Research Data Management Policy

Contents

Glossary

Term/Abbreviation	Meaning
Data Management Plan (DMP)	A data management plan is a structured guideline for the management of research data and thus an essential instrument for research data management. It describes which data are collected or generated over the course of a research project and what happens to them during their life cycle (storage, publication, citation, long-term availability, anonymisation, dissemination and accessibility, deletion, etc.). The aims of creating a DMP are to meet the good scientific practice requirements and to make research results more easily traceable over the long term (see FAIR principles).
Data Protection Act (in German: *Datenschutzgesetz*, DSG)	Federal Act on the Protection of Personal Data as amended (https://www.ris.bka.gv.at)
General Data Protection Regulation (in German: *Datenschutz-grundverordnung*, DSGVO)	Regulation (EU) 2016/679 established by the European Parliament and the EU Council on 27 April 2016 to protect natural persons with regard to personal data processing, ensure free data transmission and allow Directive 95/46/EC (General Data Protection Regulation) to be repealed http://eur-lex.europa.eu/legal-content/DE/TXT/HTML/?uri=CELEX:32016R0679&from=DE

Term/Abbreviation	Meaning
Third	A natural or legal person, authority, institution, or other body that does not belong to Med Uni Graz. This also includes the Steiermärkische Krankenanstalten Gesmbh (KAGes, the Styrian Hospital Association) and the LKH-Univ.-Klinikum Graz (University Hospital Graz).
FAIR principles	According to the "FAIR Data Principles" (Guidelines on FAIR Data Management in Horizon 2020), research data should be "Findable, Accessible, Interoperable, and Re-usable". These principles serve to optimally prepare research data for re-use and, therefore, must be considered in the context of research data management and in the creation of research data management plans. However, this does not mean that the re-use of data must always be free of charge or made possible for anyone who wishes to do so.
Research data	Research data encompasses all information required to support or validate the origin, history, outcome, observations, or findings of a research activity. These are created over the course of scientific projects, e.g. through digitisation, records, experiments, source research, measurements, surveys, or interviews. Research data have different characteristics and can go through different phases over their life cycles (e.g. raw data, processed data, released data, published data).
Research data management	Research data management includes all activities associated with the collection, documentation, storage, provision, archiving and, if necessary, destruction of research data. It encompasses all phases of the research process. The data management plan is an important instrument.
FOG	Research Organisation Act (in German: *Forschungsorganisationsgesetz*, https://www.ris.bka.gv.at)
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." (Extracted from the ESF Policy Briefing "Good Scientific Practice in Research and Scholarship", p. 5). Standards for good scientific practice thus cover all aspects of scientific work, ranging from general working principles to principles of documentation, publication and authorship. They also apply to the supervision of students and young scientists and to questions about cooperation and shared responsibility in research groups. Med Uni Graz has defined its standards for good scientific practice in a guideline. https://www.medunigraz.at/frontend/user_upload/themen-forschung/pdf/Richtlinie_Good_Scientific_Practice_EN.pdf/
Personal data	Personal data include information that relates to an identified or identifiable natural person, e.g. their name, address, date of birth, national insurance number, patient ID, or health data.
Repository	A repository is a database or data archive used to store and publish digital research data. Its primary purpose is to ensure that these data are available, citable and reusable for a limited or an unlimited period of time. Appropriate rights and licence management can be used to regulate different levels of access to the research data (e.g. project-internal, inter-project and public) and to define their access and usage conditions.

Term/Abbreviation	Meaning
Right of disposal	The right of disposal is the right to use, modify, assign value to an (in-)tangible asset and to retain the resulting profits or the obligation to bear losses.

Preamble

The Medical University of Graz (Med Uni Graz) recognises the fundamental importance of research data management, including the importance of maintaining the accompanying records, to ensure high-quality research and scientific integrity. It strives to promote the highest standard in this regard in accordance with the FAIR principles. Accurate, easily retrievable and traceable research data are a fundamental and integral part of any scientific research activity. These data are also essential in that they allow research processes and results to be reviewed and defended, among other things. Research data are of lasting value to research and teaching, opening up the potential for their broad use by members of society.

