

Standards of Good Scientific Practice and Ombuds Committee at the Medical University of Graz

Purpose and scope of this document

Integrity towards oneself and others is the fundamental principle and premise of all scientific work. It is prerequisite to producing valid and high-quality research results, and it provides the basis for society's trust in science and technology. In all scientific fields, therefore, research activities are subject to certain sets of general and discipline-specific regulations, ranging from ethical principles to detailed legal requirements (such as legal requirements regarding genetic engineering, animal experiments, clinical trials, intellectual property rights, human rights conventions, data protection, management of finances, administrative procedures, etc).

The purpose of this document is:

- to define the standards of good scientific practice which all researchers of the Medical University of Graz are expected to meet
- to have researchers commit themselves to these standards of good scientific practice by signing the respective declaration of commitment (Annex 1)
- to generate awareness to prevent cases of scientific misconduct or fraud.

These standards do not replace or eclipse existing legal requirements, ethical principles or any other norms governing scientific work, but intend to ensure a high level of consciousness of and commitment to good scientific practice. Especially, these standards do not replace or interfere with the requirements of the Ethics Committee. Good Scientific Practice includes adherence to all relevant laws, in particular those that safeguard the interests of patients and test persons.

Definition and Standards of Good Scientific Practice

"Good scientific practice embraces all the procedures and practices that are necessary for planning, conducting and reporting research and scholarship within a framework of scientific integrity. By providing a common currency, good practice facilitates the vital, external processes of peer review, verification and repeatability. This enables other scientists to judge the validity of new contributions to knowledge and understanding. Standard methodologies for collecting and interpreting information also reduce the individual bias that might be introduced, perhaps unwittingly, by a scientist's personal background and values. And the audit trail created by good scientific practice provides quality assurance and a valuable buttress against scientific misconduct and fraud" (European Science Foundation Policy Briefing "Good Scientific Practice in Research and Scholarship", p.5).

Standards of good scientific practice thus span all aspects of scientific work, ranging from general work principles to principles regarding documentation, publication and authorship as well as supervising students and junior staff and the issue of cooperation and joint responsibility in research groups.

The **general principles of good scientific practice** are:

- to work *lege artis*, i.e. to carry out all research activities according to the legal requirements, ethical principles and the current state of the art in the respective field
- to document results and procedures, and to save all primary data obtained
- to review results critically
- to handle the contributions of partners, competitors and predecessors honestly

- to avoid and prevent scientific misconduct and fraud in one's own work and, as far as possible, in one's own working environment
- when cooperating within a research group, to assume joint responsibility for joint performance
- to be familiar with and to adhere to international, national, sectoral and institutional regulations governing working and training conditions (including requirements and conditions of sponsors) and to seek all necessary approvals before starting the research
- to meet the detailed principles and regulations defined in the following sections.

The **supervision of students, doctoral/PhD students and junior staff** involves:

- performing one's own scientific work in an exemplary manner,
- familiarizing students and junior staff members with the standards of good scientific practice,
- providing a research environment which enables students and junior staff to live up to the standards, and
- encouraging students and junior staff to be open for critical discussion and evaluation of their work.

The **documentation of scientific work** must meet the following criteria:

Every scientist is responsible for

- documenting his/her work in such a way that the research results can be reproduced on the basis of the information contained in the documentation,
- archiving and safekeeping his/her original materials, primary data and research documentation within his/her institution, and
- making and keeping them traceable if they are or need to be archived outside of his/her institution.

Every scientist has to document in writing enough essential information on the execution of an experiment to enable independent experts to repeat it. If experiments are based on numeric calculations, records must be detailed enough to allow others to follow and/or retrace them. Protocols, laboratory books and files or other forms of documentation have to contain continuous page numbers and have to be kept complete at all times, i.e. it is not allowed to remove individual sheets. For data which cannot be included in a laboratory book, the respective laboratory book has to contain a precise and traceable reference to the source.

Without prejudice to other legal or discipline-specific requirements, primary data and written protocols which have served as a basis for publications or theses should be stored in a secure and accessible form for at least ten years in the institution where the respective research was conducted. If original materials and/or data are stored elsewhere, there must be a traceable reference to the place where they are stored. If a scientist moves to another laboratory or institution, the data produced by him/her must remain in the laboratory/institution of origin. Exceptions to this general rule are possible but require prior written and signed agreements between the laboratories/institutions involved.

