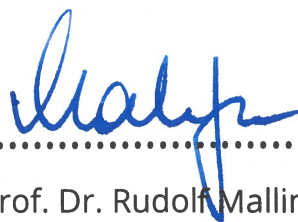


Guideline Good Scientific Practice

Valid from entry into force on May 4, 2023
until revocation or new regulation

RL_041_2023_Good_Scientific_Practice



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Summary	The GSP guideline summarises principles of Good Scientific Practice to be considered for all scientific research activities at KL
Aim	Providing a basis for scientific research according to internationally valid standards
Scope	The GSP guideline applies to all KL research activities, including research under KL co-responsibility at university hospitals.
Process	The GSP Guideline is reviewed at regular intervals by the Research Management Unit
Contact	The Research Management Unit is responsible for overseeing the GSP guideline. contact: forschung@kl.ac.at

Date	Version		Approval	Description
24.11.22	1.0	<p>Compilation:</p> <ul style="list-style-type: none"> • O. Friedrich & J. Gattringer (Research Management Unit) <p>Contributors:</p> <ul style="list-style-type: none"> • F. Trautinger, S. Schober (Committee for Scientific Integrity und Ethics) • G. Rubeis, I. Metzler (Division Biomedical and Public Health Ethics) • G. Obermair (Division Physiology) • R. Plail, R. Litauszky, D. Köprülü-Rössl (Research Management Unit) 		Final version after consultation with the heads of the KL scientific departments and the KL Committee for Scientific Integrity and Ethics
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25.04.23	1.1	Oliver Friedrich		English version added
04.05.23			JF Rektorat	Approval

1. Principles of Good Scientific Practice

The principles of Good Scientific Practice form the foundation for collaboration in a spirit of mutual trust within the scientific community and help bolster public confidence in scientific research. Karl Landsteiner University for Health (KL) is committed to the four principles of Good Scientific Practice as laid down in the European Code of Conduct for Integrity in Research¹:

- Reliability in ensuring the quality of research, reflected in the design, the methodology, the analysis and the use of resources.
- Honesty 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.

¹ [ALLEA-European-Code-of-Conduct-for-Research-Integrity-2017.pdf](#)

2. General principles of research practice

Research activities at KL cover a wide range of disciplines within the health sciences. The main focus areas are human medicine, psychology, psychotherapy and nursing sciences, plus basic physiological and pharmacological research, mental health and neuroscience, medical technology and water quality research. There is also a special focus on societal aspects in the fields of health economics, gender medicine, gerontology, medical ethics, and bioethics. The following general principles of research practice apply to all research activities at KL.

2.1. Researcher responsibilities – research participant rights

Researchers from all research areas at KL are committed to upholding their responsibilities towards research participants and society at large. These include, in particular, the following points:

- Studies must be performed in accordance with the state of the art (*lege artis*). Researchers must be familiar with the current state of research and appropriate methods.
- Researchers are committed to maintaining integrity and objectivity in how they process data and research results.
- Collaboration between researchers must be based on honesty and fairness. Researchers may not appropriate the findings of other researchers nor may they impede their scientific work. Research findings must be made publicly available. Results, theories, methods and the research design must be traceable and communicated transparently.
- Agreements on the distribution of tasks, remuneration, data access, copyrights and other rights and responsibilities must be made in advance for research or publication projects.
- A critical and unbiased exchange between colleagues about findings is an integral part of scientific practice. Conflicts of interest shall be disclosed. Researchers who are not impartial shall not review the work of their colleagues.
- Researchers have a responsibility to society. Their recommendations, decisions and statements can influence public discourse and policy-making processes. They must be mindful of this responsibility. Researchers must take a critical view of their public role and its potential for misuse.
- A discussion of research ethics is an essential part of university education. Researchers at KL are required to engage with the specific research ethics issues in their fields of research and to communicate these issues to students.

The KL will ensure that researchers have the institutional support they need to fulfil their responsibilities.

Where research is carried out with the participation of volunteers or patients, the fundamental rights of these research participants must be upheld:

- Participation in research projects is voluntary and can be revoked at any time without explanation. Research participants can only be involved after a thorough risk assessment.
- Research participants must be comprehensively informed about the nature, significance and scope of a research project. If the study design does not allow for such comprehensive information because it would distort or otherwise negatively influence the outcomes of the study, alternative forms of consent should be applied.
- Potential factors contributing to social vulnerability must always be taken into account when dealing with research participants. Participants' age, gender, sexual orientation, ethnicity, religious affiliation, disability, physical and mental health, level of education and socio-economic situation must always be appropriately taken into account. Marginalised groups are to be treated with particular sensitivity. Simple and inclusive language should be used in educational materials and face-to-face conversations.

