory technology to further develop the research models in a way that limits the suffering of the experimental animal to the essential minimum. Furthermore, it is the task of the scientist to develop methods to reduce the number of animals used for experiments or to avoid animal experiments (alternative methods).
- 1.4.3.5.4 It is the duty of the scientists to submit their justifications of animal experiments for regular critical assessment within the framework of legal requirements to protect human health, animal health, and the environment, and, where appropriate, to support the update of the legal requirements.

1.5 Guidelines for Review by the Gene Technology Committee

1.5.1 General

In Austria, dealings with genetically modified organisms (GMM), the application of gene therapy, and human gene analysis are regulated by the Gene Technology Act (Gentechnik Gesetz GTG).

1.5.1.1 Preconditions for Working with GMM

Dealings using GMM includes the production, use, reproduction, storage, and in-house transport of GMM.

Dealings using GMM comprise one cell or multi-cell organisms with a genetic material that has been altered in a way that does not occur naturally by mating, recombination, or other traditional breeding techniques. Procedures whereby genetic material is altered include, for example, DNS recombination techniques using vector systems, direct introduction of genetic information into an organism through macroinjection, microinjection, microencapsulation, electroporation, or the use of microprojectiles, cell fusion, and hybridization procedures.

1.5.1.2 Compliance with Obligation to Notify

All dealings with GMM shall be notified and approved. The GTG distinguishes four risk groups (1, 2, 3, 4) and small or large scale designations (Type A and B) for each risk group. Depending on the risk group of the organisms, the vectors, and the scale, the relevant notification or approval is necessary.

1.5.1.2.1 According to §19 GTG, notifiable dealings are:

- First use of GMM in a risk group 1 classified installation;
- First use of GMM in a risk group 2 classified installation;
- Subsequent use of GMM in a risk group 2 classified installation;
- First use of transgenic plants or animals in an installation;
- First use of transgenic plants or animals in an installation, with the exception of risk group 1; and
- Subsequent use of transgenic vertebrates in a risk group 1 classified installation.

The user shall notify, in writing, the competent authority before commencing such use and include the requisite papers (competent authority: Austrian Federal Ministry of Education, Science, and Culture).

1.5.1.2.2 According to §19 GTG, the following dealings must be approved:

- First or subsequent use of GMM in a risk group 3 classified installation; and
- First or subsequent use of GMM in a risk group 4 classified installation.

Prior to commencing such use, the user shall apply to the competent authority for an approval and include the necessary papers (competent authority: Austrian Federal Ministry of Education, Science, and Culture). A hearing shall be held for applications to approve a first or subsequent risk group 3 large-scale use, first risk group 4 use, and subsequent risk group 4 large-scale use.

1.5.1.3 Official Procedures

The competent authority shall review the notification or application if it is in line with the regulations of the Gene Technology Act, if the submitted papers and information are accurate and complete, if, in particular, the risk group is determined correctly, and if the safety measures, including waste disposal and emergency measures, are appropriate.

First risk group 1 and 2 uses (§19 paras 1 and 2) may proceed 45 days after submission of the notification in the absence of any indication contrary to §23 para 2 or 3 from the competent authority. First risk group 1 use may proceed immediately after submission of the notification if the protocol approval form of the Biological Safety Committee (§16 para 4 subpara 4) is included with the papers. Subsequent use of GMM or transgenic animals or plants may proceed without separate notification. Subsequent use of GMM in risk group 2 may proceed immediately after submission of the notification if the protocol approval form of the Biological Safety Committee (§16 para 4 subpara 4) is included with the papers.

All other notifiable dealings and dealings requiring approval are regulated by GTG §24 paras 4 to 6. Dealings requiring approval may not proceed except pursuant to an approval by the competent

authority. Dealings with transgenic animals are regulated in GTG §26, taking into account that the regulations of the Animal Experiments Act shall apply to dealings with transgenic animals in risk group 1.

