

Medical University of Graz Guideline

on

Standards for Good Scientific Practice

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1. Purpose and scope of this document

Integrity is the fundamental principle and premise of all scientific work. It is necessary to produce valid and high-quality research results, and it is required to gain the trust of members of society in the areas of research, development and technology. In all scientific fields, therefore, research activities are subject to certain basic and discipline-specific regulations, which range from ethical principles to detailed legal provisions (e.g. regulations on genetic engineering, animal experimentation, clinical trials, intellectual property, human rights, data protection, and provisions on financial and administrative matters).

The purpose of this document is:

- to define the standards of good scientific practice, whereby compliance with these is among the official duties of all those involved in research and is thus required, and
- to contribute to raising awareness of these standards to prevent cases of scientific misconduct or fraud.

In this guideline, medicine is presented from a holistic perspective. For this reason, the terms “medicine”, “research”, and “medical research” are used in this guideline to encompass all areas of research being carried out in both clinical and non-clinical fields, including approaches from the natural sciences, nursing sciences, psychology, social sciences and other fields.

In this context, the persons involved in research include not only employees who are considered as members of scientific staff, but also - insofar as they participate in a research process - non-scientific staff (e.g. supporting staff), as well as students, KAGes employees at the LKH University Hospital, visiting researchers, post-doctoral candidates who do not have an employment relationship with the university and all other persons who participate in scientific work at the Medical University of Graz or or publish as affiliate of the Medical University of Graz.

These standards do not replace the existing legal regulations, ethical principles, or other standards that apply to scientific work. Instead, they have been developed to encourage a high level of awareness about and commitment to good scientific practice. The standards also do not replace the regulations of the Ethics Committee. Good scientific practice implies compliance with all relevant laws, and especially those that protect the interests of patients and volunteers. Violations of the standards of good scientific practice may constitute breaches of duty or other violations of legal regulations, which may have civil or criminal consequences.

2. Standards for good scientific practice

2.1 Definition and principles

“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.”¹

¹ European Science Foundation Policy Briefing “Good Scientific Practice in Research and Scholarship”, 2000, pg. 5, http://archives.esf.org/fileadmin/Public_documents/Publications/ESPB10.pdf (18 December 2023)

Standards for good scientific practice represent a **code of conduct** for all persons involved in research, based on the following four principles in accordance with the “*European Code of Conduct for Research Integrity*” created by All European Academies (ALLEA)²:

- **Reliability** in ensuring the quality of research, reflected in the design, the methodology, the analysis and the use of resources,
- **Reliability** in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair, full and unbiased way,
- **Respect** for colleagues, research participants, society, ecosystems, cultural heritage and the environment,
- **Accountability** for the research from idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts.

The general principles of good scientific practice are:

- to work *lege artis*, i.e. to conduct all research activities in accordance with the legal requirements, ethical principles and the state of the art in the respective field of work;
- to document results and procedures in a consistent, comprehensible and transparent manner and to retain or store all the primary data obtained;
- to review results critically;
- to adhere to a policy of strict honesty with regard to the contributions of partners, competitors and predecessors;
- to avoid and prevent scientific misconduct and fraud in one's own work and working environment;
- to take mutual responsibility for joint achievements when cooperating with another research group;
- to be aware of and comply with international, national, sectoral and institutional regulations that govern the working and training conditions (including conditions and regulations imposed by those providing financial support) and to obtain all necessary approvals before commencing the research in question; and
- to comply with the principles and regulations defined and described in detail in this guideline.

2.2 Plagiarism and falsifying scientific achievements

According to § 51 para. 2 no. 31 UG (Universities Act) in the current version (as amended), plagiarism occurs when texts, contents or ideas are taken over and passed off as one's own. This includes, in particular, the appropriation and use of text passages, images, graphics, data, theories, hypotheses or findings through direct, paraphrased or translated adoption without appropriate acknowledgement and citation of the source and the author.