2.2. Processing data

- All data must be collected, stored, transmitted and used in accordance with applicable national and international legal standards. In particular, the relevant provisions of the Austrian Data Protection Act², the European General Data Protection Regulation³ and the Austrian Research Organisation Act⁴ must be observed.
- Confidentiality must be maintained when working with data from research participants (patients, volunteers and other research participants). Personal data must be pseudonymised or anonymised. If data is pseudonymised, the key must be kept separately from the personal data so that it is sufficiently protected from being accessed by third parties.
- Data must be collected and analysed in accordance with a detailed protocol. Primary data must be kept securely for at least ten years after the completion of a project,

² Bundesgesetz zum Schutz natürlicher Personen bei der Verarbeitung personenbezogener Daten ("Federal Act on the Protection of Natural Persons with regard to the Processing of Personal Data" – Datenschutzgesetz – DSG)

³ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation – GDPR)

⁴ Bundesgesetz über allgemeine Angelegenheiten gemäß Art. 89 DSGVO und die Forschungsorganisation, ("Federal Act on General Matters Pursuant to Article 89 of the GDPR and Research Organisation" – Forschungsorganisationsgesetz – FOG)

without prejudice to further statutory retention obligations. Researchers must ensure that results can be seamlessly traced back to the original data.

- KL is committed to the internationally recognised FAIR principles⁵ in research data management: Research data should be easy to find (findable), generally accessible (accessible), usable across different platforms (interoperable) and available for re-use (re-usable).

2.3. Authorship and publication

- KL is committed to internationally recognised standards, in particular the recommendations of the International Committee of Medical Journal Editors (ICMJE)⁶ and the Committee on Publication Ethics (COPE), on the authorship of scientific publications.⁷

These are the decisive criteria for being named as an author of a scientific publication:

- Substantial contribution to the formulation of the research question, the research plan, the implementation of the research project, the collection, evaluation or interpretation of data and results,
- Substantial contribution to the preparation or critical review of the content of the manuscript and
- Approval of the final version of the manuscript submitted for publication.

All persons who fulfil these three criteria must be named as co-authors. Honorary authorships are not permitted.

Being technically involved in data collection, providing funding or holding a management position at the research institution are not sufficient grounds for co-authorship. The same applies to solely proofreading the manuscript without contributing to the content.

- As a signatory of the Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities (Berlin Declaration)⁸, KL supports open access based publication of research results.

⁵ Wilkinson, M., Dumontier, M., Aalbersberg, I., *et al.* The FAIR Guiding Principles for scientific data management and stewardship. *Sci Data* **3**, 160018 (2016). <https://doi.org/10.1038/sdata.2016.18>

⁶ Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals (updated December 2017), International Committee of Medical Journal Editors (ICMJE),

⁷ Authorship and contributorship. Committee on Publication Ethics (COPE)

⁸ The Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities.

https://openaccess.mpg.de/67605/berlin_declaration_engl.pdf

2.4. Conflicts of interest

- A conflict of interest exists when academic, financial or personal interests can potentially impact the judgement of persons engaged in scientific activities.
- Scientists working at KL are required to disclose all potential conflicts of interest. This requirement applies in particular to collaborations with public and/or commercial partner institutions, for example when third-party funding is acquired, but also to other activities such as providing expert opinions, publications, lectures, participation in committees, and working as a consultant.

2.5. Mentoring the next generation of scientists

KL is committed to communicating the principles of good scientific practice to students and junior researchers and to creating framework conditions that enable students and junior researchers to comply with the applicable standards.

3. Medical/clinical research involving human subjects

- Researchers at KL are committed to implementing the requirements of the Declaration of Helsinki of the World Medical Association⁹ when conducting medical research on human subjects, including research on identifiable human materials and data. This includes, in particular, the obligation to submit the research protocol for approval to the concerned research ethics committee *before* the study begins.
- Clinical trials of medicinal products – including non-interventional studies as defined by the Austrian Pharmaceuticals Act (Arzneimittelgesetz – AMG), medical devices and new medical methods are assessed by the concerned lead ethics committee. All other research projects can be submitted to the KL Committee for Scientific Integrity and Ethics.
- A study plan must be prepared for each clinical research project before the study begins. It should include the following elements:
 - Synopsis: Title, list of persons responsible for the study, abstract of the project
 - Scientific section: background, rationale, detailed research question, study design, endpoints, description of study-related measures, criteria for inclusion and exclusion, recruitment strategy, information on the randomisation and blinding strategy, if applicable.
 - Statistics and data analysis: information on how data is processed, calculation of the number of cases, and details on the statistical evaluation of the data
 - Ethical aspects: Weighing up the benefits and risks
- Clinical trials/studies¹⁰ must be conducted in accordance with the ICH Guideline for good clinical practice¹¹ (GCP).
- All clinical trials must be entered in a publicly accessible registry. Projects that have been endorsed by the KL Committee for Scientific Integrity and Ethics are automatically entered in a registry set up by the Commission for this purpose. KL also provides access to the clinicaltrials.gov platform for this purpose. For clinical trials as defined in the Austrian Pharmaceuticals Act, the registry of the European Medicines Agency “EudraCT” (<https://eudract.ema.europa.eu/>) must be used.