1.5.1.4 Biological Safety Committee (GTG §16)

1.5.1.4.1 For each installation, the user shall appoint a representative for biosafety and at least one alternate representative and register them at the local fire brigade (in Vienna: Fire station Am Hof) (GTG §16). University institutes may dispense with the appointment of a representative for biosafety if there is another competent individual at another institute of the same university available to carry out the task. The representative for biosafety shall regularly monitor the compliance with the safety measures and shall immediately report safety-related problems to the user.

1.5.1.4.2 For all dealings with GMM classified as risk group 2, 3, or 4, and for each project, a project leader with sufficient practical experience in dealing with GMM, and with adequate knowledge in securing the safety, shall be appointed.

1.5.1.4.3 The user shall replace, without delay, members who resign from the Biological Safety Committee.

1.5.1.5 Safety Measures Compliance

According to GTG §10, dealings with GMM may be undertaken only if state-of-the-art scientific and technical measures to guarantee protection (§1 para 1) from risks related to GMM are complied with. Accident and emergency regulations shall be subject to GTG §11.

1.5.1.6 Obligation to Maintain Records

A record of all dealings with GMM shall be maintained. The record for risk groups 1 and 2 Type A dealings may be in the form of laboratory journals.

1.5.2 Gene Analysis and Gene Therapy

1.5.2.1 Manipulating Genetic Material

Modifying the germ line genetic identity of human beings shall be forbidden (§9 para 2 of the Austrian Reproductive Medicine Act).

1.5.2.2 Gene Analysis

1.5.2.2.1 Human gene analysis for medical purposes shall be subject to GTG §65. Predisposition analysis, as a method to detect diseases in non-coded samples, requires a laboratory authorized to conduct gene analysis.

1.5.2.2.2 Human gene analysis for scientific purposes may only be conducted with either the express written agreement of the individual sample donor or with disidentified samples.

1.5.2.2.3 Scientific gene analysis shall be submitted to the Ethical Review Board on a separate application form. (A sample application form is in development, and will be shortly made available by the Ethical Review Board.)

1.5.2.3 Gene Therapy

(A manual on how to apply for an approval authorizing gene therapy studies has been drawn up by the Federal Ministry of Social Security and Generations.) (see Reference list)

1.6 Information

1.6.1 General

- 1.6.1.1 The careful collection, processing, and maintaining of health research information is of the utmost importance for the progress of medical scientific investigation. Scientists shall have access to the original information in order to be able to answer questions that arise – including questions about information validity.
- 1.6.1.2 The Medical University expects that information will be collected, stored, disseminated, and validated by its members in accordance with the existing laws. The Medical University of Vienna hereby recommends the following procedure:

1.6.2 Collecting Information

- 1.6.2.1 For studies, the criteria for collecting information shall be determined in the relevant syllabus.
- 1.6.2.2 Tools for the collection of information (such as case report forms) shall be provided (to the extent possible in a standardized form). Such tools shall contain the original information in a clearly readable form.
- 1.6.2.3 Information collected in clinical research shall be, to the extent possible, extracted from the medical report or documented in it.

1.6.3 Storing and Maintaining Information

- 1.6.3.1 Syllabi, amendments, additions, original information, and reports shall be kept for a minimum of 10 years at the institution responsible for the research project (clinical department, clinic/institute). The information about the methods used to collect information and control its quality shall be kept in the same way.
- 1.6.3.2 Within the institution, a proper system shall be established to preserve the information in archives and to identify how the information is used and who it is used by.
- 1.6.3.3 Corrections, calculations, and statistical analyses of information shall be recorded in a way that allows the identification of the original information used in publications.

1.6.4 Conditions for the Use of Information

- 1.6.4.1 The Medical University of Vienna expects that the right to scientifically and economically use information, collected and processed in a research endeavor, shall belong to the institution where the project is undertaken, subject to special arrangements.
- 1.6.4.2 The rights that authors (original authors, investigator, project leader) can rightfully claim according to the copyright law, particularly the right to have his or her name as author or inventor on the work and the right to equitable remuneration, as far as official inventions are concerned, remain hereby unaffected.
- 1.6.4.3 Whenever the primary rights to the use of information contractually belong to another person, the institution undertaking the research project must be given those rights to the use of information that are required to meet record-keeping obligations.
- 1.6.4.4 Nonidentified information and its use in joint research projects, such as meta analyses, shall be provided in agreement with the institutions involved and with the person(s) responsible for the research project.
- 1.6.4.5 The person responsible for the conduct of the research project shall be permitted to copy information, even if he or she leaves the institution where the research project is conducted. The institution commissioning the research project shall receive advance notice of such action.