According to section 51 para 2 no 32 UG (as amended), falsifying scientific achievements is deemed to exist under any circumstances if the individual resorts to *ghostwriting* or if the data and results are invented or falsified.

2.3 Degrees of responsibility

² “*European Code of Conduct for Research Integrity, revised Edition 2023*”, All European Academies (ALLEA), <https://allea.org/wp-content/uploads/2023/06/European-Code-of-Conduct-Revised-Edition-2023.pdf> (18 December 2023)

All persons involved in research, regardless of whether they are employed by the university or otherwise involved in research activities, agree to comply with the specific regulations and requirements in their field of research and apply the standards of good scientific practice defined in this document.

To this effect, all persons involved in the research agree

- to comply with these standards in their own daily work,
- to set a good example for others, and especially for students and less experienced staff, and
- (if they are experienced or senior scientists) to familiarise students and less experienced staff with good scientific practice and teach them how to apply its principles.

All scientists are responsible for their behaviour and actions in the context of scientific work. All research group leaders are responsible for ensuring that their group fulfils the legal requirements and applies the principles of good scientific practice. Therefore, each research group leader is responsible for ensuring that their group members are familiar with or are familiarised with the principles of good scientific practice and that a working environment exists or is created that allows the group members to act accordingly. The leader must also ensure that all group members are willing to openly discuss and critically review their hypotheses, theories and scientific data and results.

3. Data handling

In the context of good scientific practice, three aspects of data handling and data protection in particular need to be considered:

- the legal and other requirements for data storage in the documentation of scientific work (section 3.1) and in clinical trials in accordance with the Medicinal Products Act and Medical Devices Law (see section 7),
- the applicable provisions on the protection of personal data (section 3.2) and
- the specifications provided for data management plans (DMPs) by research funding institutions (for example, FWF and the European Commission).

3.1 Documentation of scientific work

All persons involved in research are responsible for ensuring that

- they document their own work in such a way that the research results can be reproduced on the basis of the information available in the documentation;
- their original materials, primary data and documentation are kept secure and accessible at Med Uni Graz for a period of ten years; and
- that these are made and remain accessible if they are or need to be archived outside of the person's own institution.

Everyone involved in research must provide essential information in sufficient detail about how an experiment is carried out, documenting this information in writing or electronically, such that independent experts are able to reproduce this experiment. If experiments are based on calculations, the documented information must be detailed such that another person can repeat these calculations. Documentation (i.e. protocols and results) in written or electronic form must have a continuous page numbering, a clear structure and always be complete. If data cannot be included in a laboratory notebook or an electronic protocol, the project documentation must include a precise and clearly understandable reference to the source or storage location.

Further regulations on research data management can be found in the University's Research Data Management Policy.

3.2 Protection of personal data

The term personal data refers to both *directly personal* and *indirectly personal (pseudonymised)* data that cannot be assigned to a specific person without providing further information. *Anonymised* data is data that cannot be assigned to a specific person by anyone. **While directly personal and pseudonymised data are subject to data protection, anonymised data are exempt from the Data Protection Act.**

The Medical University of Graz "Data Protection and IT Security Guideline" regulates the conduct of all employees and explains how personal data should be handled in compliance with legal regulations. In particular, these include the EU General Data Protection Regulation (GDPR), the Data Protection Act (DPA), the Research Organisation Act (FOG, Federal Act on General Matters) and the data protection amendment laws enacted in compliance with the GDPR.

3.3 Complying with the Copyright Act

When using images and graphics from publications that appear in a scientific work (e.g. a dissertation, publication) or a scientific lecture, the provisions of the Copyright Act as amended regarding the protection of works and rights of use must be observed. An exception is granted by certain *Creative Commons* licences (e.g. for open access journals), but the source (author) must always be cited even in this case.