Regulations for **publications and authorship**

- Publications must describe materials, methods and results in sufficient detail to enable readers to understand the approach adopted and to follow and reproduce the test arrangement. Previous work (published by oneself or others) has to be indicated as such and quoted completely and correctly.
- Co-authors of scientific publications are jointly responsible for the contents of a manuscript. Authorship or co-authorship can only be granted to persons who have contributed substantially to the respective research. Granting "honorary authorship(s)" is inconsistent with good scientific practice. Every co-author has the right and the duty to read the full paper before publication.
- All persons designated as authors should qualify for authorship according to these conditions; and all those who qualify should be designated. Other major contributions should be documented in acknowledgements.
- When manuscripts are submitted to a publisher, affiliation and/or address for correspondence must be indicated according to the following standard: [Name of Author], [Official Name of Organisational Unit (Institute, Department etc.)], Medical University of Graz, [Address of Organisational Unit]

The Medical University of Graz adopts the International Committee of Medical Journal Editors' (ICMJE) recommendations as to criteria for authorship. According to these, authorship credit should be based on 1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3. Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship. Contributors who do not meet the criteria for authorship should be listed in an acknowledgements section (e.g. a person who provided purely technical help or writing assistance; persons who provided only general, financial or material support).

When a large, multi-center group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship defined above. When submitting a group author manuscript, the corresponding author should clearly indicate the preferred citation and should clearly identify all individual authors as well as the group name.

In order to give appropriate consideration to all contributors to a publication and to avoid conflicts about (co-)authorship, it is strongly recommended to discuss the names of (co-)authors and the order of their appearance as (co-)authors or at least the criteria governing the ultimate list and order of (co-)authorship in time, i.e. before or during the research work instead of just before submitting the manuscript to a publisher. The list of names to be included as (co-)authors and the order of authorship should be a joint decision of the co-authors. If the type and scope of the research work and the number of contributors allow it, it should also be indicated which co-author has contributed which part of the work. Ideally, (co-)authors prepare a co-author statement describing the nature and extent of each co-author's contribution. At least, (co-) authors should be prepared to explain the order in which authors are listed.

Regulations for **(peer) reviewing, evaluating** and similar activities:

- When participating in peer review processes for journals, funding bodies or other institutions, researchers are obliged to disclose relationships which might be considered to create potential conflicts of interest.
- Researchers participating in peer review processes must not use for themselves ideas or knowledge from material to be assessed by them. They must respect authors' rights by not discussing the respective work in public or appropriating their ideas before the respective manuscript has been published.

Levels of Responsibility

All individuals involved in research activities at the Medical University of Graz – irrespective of whether they are employed by the University or involved in research activities in any other way – commit themselves to the special rules and requirements governing their specific fields and to the standards of good scientific practice outlined in this document.

Thus, all researchers are obliged

- to meet the standards in their own daily work,
- by doing so, to set a good example for others, especially for students and junior staff members, and
- (if they are senior or supervising scientists) to teach and train students and junior staff members in matters of good scientific practice.

Every scientist is responsible for his/her own behaviour and actions in the context of his/her scientific work. Every leader of a research group is responsible for his/her group's compliance with legal requirements and with the principles of good scientific practice. Therefore, every leader of a research group is responsible for familiarizing the members of his/her group with the principles of good scientific practice and for providing an environment which enables them to act accordingly. Also, the leader has to make sure that all members of his/her group are willing to discuss their hypotheses, theories and scientific data and results openly in order to obtain a critical evaluation.

Scientific Misconduct and Scientific Fraud

Scientific fraud is defined as deliberate deception (or attempted deception) of the scientific community, funding bodies, decision-makers and other recipients of publicized research results, whereas scientific misconduct usually results from gross negligence and/or irresponsibility in the conduct of research. The following acts, when carried out deliberately or by negligence, are regarded as violations of good scientific practice and constitute acts of scientific misconduct or fraud:

- fabricating and falsifying data (including but not limited to tacitly selecting and eliminating unwelcome results, manipulating graphs, making wrong statements in grant and job applications)
- loss of primary data as a consequence of negligence, elimination of primary data, or removal of primary data from the laboratory/institution, if no agreement regarding this matter exists between the laboratories/institutions concerned or if, by doing so, existing legal requirements, discipline-specific standards or the regulations in this document are violated
- violating intellectual property rights (including but not limited to plagiarism and unauthorized exploitation or dissemination of someone else's approaches and/or ideas)
- unjustified acceptance of (co-)authorship
- double publication of original papers (i.e. repeated publication of the content of an original paper in another original paper (under the same or a modified title, or with the same or modified list of authors)
- excluding others from legitimate (co-)authorship or claiming others' (co-)authorship without their approval
- sabotage of research activities (including but not limited to damaging, destroying or manipulating test arrangements, equipment, documents, software, consumables etc.)
- (for senior and/or supervising scientists) neglecting the duty to teach and train students and junior staff members (research assistants/co-workers) in the principles of good scientific practice
- defamation of the principles of good scientific practice
- breach of confidence while acting as an expert, advisor, evaluator, reviewer or similar

