MEDICAL UNIVERSITY OF VIENNA

Medical University of Vienna

Policy for Research Data Management

Version 1.1

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Glossary

Term/Abbreviation	Meaning
Data Clearing House	Before each transfer of personal data from MedUni Vienna to third parties the Data Clearing House reviews whether this is permissible under the applicable data protection laws, contractual provisions and MedUni Vienna's internal requirements and whether measures need to be taken before the data are transferred. The personal data to be reviewed include genetic and biometric data as well as data derived from biological material. Furthermore, the data clearing office reviews data that have already been anonymized or pseudonymized before they may be passed on to third parties. https://www.meduniwien.ac.at/web/en/about-us/organisation/committees/data-clearing-house/
Data management plan (DMP)	A data management plan is a structured guideline for the management of research data and thus an essential instrument of research data management. It describes which data are collected or generated in the course of a research project and how they will be handled during their further life cycle (storage, publication, citability, long-term availability, anonymization, deletion, etc.). The aim of using a DMP is to meet the requirements of good scientific practice and to make research results traceable in the long term (see FAIR principles).
Austrian Data Protection Act (*Datenschutz-gesetz*-- DSG)	The Austrian Act on the Protection of Personal Data (***Bundesgesetz über den Schutz personenbezogener Daten***) https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10001597
General Data Protection Regulation (GDPR)	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) https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=OJ:L:2016:119:FULL&from=EN
Third Parties	A natural person or legal entity, authority, institution or other body that is not affiliated with MedUni Vienna
FAIR-Principles	Under the „FAIR Data Principles“ (Guidelines on FAIR Data Management in Horizon 2020) research data must be "Findable, Accessible, Interoperable, and Reusable". These principles serve to optimally prepare research data for reuse and must therefore be taken into account in the context of research data management and in the preparation of research data management plans.

Term/Abbreviation	Meaning
Research data	Research data are defined as all information required to support or validate the origin, history, results, observations or findings of a research activity. They are created in the course of scientific projects, e.g. through digitization, recording, experiments, source research, measurements, surveys or interviews. Research data have different characteristics and can pass through different phases in their life cycle (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. An important instrument is the data management plan.
Good Scientific Practice (GSP)	Good Scientific Practice – Ethics in Science and Research; Guidelines of the Medical University of Vienna. https://www.meduniwien.ac.at/web/en/rechtliches/good-scientific-practice/
Personal Data	Personal data include any information relating to an identified or identifiable natural person, e.g. name, address, date of birth, social security number, patient ID, health records, marital status, etc.
Repository	A repository is a database or data archive for storing and publishing digital research data with the primary purpose of preserving them for an unlimited period of time and keeping them available, citable and reusable. Through appropriate rights and license management, different levels of access to the research data (e.g., project-internal, cross-project, and public), as well as their access and usage conditions can be managed.
Right of disposal	The right of disposal is the right to use, modify or exploit a tangible or intangible asset and to retain the resulting profits and the obligation to bear losses, respectively.

1 Preamble

The Medical University of Vienna (MedUni Vienna) recognizes the fundamental importance of the management of research data and their accompanying records for high quality research and scientific integrity, and strives to promote the highest standards in this regard in accordance with the FAIR principles. Research data that are accurate and easily retrievable are the foundation and a fundamental component of any research activity. They are essential for reviewing and defending the research process and the research result, as well as for reuse of the data.

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

2 Scope of Application

This policy for the management of research data refers to the collection, processing, utilization, storage and reuse of research data and applies to all persons working at MedUni Vienna (e.g. researchers, employees, students and visiting researchers). If the specific research activity is promoted, financed or sponsored by a third party and the underlying contract contains special provisions regarding the research data, the provisions of the specific contract shall take precedence over the provisions of this Policy.

3 Rights of Use

Unless otherwise agreed in writing, MedUni Vienna shall be entitled to the scientific and commercial use of data collected and processed in the course of research activities. This shall not affect patent rights or other rights (of disposal). The authors or inventors retain the legally reserved right to be named, the right to service inventor remuneration, the right of university members to independent publication of scientific work as well as the right to be named as co-author in the publication of research results.

If the primary right to use the data is contractually granted to a legal entity other than MedUni Vienna (e.g. in the case of contract research agreements), it must be ensured that MedUni Vienna is in any case granted those rights of disposal over the data that are necessary to fulfill its obligation of storing the data. Furthermore, it must be ensured that MedUni Vienna is granted the right to use the results generated in the course of the research activity for non-commercial research and teaching.