4. Publications and authorship

4.1 General principles

- In publications, the author(s) must describe materials, methods and results in enough detail that the readers can understand the approach used and understand and reproduce the experimental design. If the individual publishers or journals have restrictive requirements that limit the comprehensiveness of the description (e.g. by limiting the number of characters or words), this aspect must be taken into account as far as possible (e.g. by providing *supplementary information*). Previous work (that of the author(s) and of others) must be identified as such and cited completely and correctly.
- Authors of scientific publications are jointly responsible for the content of a manuscript. Authorship can only be granted to persons who have contributed substantially to the research in question (see section 4.2). "Honorary authorships" are not compatible with good scientific practice. Every author has the right and the responsibility to read the publication before it is published.
- If manuscripts are sent to an editor for publication in a journal, book, or collective work, the institutional affiliation and/or correspondence address must minimally contain the following information: [name of the author], [official name of the organisational unit (centre, institute, clinic, clinical department, and department chair (optional))], Medical University of Graz, [address of the organisational unit (if possible)].
- Authors must bear in mind that publishing or carrying out prior discussions about manuscripts or parts of manuscripts in social media can also be problematic, resulting in copyright infringements and limiting possible intellectual property rights, etc. For this reason, the possibility of posting information about manuscripts or parts of manuscripts in social media must be discussed with all

authors ahead of time, they must all agree to this form of publication, and this form of publication must comply with the publisher's terms and conditions.

- Under any circumstances, the consent of all authors involved must be obtained before the material is published in another form.
- All authors are required to disclose relationships that could be considered as sources of a potential conflict of interest.

4.2 Criteria and responsibilities

The Medical University of Graz bases its authorship criteria on the recommendations provided by the International Committee of Medical Journal Editors (ICMJE)³, the Council of Science Editors (CSE)⁴, the Committee on Publication Ethics (COPE)⁵ and the National Institutes of Health (NIH)⁶.

Before submitting a manuscript to a scientific journal, authors should first read and consider the authorship criteria of the journal in question. The following minimum requirements for authorship must be met:

1. The individual must make a substantial contribution to the conception and design of the study OR
2. they must make a substantial contribution to the collection, analysis and interpretation of the study data OR
3. to the formulation or critical revision of the article with regard to important intellectual content AND
4. they must have the opportunity to perform a final review of and approve the version to be published AND
5. all authors must consent to the disclosure of the study contributions (contributorship disclosure, i.e. the provision of a precise description of each author's contribution to the study from the planning to the publication).

All persons designated as authors should meet criteria 1, 2, or 3 and must meet criteria 4 and 5 under all circumstances. All those who meet these criteria should be named as authors. Persons who do not meet the above criteria but have provided a contribution to the work should be listed in the *Acknowledgements*.

Activities which do not individually justify authorship:

1. The provision of space and infrastructure (i.e. substantial intellectual contribution to the publication not provided);
2. The implementation of a study and collection of data using routine methods without being involved in the interpretation of the data; or

³ Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals (updated December 2017), International Committee of Medical Journal Editors, <http://www.icmje.org/recommendations/> (18 December 2023)

⁴ White Paper on Publication Ethics. 2.2. Authorship and Authorship Responsibilities, Council of Science Editors (CSE), <https://www.councilscienceeditors.org/2-2-authorship-and-authorship-responsibilities> (18 December 2023)

⁵ Authorship and Contributorship. Committee on Publication Ethics (COPE), <https://publicationethics.org/authorship/> (18 December 2023)

⁶ NIH, General Guidelines for Authorship Contributions, https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/ethical_conduct/guidelines-authorship_contributions.pdf (18 December 2023)

3. The general management of a research group without providing an intellectual contribution to publication or the general management of an organisational unit or sub-organisational unit.

Responsibilities associated with authorship:

1. Compliance with all principles of good scientific practice and, in particular, the Copyright Act and Data Protection Act;
2. Responsibility for one's own contribution to the study;
3. Trust in the scientific integrity of the authors while maintaining critical vigilance (approval of publication and authorship only if no reasonable doubts about scientific integrity exist),
4. Responsibility to select publication bodies that follow the principles of good scientific practice (exclusion of *predatory* journals that disregard the principles of good scientific practice).