1.7 Publication and Authorship

1.7.1 General

1.7.1.1 Publication and clear definition of authorship are of paramount importance to any scientific project.

1.7.1.2 The Faculty expects that its members comply with the legal requirements about the protection of copyright in relation to the publication of scientific work.

The Medical University hereby recommends the following procedure to guarantee adherence to copyright requirements, in accordance with international scientific practice.

1.7.2 Copyright

1.7.2.1 The copyright for scientific publications shall be respected not only with regard to the original publication but also with regard to syllabi, documents submitted to the Ethical Review Board, grant submissions, and published abstracts.

1.7.2.2 The Medical University of Vienna regards the design or publication of a syllabus, in an appropriate manner (at least its publicly accessibility), as the first step in copyright documentation.

1.7.2.3 To avoid uncertainty about copyright, a definition, to the extent possible and before the research project commences, of the tasks of each member of the project team is recommended, as well as ensuring that the definitions are, at all times, up to date.

1.7.3 Authorship

1.7.3.1 General

Credit as the author of a scientific work is bound to his or her active contributing in an intellectual, practical, or procedural manner.

1.7.3.2 Authorship Credit

Authorship requires at least three of the conditions outlined in 1.7.3.2.1 to 1.7.3.2.5.

1.7.3.2.1 Initiative for a scientific work with a substantial contribution to concept and study design.

1.7.3.2.2 Collection, processing, interpretation and formalization of the information, if well-known and established methods are not routinely used.

1.7.3.2.3 Drafting and/or critical revision of the content.

1.7.3.2.4 Final approval of the version to be published.

1.7.3.2.5 Guiding and monitoring younger academic and non-academic members in collecting the information.

1.7.3.3 Right to Authorship

- 1.7.3.3.1 The author who meets the conditions outlined in the authorship section (1.7.3) has the right to be credited for the work, based on his or her substantial contribution to the project.
- 1.7.3.3.2 Administrative guidance of a scientific field, patient recruitment, and collection and compilation of information, *per se*, do not justify authorship credit. Authorship credit solely for participation in the assignment of patients or credit as honorary authorship shall be prohibited.
- 1.7.3.3.3 Provision of commonly available or published clones or techniques, as well as reading the manuscript, do not justify authorship credit, but reference shall be given in the Acknowledgment section.

1.7.3.4 Listing the Authors

1.7.3.4.1 Original Author

The member with the most procedural, intellectual, or conceptual contribution to the project deserves the right to first-author credit.

It is the duty of the original author to write at least a preliminary manuscript and to provide illustrations. The author renounces his or her right to original authorship credit if he or she does not finish the manuscript within an adequate timeframe.

Footnotes to make clear that the first author and second author contributed equally to the collection of information should be used only in exceptional cases.

1.7.3.4.2 Authorship of Investigator or Project Leader

Authorship of the investigator or project leader can be, according to international practices, documented as a second or last authorship. This list acknowledges how the person contributed ideally, conceptually, and infrastructurally (training and guidance of academic and non-academic members, access to laboratories and instruments, grant approvals and other support, forming a work group of experts in various fields). The person who contributed most significantly to the work/publication according to paragraphs 1.7.3.2.1 to 1.7.3.2.5 should be given the right to this second or last authorship.

1.7.3.4.3 Corresponding Author

The corresponding author is the author who exchanges correspondence with the persons responsible for the printing of a publication. In principle, the original author or investigator (unless a diploma or dissertation candidate) shall be listed as corresponding author.

1.7.3.4.4 Co-Authorship

If more than one institution contributes to a work, the most important contributing members, as well as their position in the authorship list, should be discussed, preferably as early as the planning stages of the project.