⁹ [WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects – WMA – The World Medical Association](#)

¹⁰ Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy (Guideline for good clinical practice E6 R2, 1.13).

¹¹ ICH Guideline for good clinical practice E6(R2). https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-6-r2-guideline-good-clinical-practice-step-5_en.pdf (08.11.21)

4. Preclinical research – animal testing

- KL is committed to the principle of respect for life. The necessity and reasonableness of animal testing must therefore always be weighed against the resulting stress on the laboratory animal. This must be kept to a minimum. The use of animal testing is not permissible if there is a valid and recognised alternative method for obtaining the desired results.¹²
- Animal testing must be carried out in compliance with applicable law. In addition to the Austrian Animal Testing Act¹³ and Animal Protection Act¹⁴, the provisions of the EU Animal Testing Directive¹⁵ and the Council of Europe Laboratory Animals Convention¹⁶ must be observed. Animal experiments involving genetic engineering or biological agents are also subject to the Austrian Genetic Engineering Act¹⁷ and Ordinance on Biological Agents¹⁸. The Austrian Animal Materials Act¹⁹, TSE Animal Materials Disposal Ordinance²⁰ and Animal Diseases Act²¹ must also be observed.
- Animal testing at universities always requires the approval of the competent federal ministry. All applications under the TVG 2012 (animal experimentation projects) planned at KL must be submitted to the user's animal welfare committee for

¹² Cf. 3Rs principle. Russell, William M.S. / Burch, Rex L. (1959): The Principles of Humane Experimental Technique. London: Methuen, in particular 69-154. <https://caat.jhsph.edu/principles/the-principles-of-humane-experimental-technique>

¹³ Bundesgesetz vom 27. September 1989 über Versuche an lebenden Tieren ("Federal Act of 27 September 1989 on Experiments on Living Animals" – Tierversuchsgesetz – TVG), BGBl. No. 501/1989, as last amended by BGBl. I No. 136/2001.

¹⁴ Bundesgesetz über den Schutz der Tiere (Tierschutzgesetz – TSchG), BGBl. I No. 118/2004.

¹⁵ Council Directive of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (86/609/EEC), ABl. No. L 358, 18.12.1986, p 1.

¹⁶ European Convention for the protection of vertebrate animals used for experimental and other scientific purposes (ETS No. 123)

¹⁷ Bundesgesetz, mit dem Arbeiten mit gentechnisch veränderten Organismen, das Freisetzen und Inverkehrbringen von gentechnisch veränderten Organismen und die Anwendung von Genanalyse und Genterapie am Menschen geregelt werden ("Federal Act regulating work involving genetically modified organisms, the release and circulation of genetically modified organisms and the use of gene analysis and gene therapy on humans" – Gentechnikgesetz – GTG), BGBl. No. 510/1994 as amended by BGBl. I No. 94/2002.

¹⁸ Verordnung der Bundesministerin für Arbeit, Gesundheit und Soziales über den Schutz von Arbeitnehmer/innen gegen Gefährdung durch biologische Arbeitsstoffe ("Ordinance of the Austrian Federal Minister of Labour, Health and Social Affairs on the Protection of Workers against Risks from Biological Agents" – Verordnung biologische Arbeitsstoffe – VbA), BGBl. II No. 237/1998.

¹⁹ Austrian Federal Act on hygiene regulations for animal by-products and materials not intended for human consumption (Bundesgesetz betreffend Hygienevorschriften für nicht für den menschlichen Verzehr bestimmte tierische Nebenprodukte und Materialien, Tiermaterialiengesetz – TMG, BGBl. I Nr. 141/2003).

²⁰ Verordnung der Bundesministerin für Gesundheit und Frauen betreffend tierische Nebenprodukte, von denen in Bezug auf bestimmte Transmissible Spongiforme Enzephalopathien (TSE) Gesundheitsrisiken ausgehen können ("Ordinance of the Austrian Federal Minister for Health and Women's Affairs on animal by-products that may pose health risks in relation to certain transmissible spongiform encephalopathies" – TSE-Tiermaterial-Beseitigungsverordnung), BGBl. II No. 473/2003.