Responsibilities in the selection of publication media

Authors are obliged to select publication media that are committed to the principles of good scientific practice. This applies in particular to the exclusion of predatory journals and predatory (fake) conferences⁷, which operate without adequate scientific quality control and thus disregard the principles of good scientific practice. Some mega-journals that publish an unusually high number of special issues⁸ are also suspected of neglecting scientific quality control. Presentation at predatory (fake) conferences and publication in predatory journals and mega-journals that are not listed in the Web of Science therefore represent a violation of good scientific practice.

Authors should therefore consult the Web of Science Master Journal List⁹ and, in the case of open access publications, the Directory of Open Access Journals¹⁰ and Think.Check.Submit.¹¹. To avoid predatory (fake) conferences, Think.Check.Attend.¹² and the UNESCO Open Science Toolkit "Identifying predatory academic journals and conferences"¹³ provide assistance.

Responsibilities when using artificial intelligence

The use of artificial intelligence (AI) tools (AI methods and generative AI models/chatbots) in the writing of scientific manuscripts (theses, publications, research project proposals) affects the principles of good scientific practice and thus the responsibility of the authors. The respective regulations of scientific publishers and journals must be followed. The guidelines of the Medical University of Graz are based on international standards, in particular the WAME Recommendations on Chatbots and Generative Artificial Intelligence in Relation to Scholarly Publications, which also explain the terms *generative AI* and *chatbots*¹⁴:

- In general, only AI tools whose use does not violate any applicable legal requirements (in particular laws, regulations) may be used.

⁷ <https://www.interacademies.org/publication/predatory-practices-report-English>;
<https://unesdoc.unesco.org/ark:/48223/pf0000383324>

⁸ <https://predatoryreports.org/news/f/the-miracle-of-special-issues-multiplication>

⁹ <https://mjl.clarivate.com/home>

¹⁰ <https://doaj.org>

¹¹ <https://thinkchecksubmit.org/>

¹² <https://thinkcheckattend.org/>

¹³ <https://unesdoc.unesco.org/ark:/48223/pf0000383324>

¹⁴ <https://wame.org/page3.php?id=106>

- Any use of AI tools in the preparation of scientific manuscripts (theses, publications, research project proposals) must be disclosed. For this purpose, the name and version of the AI tool used as well as the purpose and scope of the AI use should be stated in the appropriate place in the manuscript. When using generative AI models, the prompt of the input should also be mentioned.
- As any input into generative AI models is also used for their training, care must be taken to ensure that the input of text and data does not violate third-party intellectual property or data protection regulations. This also applies to the input of data or findings that could serve as the basis for a later patent application and therefore may not be made public (conduct prejudicial to novelty) or are considered confidential for other reasons.
- Generative AI models cannot be listed as authors, as it is not AI tools but only their users who are responsible for the copyright of the generated texts. The users/authors must ensure that the AI-generated texts do not violate copyrights or other rights of third parties, in particular with regard to previously published works.
- Texts created with the help of generative AI models must be carefully checked and edited, as AI can generate false and misleading texts.
- Generative AI models can be used to improve the language and readability of texts. The interpretation of the results and scientific conclusions are the responsibility of the authors.

4.3 Avoiding authorship conflicts in collaborative publications

When a larger (especially multicentre) group publishes the results of a study, that group should nominate individuals who will take direct responsibility for the manuscript. These individuals should meet all the criteria for authorship defined above. If a group submits a manuscript collaboratively, the corresponding author should clearly indicate how the publication should be cited and should list all individual authors and the name of the group, if applicable.

