

Policy Framework for Research Data Management (RDM)

Max-Delbrück-Centrum für Molekulare Medizin in der
Helmholtz-Gemeinschaft

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01.03.2021	2.0	Sara El-Gebali	Approved by MDC-Board

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Preamble

The Max Delbrück Center for Molecular Medicine in the Helmholtz Association (MDC) and other Health Centers of the Helmholtz Gemeinschaft recognize the fundamental importance of **research data** and its management in maintaining research excellence and scientific integrity, and are committed to pursuing the highest standards of research practice. Increased developments in computational advances, internationalization and data protection regulations present significant new opportunities and challenges in this regard.

The purpose of this policy is to provide a framework that defines the responsibilities of the MDC-management and its researchers, and to provide guidance for the proper management of research data throughout its full life cycle. This includes promoting data sharing and re-use to the widest extent feasible, in order to maximize research transparency, quality and impact.

The MDC is committed to a goal of making data created as part of the research process compliant with the FAIR principles [1]. Data should be: **F**indable, **A**ccessible, **I**nteroperable and **R**eusable. Implementation of this policy also aims to ensure conformity with pertinent legal obligations, ethical responsibilities and the rules of funding bodies, including the:

- Helmholtz Association position paper [2] and guidelines [3] on research data management research software
- Guidelines of the German Research Foundation for handling research data [4] and good scientific practice [5]
- Federal Data Protection Act [6]
- Berlin Data Protection Act [7]
- EU Open Science Policy [8]
- EU General Data Protection Regulation [9]

1. Jurisdiction

This policy was developed based on consensus discussion among working group members from the Helmholtz Health Centers, and was approved by the MDC board of directorates on 01.03.2021. It applies to all researchers active at the MDC. In cases when research is funded by a third party, any agreements made with that party concerning intellectual property rights, access rights and the storage of research data take precedence over this policy.

2. Intellectual property rights

Intellectual property rights and ownership determine the basic conditions for use and sharing of research data. The MDC technology transfer office serves as the first point of contact regarding Intellectual Property Rights (IPR) questions about research data/results and initiates suitable protection measures where appropriate.

3. Handling research data

Researchers are strongly encouraged to develop a written Data Management Plan (DMP) at the design stage of each project, even when not specifically required with the assistance and support of the Research Data Management unit.

Data storage

Research data must be stored in a correct, complete, unadulterated and reliable manner in order to preserve its integrity. Furthermore, data must be identifiable (including through use of persistent identifiers), accessible, traceable, interoperable and, whenever possible, available for subsequent use. All research data generated and elaborated at the MDC must be stored at the MDC, in the institutional storage systems, with secure backup storage. Data may be also archived/shared in reliable trusted external repositories, in addition to the institutional storage, under written agreement. Incoming data from other institutions or repositories to be stored at the MDC must be accompanied by appropriate written agreements in consultation with the Legal department and the Data Protection Office. Storage infrastructures should be compliant with best practices in the field as well as technical specifications per legal requirements.

Where research involves the collection, processing and/or use of identifiable personal data, the storage and sharing of the data must comply with relevant ethical, legal, disciplinary and regulatory requirements and be in line with the consent under which the data was collected or provided.

Research data and related material should be retained for a minimum of ten years after acquisition or generation based on the recommendation of the DFG (in English [10], German [11]). Longer or shorter retention periods prevail in accordance to legal regulations, funders' and other contractual requirements (e.g. clinical trials, patents).

Data access and re-use

The MDC supports access to research data following the European Commission for Open Data principle [12], "as open as possible, as closed as necessary". This includes not only the data/dataset itself, but also elements such as **metadata**, methods, protocols and software/code needed to support effective data use. The use of open-source software/code to support analysis is strongly encouraged in-line with European Open Science guidelines [13] and recommendations.

When licensing is indicated to allow data sharing and re-use, the data should be made available under an open license, unless legal obligations, third party rights, intellectual property rights and privacy rights preclude this (e.g. Creative Commons [14] and licenses approved by the Open Source Initiative [15]).

In publications and any other presentations of data, the data sources (original and subsequently-used) must be acknowledged and traceable in accordance with the MDC publication policy, see table Related Documents.