²¹ Gesetz vom 6. August 1909 betreffend die Abwehr und Tilgung von Tierseuchen ("Act of 6 August 1909 on the prevention and eradication of animal epidemics" – Tierseuchengesetz – TSG), RGBl. No. 177/1909, as amended by BGBl. No. 71/2003.

preliminary review and, if necessary, revised in accordance with the recommendations of the animal welfare committee. The final application will be submitted by the animal protection committee to the competent authority (BMBWF – V/3b (Animal Testing and Genetic Engineering)). Work on a project cannot begin until it has been approved by the competent ministry.

5. Research involving genetically modified organisms

- Research involving genetically modified organisms (GMOs) is subject to the Austrian Genetic Engineering Act (GTG)²² and must be registered with the competent federal ministry before work begins, with due regard to the relevant safety level.
- A detailed description of the genetically modified organism/cells used and a safety rating issued by the operator and the Biosafety Committee must be provided for each project. All the necessary safety measures and the procedure for the harmless disposal of the genetically modified organisms used must be described in detail and ensured before the work is carried out.

6. Other health science research involving human subjects

In addition to medical research (see sections 3 and 4), the health sciences also include other fields of research based on methods and traditions from the natural, social and human sciences. These often do not involve physical interventions and do not always fall under the categories of medical research. Nevertheless, this health science research also raises many ethical questions, especially when research participants are involved (e.g. in interviews, group discussions, participatory observations and surveys) and/or personal data is used.

In order to ensure compliance with ethical principles in these areas as well, researchers at KL are required to carry out a self-assessment before starting empirical research work and projects, and to document this in their records. If any potential risks are identified in this self-assessment, the project must be submitted to and endorsed by a competent ethics committee prior to implementation.

²² Bundesgesetz, mit dem Arbeiten mit gentechnisch veränderten Organismen, das Freisetzen und Inverkehrbringen von gentechnisch veränderten Organismen und die Anwendung von Genanalyse und Genterapie am Menschen geregelt werden ("Federal Act regulating work involving genetically modified organisms, the release and circulation of genetically modified organisms and the use of gene analysis and gene therapy on humans" – Gentechnikgesetz – GTG), BGBl. No. 510/1994 as amended by BGBl. I No. 94/2002.

7. Scientific misconduct

Scientific misconduct is defined as the deliberate, intentional or grossly negligent violation of the standards of good scientific practice. According to the Austrian Agency for Research Integrity (Österreichische Agentur für Wissenschaftlichen Integrität – ÖAWI) Guidelines for Good Scientific Practice²³, scientific misconduct includes in particular the following actions:

- The fabrication of data, for example the fabrication of research results (measurements, observations, statistics).
- The falsification of data, for example by manipulating the research process, altering or selectively omitting data which contradict the research proposition, or the misleading interpretation of data with a view to obtaining a desired result.
- Plagiarism, which is defined as the wrongful appropriation of texts, thoughts or ideas from other persons. In particular, it includes the appropriation and use of text passages, theories, hypotheses, insights or data directly, in paraphrased form or in translated form without labelling and citing the source and originator. This also includes the use (including the publication) of others' research ideas or plans which come to a researcher's attention in a confidential context (e.g. in the course of a peer review or other review procedure).
- The unjustified refusal to provide access to primary and original data, including information on how such data was obtained, or the disposal of such data before the applicable retention periods have passed.
- Obstructing the research activities of other scientists/researchers as well as other unfair attempts to damage the scientific/scholarly reputation of another scientist/researcher; in particular, this includes anonymous, non-specific and unjustified allegations of violations of the Standards of Good Scientific Practice.
- Sabotaging research activities, in particular damaging or destroying experiments, equipment, documents, hardware, software, chemicals or other materials that another scientist/researcher requires to undertake his or her research.
- Providing inaccurate information in a grant proposal which may place competing scientists/researchers at a disadvantage.
- Creating disadvantages to the career advancement of junior scientists and researchers who have reported potential research misconduct (whistle-blowers)

²³ Austrian Agency for Research Integrity Guidelines for Good Scientific Practice, 2019, p14ff, [OeAWI_Brochure_Print_2019.pdf](#)

8. Responding to suspected violations of good scientific practice

All violations of the principles of good scientific practice are addressed by the KL Committee for Scientific Integrity and Ethics. The Committee will treat any reports of scientific misconduct confidentially. Alleged violations are investigated in a manner that is both transparent and fair to all parties involved. The Committee reserves the right to involve external experts in this process.

9. Sources

The following sources were used to formulate the KL Good Scientific Practice Guidelines:

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