Research data shall be handled exclusively in accordance with the applicable national and international legal provisions.

Due to the diversity of research data and processes, it is not possible to define uniform guidelines for the management of research data in detail (e.g. with regard to file structures, repositories, software, metadata). In addition, both the requirements and data management systems develop differently and extremely dynamically in specific research areas. For these reasons, this policy establishes general principles that are independent of research topics and will be continuously adapted as a living document to take into account current developments.

1. Scope

This research data management policy refers to the collection, documentation, processing, utilisation, storage and further use of data and applies to all persons working at Med Uni Graz (e.g. researchers, non-scientific employees involved in the research process, students, doctors and employees of the University Hospital Graz and guest researchers) and their research activities. In principle, the policy also applies to those research activities that are promoted, financed, or materially supported by a third party and should be reflected in the corresponding contracts insofar as possible. If questions arise, the provisions established in the specific contract take precedence over the provisions of this policy.

2. Usage rights

Med Uni Graz is entitled to exercise the unrestricted right to use data generated on behalf of or in the interest of Med Uni Graz for commercial and non-commercial purposes of exploitation with regard to all types of exploitation, including the right to edit these data, without any restrictions in terms of time and place. Section 106 (2) and (3) of the UG (Universities Act, in German: *Universitätsgesetz*) and the applicable provisions of the Patent Act (in German: *Patentgesetz*) apply to service inventions. The authors or inventors retain the legally reserved right to be named, the right to receive remuneration for service inventions, the right of university staff to independently publish scientific work and the right to be named as a (co-)author in the publication of research results.

Insofar as the primary right to use the data is contractually granted to third legal entities (e.g. in the case of contract research agreements), it must be ensured that Med Uni Graz is in any case granted those rights of disposal over the data that are necessary to fulfil its data storage obligations to support good scientific practice. Furthermore, Med Uni Graz should be granted the right to use the results generated over the course of research activities for non-commercial research, teaching and, if possible, patient care.

In order to comply with data protection regulations, the transfer of personal data to third parties is only permissible if the consent of a data clearing house is provided and with respect to legally compliant contractual agreements. The personal data to be reviewed should also include genetic and biometric data as well as data derived from biological material. The legality of the transfer of personal, pseudonymised, or anonymised data to third parties must be reviewed during the contractual review as part of the third-party funding process. If a data transfer is planned that is not regulated by a project contract, the research management must be informed in order to initiate a separate review, decision and, if necessary, contractual regulation process. The research management also represents the liaison to the Med Uni Graz data protection officer.

Where possible and appropriate, research data must be provided with a corresponding licence to use the work in order to enable the re-use of these data, provided that no third-party rights, legal obligations, or disposal rights conflict with this re-use. In any case, compliance with any specifications issued by funding agencies regarding the type of licence to be granted must be ensured.

3. Handling research data

3.1. Basic information

Research data and their metadata must be kept accurately, completely and reliably in accordance with good scientific practice to ensure the traceability of these data. Furthermore, efforts must be made to ensure the identifiability, findability, availability and, wherever possible, re-usability and interoperability of these data. If possible, the data should be given permanent identifiers.

Records need to be kept of the methodology used to obtain the data, their processing (such as corrections, calculations, transformations, statistical analyses) and quality control measures. These records are considered as part of the data and should be archived together with these (metadata).

The retention period for research data and records is – unless other legal regulations apply - dated least ten years either from the date of publishing the research results or, if no publication takes place, from the date of completing the relevant research activity. Justified deviations may result from the legal regulations (e.g. patent law, pharmaceutical law, requirements for the documentation of patient care), the requirements of third-party funding providers, or specific guidelines issued by the Rectorate.