The following acts, when carried out deliberately or by negligence, are regarded as contributing to violations of the standards of good scientific practice and result in joint responsibility for scientific misconduct or fraud:

- active and knowing involvement in the misconduct or fraud of others
- gross negligence of one's duty as a supervisor

Special Regulations concerning Research with Patients or Test Persons

- All research projects involving human subjects must be submitted to the Ethics Committee. According to § 30 Universities Act 2002 in the valid version, this includes research on drugs, medical devices, new medical methods, and applied medical research on human subjects. Also, it includes research on identifiable human material and identifiable data as well as gene analyses for scientific purposes. The submission must be made prior to the beginning of the project and in compliance with the guidelines of the Ethics Committee, the valid version of which is posted on the website of the Ethics Committee.
- Research projects may only commence after a written approval of the Ethics Committee has been issued. Applications for multicentre drug trials must be submitted to one of the Austrian Leading Ethics Committees (e.g. the Ethics Committee of the Medical University of Graz) and sent in copy to all local responsible Ethics Committees.
- No submission to the Ethics Committee is necessary when the planned measures represent solely patient care in the interest of an individual patient and no research interests are followed. This is true even when drugs are used off-label or off-license.
- The protection of the confidentiality of patient data must be guaranteed. Data must be anonymized whenever possible.

Special Regulations concerning Research involving Animals

- All research projects involving animals are subject to the Austrian Animal Experimentations Act (TVG) and must be submitted to the Austrian Committee for Animal Trials ("Tierversuchskommission"). In addition, the Ministry of Education, Science and Culture must be notified of such projects.
- When submitting a project, the researcher has to describe and explain why the respective animal experiment is necessary and appropriate to achieve the expected gain of knowledge.
- Animal experiments are not permissible if accepted alternative methods exist to reach the gain of knowledge aimed for.
- Any efforts have to be undertaken to keep the number of animal experiments, the number of animals in the experiments, and the burden for the animals at the minimum level necessary to reach the gain of knowledge aimed for.
- Clear criteria for the termination of the experiment on an individual animal have to be laid down in advance.

Special Regulations concerning Gene Research and Technology

- All research projects involving work with or use of genetically modified organisms (GMO) are subject to the Austrian Gene Technology Act (GTG) and must be submitted to the Ministry of Education, Science and Culture according to the regulations in Section II of GTG ("Working with GMOs in Closed Systems").

Gene analyses involving human subjects are subject to the Austrian Gene Technology Act (GTG), especially Section IV ("Gene Analysis and Gene Therapy involving Human Subjects"), and must be reported to the Ministry of Health and Women according to the regulations in Section IV of GTG.

Gene analyses for scientific and training purposes can only be carried out if the donor of the respective sample has explicitly given his/her consent in writing or if the sample has been anonymized. (A sample which serves scientific purposes is also considered anonymized, if it is marked without a name but with a code and if this code can only be linked to the donor of the sample in the respective institution.)

Results from gene analyses can only be passed on to third parties or published if suitable measures are taken to ensure that the donor of the sample cannot be identified, except for the possibility of identification mentioned in the previous paragraph (cp. Section IV, § 66 GTG).

- Gene therapies involving human subjects are subject to the Austrian Gene Technology Act (GTG), especially Section IV ("Gene Analysis and Gene Therapy involving Human Subjects"), and must be carried out in adherence to the conditions established therein.
- Regarding the collection of and research on human tissue samples researchers are recommended to consult the document "Biobanken fuer die Forschung: Stellungnahme" of the German National Ethics Council.

Ombuds Committee for Quality Assurance in Science

The Medical University of Graz has established an Ombuds Committee for Quality Assurance in Science ("Ombudsstelle für wissenschaftliche Qualitätssicherung"). The Ombuds Committee is an ad-hoc committee established for a trial period of 3 years beginning on 1 July 2004. The Ombuds Committee's task is to help promote good scientific practice and prevent scientific misconduct or fraud by providing respective information to researchers at the Medical University. In addition, the Ombuds Committee may act as an advisory body to those persons and bodies within the University who are entitled to investigate and to take disciplinary measures in cases of alleged scientific misconduct or fraud.