In order to give due consideration to all those who have contributed to a publication and to avoid conflicts regarding authorship, we recommend that the names of the authors and their order - or at least the criteria that determine the inclusion and order of authors - be discussed in good time, i.e. before or during the creation of the manuscript rather than shortly before submission of the manuscript. However, it should be noted that the relative contributions of individual authors to the overall study may change over the course of a study. Taking such circumstances into account, the inclusion and order of authors must be determined in a joint decision before submitting a publication, whereby all authors are obliged to participate in the decision and the consent of all authors is required for a decision. The corresponding author or group leader has a special responsibility to coordinate the decision-making process in an open, fair and transparent manner. Furthermore, we recommend preparing a detailed description of all authors' contributions (*contributorship disclosure*).

4.4 Special recommendations for publications from clinical departments

When preparing a manuscript based on work performed in clinical departments, the authors must take into account the fact that the publications are often based on treatment results that were (also) produced by persons other than the authors. Before publishing such contributions, therefore, the following recommendations should be considered:

- Authors are required to ensure the transparency of their actions and to inform persons involved in the patient treatment in question well ahead time when a publication is planned. Therefore, the eligibility for authorship should be discussed and determined

among the persons involved, taking into account the criteria described above. The respective heads of the organisational units should create the collegial environment for such discussions and, if necessary, supervise these discussions.

- If a doctor carried out routine treatment and undertook substantial additional activities relevant to the research that went beyond the steps required to perform the medical treatment (e.g. photographing a feature or carrying out an operation that revealed something relevant to the research), then the planned publication and its contribution should be discussed with this person.
- Likewise, experts who frequently carry out specialised activities and contribute their expertise to a publication in the sense of the authorship criteria listed above should be considered as authors, listed in the *acknowledgements*, or recognised in the form of a citation in the publication, where appropriate.

5. (Peer) reviewing, evaluation, assessment and similar activities

Researchers who act as peer reviewers for journals, funding agencies, or other institutions are required to disclose relationships that could be considered sources of a potential conflict of interest.

Researchers who participate in peer review processes as reviewers must not use ideas and knowledge from the material they are reviewing for their own benefit or pass these on to others. They must respect the authors' rights by not discussing the work in question in public or appropriating their ideas before the manuscript in question has been published. In addition, they should prepare the review in a timely manner and without deliberate delay. Even when researchers provide negative assessments on the content of publications, project proposals, or other documents that they have reviewed, the criticism must be formulated in a factual and respectful manner.

Since documents provided for review constitute third-party intellectual property and are therefore confidential, their input into generative AI models is not permitted.

Before accepting positions as reviewers or other functions in the *scientific community*, researchers should assess the quality and professionalism of the commissioning institution, so that their work does not support so-called *predatory journals*, *predatory (fake) conferences* or only ostensibly scientific publications/events.

6. Supervision of young scientists

The introduction of students, doctoral students and young scientists to good scientific practice includes:

- Acting as a role model to achieve the purposes described in this guideline when carrying out their own academic work,
- Familiarising students and young scientists with the standards for good scientific practice,
- Providing a research environment that enables students and researchers early on in their careers to meet the standards, and
- Encouraging students and young researchers to openly engage in critical discussions and evaluations of their work.

In particular, the following points must be addressed when supervising and publishing academic manuscripts as pursuant to §§ 80-86 of the Universities Act 2002 (UG) as amended:

- If the work has already been published by a publisher/journal prior to its publication in another form according to § 86 UG idgF, it must be ensured that **permission for a second publication** in the form of a diploma/master's thesis or dissertation has been granted in the contract that was signed between the authors and the publisher. Under all circumstances, such publications must be cited correctly in the diploma/master's thesis or dissertation.
- Students should be made aware during their supervisory period that **granting publishers/journals exclusive data usage rights** may have far-reaching consequences and may conflict with their obligation to publish these data in theses according to the UG. If the publications appear in an *open access journal*, the data usage rights remain with the authors, depending on the respective *Creative Commons licence* applied (<https://creativecommons.org/licenses/>). This means that it is possible for the author to reuse data in another publication (e.g. in a thesis) if the source (author) is cited.
- Results obtained in the context of diploma/master's theses or dissertations may also be published in a journal after approval of the thesis, provided that the thesis is cited in full (author, title, name of the approving institution, year of approval). If it is already known at the time of submission of the thesis in which journal the results of the thesis will be published in the near future, this must also be stated in the disclosures of the thesis (authors, title, journal). It must be clarified in advance that the selected journal permits the secondary publication of a thesis or the results described therein¹⁵.
- When choosing a journal for the publication of scientific works according to the UG, attention must be paid to any existing **publishing embargoes** set by the chosen journal that may conflict with the obligation to publish the information elsewhere within a certain time period according to the UG. In this case, as well as in the case of patent applications, it is possible to apply for a temporary exclusion from library use (a so-called "blocking request") pursuant to § 86 para. 2 UG as amended.
 - During the supervisory period, the supervisors need to check whether the **academic achievement contains plagiarised or falsified information** as defined in § 51 para. 2 no. 31 and no. 32 UG idgF or whether there are indications thereof. The use of *ghostwriting services* is also defined as falsifying academic performance and is punishable by law (§ 116a UG). Under all circumstances, students must be instructed as to the correct procedure and citation method(s).

¹⁵ Additional information is available at <https://libraries.mit.edu/scholarly/copyright/theses-copyright/theses-and-article-publishing/> (18 December 2023).

7. Research on patients and test persons (clinical research)

- In the context of medical research, the Medical University of Graz is committed to adhering to the principles outlined in the Declaration of Helsinki¹⁶ and the guidelines of Good Clinical Practice¹⁷.
- All research projects involving human subjects must be submitted to the Ethics Committee for review and approval in accordance with § 30 UG idgF. This includes projects in which any kinds of measures are performed on patients and/or test persons, on potentially identifiable human material (e.g. blood, serum, tissue samples, DNA), or on data (e.g. medical records), and specifically referring to measures which are carried out to purely gain knowledge and/or which do not exclusively provide health benefits for the patients and/or test persons on whom the measures are carried out.
- It is irrelevant whether the project involves the testing of a medicinal product, a medical device, a new method, or falls into any other research project category.
- The following research projects must be submitted to the Ethics Committee:
 - Clinical trials on medicinal products
 - Clinical trials on medical devices
 - Applications of new medical methods
 - Non-interventional studies
 - Applied medical research on humans
 - Research on potentially identifiable human material or that involves personal data (this also applies to retrospective studies, and only fully anonymised data are excluded),
 - genetic analyses for scientific purposes
 - Research involving foodstuffs, food supplements, or cosmetic products in accordance with the Food Safety and Consumer Protection Act §5 Para. 6
- Therapeutic trials always concern only the individual patient and do not require the approval of the Ethics Committee or authorities. However, if a scientific evaluation is planned, the study is no longer considered as a "therapeutic trial", but a clinical study, and an evaluation by an ethical committee or other regulatory authority must be performed. The trial must be submitted for evaluation before the project begins and must comply with the requirements of the Ethics Committee. The updated version of these requirements is available on the website of the Ethics Committee (<https://www.medunigraz.at/en/ethics-committee/>). Research projects may only be started after the Ethics Committee has given its written approval.
- It is not necessary to submit your project for approval to the Ethics Committee if the planned measures only address aspects of patient care that are in the interest of the patients and are not carried out to specifically pursue research interests. This also applies to the use of medicines for an unapproved indication (*off-label use*).