In order to comply with data protection, the transfer of personal data to third parties is only permitted with the consent of the MedUni Vienna's Data Clearing House and in compliance with contractual agreements in compliance with the law. The personal data to be reviewed by the Data Clearing House also include genetic and biometric data as well as data derived from biological material. Furthermore, the Data Clearing House reviews data that has already been anonymized or pseudonymized before it may be passed on to third parties.

If required by the funding body, research data must be provided with a free license and made openly available for reuse, unless third-party rights, legal obligations or rights of disposal require otherwise.

4 Handling of Research Data

4.1 General Principles

Research data must be maintained in an accurate, complete, unaltered and reliable manner. Furthermore, identifiability, retrievability, availability and, wherever possible, reusability and interoperability must be ensured. If possible, the data must be provided with persistent identifiers.

Records must be kept of the methodology used to obtain the data, its processing (such as corrections, calculations, transformations, statistical analyses), and quality control methods.

The retention period for research data and records shall be at least ten years either from the publication of the research results or from the completion of the relevant research activity, unless provided otherwise by law. Justified deviations may result from legal provisions (e.g. patent law), requirements of third-party funding bodies or guidelines of 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 under the aspect of traceability. The interests of other involved parties (e.g. funding bodies) as well as aspects of confidentiality and security must be taken into account.

Research data must be made accessible within the MedUni Vienna's area of disposition. If required by third parties (e.g. funding bodies or journal editors), research data must be stored and made accessible in a suitable repository, taking into account data protection. The use of an external repository must be reported to MedUni Vienna by means of a data management plan (DMP).

Persons working at MedUni Vienna (e.g. researchers, staff and students) and other authorized persons (e.g. institutions funding research; authorities) must have access to the original data in order to be able to answer questions that may arise (e.g. for validation, reproducibility and quality assurance).

4.2 Handling of Personal Data

Personal data are also processed in the course of research activities at MedUni Vienna (e.g. data of patients, test persons and employees). Personal data are specially protected by data protection regulations. They must therefore be properly processed and used with due care in accordance with the legal provisions. When dealing with health data, the increased requirements of data protection must be met.

The Austrian Data Protection Act (DSG) and the General Data Protection Regulation (GDPR) must be obeyed at all times. This applies to the processing of electronic data as well as to information that is not processed automatically (e.g. on paper).

Aware of its responsibility, MedUni Vienna has central facilities and internal guidelines (e.g. Good Scientific Practice) that aim to ensure the uniform handling of research data.

5 Responsibilities, Rights and Obligations

The responsibility for research data management in the context of a research activity lies with both the researchers and the MedUni Vienna in accordance with the guidelines of the MedUni Vienna.

5.1 Responsibilities of the Researchers

The following duties fall under the responsibility of the researchers:

a. Preparation of data management plans[1]
b. Management of research data
c. Adherence to appropriate policies and guidelines with particular attention to data protection measures (e.g., defining access rights, storage locations, etc.)
d. Collection, documentation, storage, provision, archiving, and, if necessary, destruction of research data
e. Meeting the requirements of clients, sponsors, or funding agencies
f. Compliance with all legal, contractual and internal MedUni Vienna regulations regarding research data

5.2 Responsibilities of MedUni Vienna

MedUni Vienna undertakes to create the conditions for the fulfillment of this Policy by promoting research-supporting practices.

The following duties fall under the responsibility of MedUni Vienna:

a. Measures to raise awareness of the importance of research data management (e.g. Third Party Funding Manual, Good Scientific Practice)
b. Provision of directives for the uniform handling of research data
c. Offering education and training in the area of research data management
d. Provision of templates for data management plans, as well as guidance and training on creating and maintaining data management plans
e. Technical assistance, according to financial possibilities, and advice on the collection, documentation, storage, retrieval, archiving, and, if necessary, destruction of research data
f. Provision of a processing directory in accordance with Art. 30 of the GDPR
g. Advice and training on data protection with special attention to personal data
h. Establishment of central institutions such as the intramural Data Protection Commission, the Data Clearing House, an ethics commission, and a data protection officer

[1] The use of an external repository must be listed in the DMP and reported to MedUni Vienna

6 Validity

This policy was slightly adapted and confirmed by the Rectorate on January 13, 2021. It will be reviewed for validity by the Rectorate of the Medical University of Vienna at least every three years.