1.7.4 Publishing

- 1.7.4.1 The guidelines for scientific publishing shall apply to any publication in oral or written form. This includes presentations, scientific abstracts, original works, case reports, letters to the editor, reviews, book chapters, and any other publishing of scientific character by members or staff members of the Medical University of Vienna.
- 1.7.4.2 An original scientific work is characterized by its innovative approach to either discover answers to a clearly formulated question or to prove a hypothesis based on the principles of determining the truth. This demands a clearly defined research plan, exact definition of the applied method to ensure that results can be reproduced, accurate and statistical analysis of the collected information, critical discussion of the results on the basis of literature review, and sound conclusions.
- 1.7.4.3 It is expected that complete and comprehensibly described scientific works designed to answer a clearly formulated question will be published.
- 1.7.4.4 Publishing temporary and incomplete results as well as fragmentary information shall be prohibited.
- 1.7.4.5 The publishing purely descriptive reports and case studies shall be carefully considered due to their limited significance.
- 1.7.4.6 No duplication of any kind, no alternate authorship in published summaries, and no alternate authorship in the subsequently written original work shall be permitted.
- 1.7.4.7 Recommendations concerning authorship and scientific work (see relevant paragraphs), as well as the ethical guidelines of the Declaration of Helsinki and those for animal experiments, shall apply when publishing.

2. Scientific Misconduct (Fraud)

2.1.1 Definitions

2.1.2 According to internationally accepted standards (US Office of Research Integrity), scientific misconduct is defined as follows:

Fabrication of information;

Falsification and manipulation of information;

Elimination of information;

Plagiarism; and

All other practices that deviate from accepted standards of design, conduct, or publication of a scientific work (such as duplicate and multiple publication, violation of clearly defined rules of authorship, forgery of signature, or intention to cover scientific fraud).

2.1.3 Fabrication and manipulation of information means the fabricated, that is to say false, use or publication of information in scientific experiments or scientific studies.

2.1.4 Falsification and manipulation of information means corruption of information, its distorted selection, and/or incorrect analysis.

2.1.5 Elimination of information means unfounded omitting of information acquired in experiments or clinical studies (often for the purpose of glossing over results).

2.1.6 Plagiarism is defined as:

The reproduction of words or copying of the text passages of other writers, without citing the original author by name and without using inverted commas;

Incomplete citation of sources of written text passages that are based on or derive significantly from the ideas of other authors;

Appropriation and use of thoughts, ideas, text passages, publications, techniques, and information of other scientists as one's own without proper citation.

2.1.7 Duplication or multiple publication means the publication of information in various works and/or journals without proper citation and explicit reference to the primary publication medium.

3. Evaluation

3.1. General

- 3.1.1 Ensuring compliance with the guidelines for scientific ethics requires concrete measures, in accordance with the principles of quality maintenance and quality management. This includes, in particular, the evaluation process.
- 3.1.2 Scientific evaluation is based on two components: the obligation of the scientists of the Medical University of Vienna to deliver knowledge, and the obligation of the University to collect knowledge.

3.2 Evaluation Measures

- 3.2.1 Each person who conducts research at the Medical University of Vienna is obligated to make the acquired information (raw data, database, statistical analyses) available whenever required to do so by a nominated person or institution (see below). Collected information shall, therefore, be stored and available for inspection at any time, in agreement with the responsible institution (see Storing Information). The information shall be kept available for a period of 10 years.
- 3.2.2 The following evaluation measures have been established:
 - 3.2.2.1 Inspection of original scientific information and protocols by experts within the framework of the selection or recruitment procedures.
 - 3.2.2.2 Inspection of the original information and protocols of the habilitation candidate by members of the Habilitation Committee, represented by the chairperson.
 - 3.2.2.3 Random inspection of randomly selected scientists and their original information and protocols (within the framework of an audit) by persons nominated by the Medical University of Vienna. Scientific experts, primarily from outside the Medical University of Vienna, hereby shall be obligated or encouraged to participate as reviewers.