¹⁶English version: <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/> (18 December 2023)

German version: https://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/pdf-Ordner/International/Deklaration_von_Helsinki_2013_20190905.pdf (18 December 2023)

¹⁷ICH-GCP Good Clinical Practice Guideline:

https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf (18 December 2023)

ISO 14155 - Clinical investigation of medical devices for human subjects - Good clinical practice: <https://www.iso.org/standard/71690.html> (18 December 2023)

- The project must be in compliance with the provisions of the Data Protection Act. The legal basis for data protection can be found on the website of the Medical University of Graz: <https://www.medunigraz.at/en/data-protection>.
- Confidentiality must be guaranteed when handling patient and volunteer data. Personal data must be pseudonymised or anonymised immediately, as soon as the personal reference is no longer necessary for research purposes. If the data are pseudonymised, the “key” must be stored separately from the personal data so that adequate protection is provided from access by third parties. It is recommended that the pseudonymisation/anonymisation procedure(s) be carried out by the Institute for Medical Informatics, Statistics and Documentation at the Medical University of Graz.
- In addition to meeting the above-mentioned requirements prior to submitting the project to the Ethics Committee, the authors must observe the requirements stated by publishers (for publications) or funding bodies (for funding applications) regarding ethical evaluations.

8. Animal testing

- All animal experiments are subject to the Austrian Animal Experiments Act 2012 (TVG) and, if they are carried out in the area of the Medical University of Graz, must be applied for approval to the Federal Animal Experiments Commission at the Federal Ministry responsible for science and research. The Department of Biomedical Research at the Medical University of Graz receives applications for approval and submits them to the Rectorate. Applications for animal experiments can only be submitted via the Rectorate.
- In the application, the researcher must describe and explain why the animal experiment in question is necessary and appropriate to achieve the expected gain in knowledge.
- Animal experiments must not be carried out if the intended experimental objectives can be achieved by other recognised methods and procedures (alternative methods).
- Every effort must be made to reduce the number of animal experiments, the number of animals used in animal experiments and the stress on the animals to the lowest possible level necessary for the desired gain in knowledge.
- Clear criteria must be established in advance for when an experiment on an individual animal is terminated.
- Animal experiments can only be carried out after all the necessary permits have been obtained.

9. Genetic research and genetic engineering

- All research projects in which genetically modified organisms are worked with or used (including production, propagation, storage, inactivation, or disposal) are subject to the Austrian Gene Technology Act (GTG, *Gentechnikgesetz*). The project must be submitted to the Federal Ministry of Education, Science and Research or this organisation must be notified about the project, as it is responsible for assessing the safety level of the research, in accordance with Section II of the GTG entitled “Work with genetically modified organisms in contained systems”. Depending on the assessed safety level, the Federal Ministry of Education, Science and Research must be notified about the project or the project must be submitted for approval before work begins. Each project must be submitted internally to the responsible biosafety committee at the University so that the committee can carry out the necessary safety classification.
- **Gene therapies** on humans are subject to the Austrian GTG and, in particular, Section IV entitled “Gene analysis and gene therapy on humans”. These therapies must be carried out in accordance with the provisions described therein and submitted to the Federal Ministry of Health for approval. Depending on the project, it must be submitted internally to the responsible biosafety

committee at the University so that the committee can carry out the necessary safety classification.

- **Gene analyses** on humans are also subject to the Austrian GTG and, in particular, Section IV entitled "Gene analysis and gene therapy on humans". These must be reported to the Federal Ministry of Health in accordance with the provisions described in Section IV.
- Genetic analyses performed for scientific and educational purposes may only be carried out if the donor of the corresponding sample has expressly consented to this use in writing or if the sample has been de-identified¹⁸. Non-genetic medical data that will be linked to genetic data of the same person must also be de-identified. The allocation of these data to the respective sample donor may only take place if the valid consent of the person concerned has been obtained with the approval of the Ethics Committee.
- Results of genetic analyses may only be combined or published if suitable measures are taken to ensure that the sample donor cannot be identified (cf. Section IV, § 66 GTG), considering aspects described in para. 1, § 66 GTG, Section IV.
- With regard to the collection of and research on human tissue samples, researchers are advised to read the document entitled "Human Biobanks for Research" (published by the German National Ethics Council, 2010) and consider the information therein.