If research data and records are deleted or destroyed, this must be done in accordance with all legal and internal university requirements and in consideration of the aspect of traceability. The interests of other stakeholders (e.g. funding bodies) as well as aspects of confidentiality and security must be taken into account.

Research data management must be organised at each organisational unit to ensure that individual persons can find and access certain data but also to guarantee the findability and accessibility of the data, even in the absence of individual persons involved in the research process. In justified cases and in accordance with good scientific practice, it must be ensured that direct access (e.g. for managers, project leaders) or indirect access (e.g. for co-authors of joint manuscripts/publications, project partners, research-supporting institutions, authorities) can be granted to relevant original data. Such access may be necessary, e.g. to complete manuscripts or

to answer questions that arise (e.g. with regard to validation, traceability and quality assurance). In any case, it is recommended that data management plans be drawn up at the beginning of specific research projects and that these plans also be developed independently of the funding bodies' specifications with regard to their research projects. Data management plans for funded research projects should be deposited in the Research Portal (in German: *Forschungsportal*). The use of external repositories must be indicated in the data management plan.

If third parties (e.g. funding bodies or journal editors) make requirements in this regard, research data must be stored and made accessible in a suitable repository, taking aspects of data protection into account.

3.2. Handling personal data

During research activities at Med Uni Graz, personal data are also processed (e.g. data from patients, test persons and employees). Personal data are placed under special protection by data protection regulations. Therefore, they should be processed and used properly, taking due care in accordance with the legal provisions. When dealing with health data and other sensitive data, the increased requirements of the data protection regulations must be met.

Compliance with the General Data Protection Regulation (in German: *Datenschutzgrundverordnung*, DSGVO), the Austrian Data Protection Act (in German: *Datenschutzgesetz*, DSG) and the Research Organisation Act (in German: *Forschungsorganisationsgesetz*, FOG) as well as any relevant Med Uni Graz guidelines (e.g. the guideline for data protection and IT security) must be ensured. This applies to the processing of electronic data as well as to information that is not processed through automation (e.g. on paper).

4. Responsibilities, rights and duties

The responsibility with regard to research data management during and after a research activity is carried by Med Uni Graz and its researchers and the research support staff.

4.1. Responsibilities of the researchers

The following tasks are the responsibility of the researchers:

a. Management of research data within their own area of authority and in the sense of this policy

b. Creation of data management plans

c. Collection, documentation, storage, provision, archiving and, if necessary, destruction of the research data

d. Fulfilment of the requirements of clients, sponsors, or funding bodies in this respect.

e. Compliance with all legal, contractual and internal Med Uni Graz regulations regarding research data, data protection, IT security and good scientific practice

4.2. Responsibilities of Med Uni Graz

Med Uni Graz as an institution undertakes the responsibility to create conditions that enable staff to fulfil the requirements of this policy by promoting measures that support research.
The following tasks are the responsibility of Med Uni Graz as an institution:

a. Provision of policies and guidelines for the correct handling of research data

b. Measures to raise awareness about the importance of research data management

c. Training and continuing education offers in the field of research data management

d. Advice on the collection, documentation, storage, provision, archiving and, if necessary, destruction of research data

e. Provision of templates for data management plans as well as advice and training on the creation and maintenance of data management plans

f. Establishment and operation of specific infrastructures and technical support regarding financial possibilities

g. Advice and training on data protection, placing a special focus on personal data

h. Establishment of central institutions, such as the Data Protection Officer, internal university Data Protection Advisory Board, Data Clearing Unit, Ethics Commission

5. Validity

This policy was adopted by the Rectorate on 19 January 2021 and is valid from the date of publication in the official university gazette (*Mitteilungsblatt*). It will be reviewed for validity at least every three years and adapted if necessary.

We draw attention to the fact that this English translation is provided for convenience purposes only and that the German original is the only legally binding version.