The Rectorate of the Medical University of Graz (rector and all vice-rectors) appoints the members of the Ombuds Committee. The Ombuds Committee consists of four members, who elect their own speaker/president. Its term of office is three years. The Ombuds Committee's activities are coordinated and supported by the Research Management Office of the Medical University of Graz.

Procedure for Ensuring Good Scientific Practice and for Investigating Allegations of Scientific Misconduct

Researchers active at the Medical University of Graz commit themselves to adhering to these Standards by signing the Declaration of Commitment (Annex 1).

Allegations of scientific misconduct or fraud are handled according to the procedures foreseen in the legal regulations and the University's internal regulations applying to the specific case and the employees involved.

References:

For this text, the Medical University of Graz has drawn upon and benefited from the following documents:

- "Sicherung guter wissenschaftlicher Praxis: Empfehlungen der Kommission ‚Selbstkontrolle in der Wissenschaft‘", Deutsche Forschungsgemeinschaft. Weinheim: Wiley-VCH, 1998
- "Zum Umgang mit wissenschaftlichem Fehlverhalten in den Hochschulen", Deutsche Hochschulrektorenkonferenz, 1998, <http://www.hrk.de> (8 Feb 2005)
- "Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication" (Updated Version of October 2004), International Committee of Medical Journal Editors, <http://www.icmje.org/> (8 Feb 2005)
- "Good Scientific Practice in Research and Scholarship" European Science Foundation Policy Briefing 10 (December 2000), European Science Foundation <http://www.esf.org/publications/science-policy-briefings.html> (8 Feb 2005)
- "Good scientific practice and procedures for handling misconduct and fraud in science", National Advisory Board on Research Ethics, Finland (2001) http://www.tenk.fi/en/good_scientific_practice/procedures.html (8 Feb 2005)
- "Guidelines for good scientific practice", The Danish Committees on Scientific Dishonesty (1998), <http://en.fi.dk/councils-commissions/the-danish-committees-on-scientific-dishonesty/publications> (8 Feb 2005)
- "Commission Recommendation of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (2005/251/EC), http://ec.europa.eu/eracareers/pdf/am509774CEE_EN_E4.pdf
- "Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the application of biology and medicine" (Convention on Human Rights and Biomedicine), European Treaty Series (ETS) No. 164; <http://conventions.coe.int/Treaty/en/Treaties/Word/164.doc>
- "Good Scientific Practice / Ethik in Wissenschaft und Forschung: Richtlinien der Medizinischen Universität Wien" http://www.meduniwien.ac.at/forschung/fileadmin/HP-Relaunch/drittmittel/GSP_MedUni_Wien_NEU.pdf

Links:

"Biobanken fuer die Forschung: Stellungnahme", Nationaler Ethikrat, Berlin (2004)

http://www.ethikrat.org/dateien/pdf/NER_Stellungnahme_Biobanken.pdf

Genetic Engineering:

<http://www.bmwf.gv.at/startseite/forschung/national/forschungsrecht/gentechnik/>

Data Protection: <http://www.dsk.gv.at/site/6200/default.aspx>

Animal Trials:

<http://www.bmwf.gv.at/startseite/forschung/national/forschungsrecht/tierversuche/>

Declaration of Helsinki: <http://www.wma.net/en/30publications/10policies/b3/>

Ethics Committee at the Medical University of Graz:

<http://www.medunigraz.at/ethikkommission/Graz/>

Declaration of Commitment

to the Standards of Good Scientific Practice of the Medical University of Graz

As a researcher or co-worker in the area of research, I

Title: _____

Name: _____

Institute / Clinical Department:

Status: employed by the Medical University of Graz
 not employed by the Medical University of Graz

commit myself to adhering to the Standards of Good Scientific Practice valid at the time of my research-related activities at the University.

Graz,
Date: _____

Name: _____

Signature: _____

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- Persons employed or about to be employed by the Medical University of Graz sign this Declaration together with their employment contract.
 - Persons not employed by the Medical University of Graz (e.g. students, research fellow, visiting scientists or other persons carrying out research-related activities) have to be registered with the University administration by their supervisors or hosts. The signed Declaration of Commitment has to be enclosed with the registration form.