10. Scientific misconduct and scientific fraud

Scientific fraud is the deliberate (or attempted) deception of the *scientific community*, funding agencies, decision-makers and other recipients of published research results. Scientific misconduct usually results from gross negligence and/or irresponsibility in research conduct. The following acts, when performed either intentionally or negligently, are considered as violations of good scientific practice and constitute acts of scientific misconduct or fraud:

- Inventing or falsifying data (including tacitly selecting and eliminating unwanted results, manipulating graphical representations, or providing false information in funding applications or in the context of scientific job applications);
- Losing primary data as a result of negligence, elimination of primary data, removing primary data from the laboratory or institution without coming to an agreement with the laboratories or institutions involved, or resulting in a violation of applicable legal provisions, discipline-specific standards, or these good scientific practice standards;
- Infringement of intellectual property rights (including, but not limited to, plagiarism and the unauthorised use or distribution of other people's approaches, ideas and graphics/illustrations);
- Publication in predatory journals and mega-journals that are not listed in the Web of Science, and presentation at predatory (fake) conferences;
- Publication of fake papers and participation in *research paper mills*¹⁹;
- Non-disclosure of the use of AI methods and generative AI models in the writing of scientific manuscripts (theses, publications, research project proposals);
- Input of texts and data that are protected by copyright, subject to data protection or considered confidential into generative AI models;
- Including persons who do not fulfil the authorship criteria in the list of authors;
- Assuming authorship for unjustifiable reasons;

¹⁸ The GTG explicitly refers to "de-identification" instead of using the terms "anonymisation" and "pseudonymisation", which are used in the GDPR and the Data Protection Act.

¹⁹ <https://publicationethics.org/resources/research/paper-mills-research> (18 December 2023)

- Excluding another person from a justified authorship or indicating another person as an author without that person's consent;
 - Publishing an original work twice (or more often), i.e. repeatedly publishing the contents of an original work in another original work under the same or a modified title, or with the same or a modified list of authors, unless this is covered by the agreement to grant rights of use as described in Section 37a of the Copyright Act (UrhG, *Urheberrechtsgesetz*);
 - Sabotaging research activities (including damaging, destroying, or manipulating experimental set-ups, equipment, documents, software, consumables, etc.);
 - Referring to experienced and/or senior scientists: Neglecting the duty to teach students and less experienced staff (research assistants) the principles of good scientific practice;
 - Defaming the principles of good scientific practice; and
 - Committing a breach of trust in a function as an expert, consultant, evaluator, reviewer, or similar function.
- The following acts, if performed either intentionally or negligently, are considered as contributing to the violation of good scientific practice and result in joint responsibility being taken for scientific misconduct or fraud:
- Active and conscious participation in the misconduct or fraud of others
 - Gross neglect of one's own duties as a supervisor or as a leader of a research group

11. Ombuds Committee for Good Scientific Practice

In order to ensure good scientific practice, the Medical University of Graz has established an Ombuds Committee for Good Scientific Practice. The tasks and working methods of this Committee are regulated in separate rules of procedure.

Sources

While preparing this text, the Medical University of Graz has taken passages from the following documents or referred to their content:

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- "Humanbiobanken für die Forschung [Human Biobanks for Research]", Statement of the German National Ethics Council 2010, <https://www.ethikrat.org/en/topics/research-and-technology/biobanks/?cookieLevel=not-set&cHash=cd647e2d67520ba77b2e80f64485e509> (18 December 2023)
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- "Verfahrensleitfaden zur guten wissenschaftlichen Praxis [Procedural Guide to Good Scientific Practice]". German Research Foundation, <https://www.dfg.de/resource/blob/172176/41689f880027cbef9e2d8c1ad4dc006a/verfahrensleitfad-en-gwp-data.pdf> (18 December 2023)