Deletion of data

Deletion or destruction of research data and records, either after expiration of the retention period or for legal or ethical reasons, has to be carried out considering contractual obligations of third-party funders and other stakeholders, including collaboration partners. Such actions should be documented and be accessible for future audit. Backup data copies should also be deleted. Automated deletion of research data is to be avoided. Plans outlining data deletion and destruction should be documented and agreed upon between the principal investigators or data producers with the IT department; see section 5 for more details on roles and responsibilities.

4. Responsibilities, rights, duties

MDC-Management, Principal Investigators (PIs) and all researchers at the MDC, hold the primary responsibility for compliance with this policy and the responsibility for research data management during and after a research project.

Furthermore, compliance with the “Guidelines for Safeguarding Good Scientific Practice” of the German Research Foundation (DFG) and the “Rules for safeguarding good scientific practice at the Max Delbrück Center for Molecular Medicine (MDC)” as well as relevant policies and guidelines, see table Related Documents, should be taken into account in all aspects of research activities.

In cases where research is funded by a third party, any agreements made with that party concerning intellectual property rights, access rights and the storage of research data take precedence over this policy.

Principal Investigators and Researchers are responsible for:

- a) Management of research data and data sets through their life cycle in adherence with principles and requirements expressed in the MDC’s policies, see table Related Documents.
- b) Definition of the DMPs including responsible person(s), general responsibilities and decisions (e.g. about sharing/access, central storage of data, data deletion, quality of content, definition of formats). This responsibility lies with the Principal Investigator(s) generating the data.
- c) Allocation of appropriate resources (time and financial resources) for data management in grant proposals.
- d) Registration of proposals for third party funded projects with the Research Funding Department [16] of the MDC, to ensure appropriate institutional support.
- e) Collection, documentation, archiving, access to and storage or proper destruction of research data and research-related records. This also includes the definition of protocols and responsibilities within a joint research project. Such information should be included in a DMP, as well as in protocols that explicitly define the collection, administration, integrity, confidentiality, storage, use and publication of data that will be employed.
- f) Compliance with the general requirements of the funders and the research institution.
- g) Planning to enable, wherever possible, the continued use of data even after project completion. This includes defining post-project usage rights, with the assignation of appropriate licenses, as well as the clarification of data storage and archiving in the case of discontinued involvement of the researcher(s) at the MDC.

- h) Acknowledgment of data sources and abiding by the terms and conditions under which original data was accessed.

The MDC is responsible for:

- a) Provisioning its researchers and research groups with a basic research infrastructure that includes tools and services for supporting the management, use, findability and sharing of data as well as with the capacity for appropriate storage, preservation, computing and processing. Provisioning of specific requirements by the researchers to carry out their research activities, are taken into consideration and require detailed discussions by all stakeholders involved (e.g. including the researchers, RDM, IT and purchasing).
- b) Providing support, training, guidance and advice on research data management starting from planning to execution and thus enable researchers to exercise their responsibilities outlined above and to comply to requirements of third-party funders and other legal entities.
- c) Supporting retention of research data sets and related metadata and software in the appropriate format in line with its agreed policy and those of its research funders.
- d) Supporting the identification and resolution of legal issues to research data.
- e) Allocation of appropriate and sufficient workforce as well as financial support for IT and RDM activities.

5. Definitions

Research is any creative and systematically performed work with the goal of furthering knowledge, including discoveries regarding people, culture and society, in addition to the use of such knowledge for new applications.

Principal investigator is the most senior researcher associated with the research and the primary individual responsible for the research project implementation, management and integrity of the design, conduct, and reporting. Additionally, the PI holds the responsibility for the direction and oversight of compliance.

Researchers refers to all members of an institution including employed scientists, students and support staff as well as others with a formal affiliation at [*name of research institution*], who have access to, generate and/or manage research data. Visiting researchers or collaborators may also be expected to comply with the policy.

Research data refers to all information (independent of form or presentation) needed to support or validate the development, results, observations or findings of a research project, including contextual information. Research data include all materials that are created in the course of academic work, including digitization, records, source research, experiments, measurements, surveys and interviews. This includes methods/protocols, metadata, software and code. Research data can take on several forms: during the lifespan of a research project, data can exist as gradations of raw data, processed data (including negative and inconclusive results), shared data, published data and Open Access published data, and with varying levels of access, including open data, restricted data and closed data.

Metadata [17] is data providing information about data that makes findable, trackable and (re)usable. It can include information such as contact information, geographic locations, details about units of

measure, abbreviations or codes used in the dataset, instrument and protocol information, survey tool details, provenance and version information and much more.

Data sharing is the practice of making scientific data used for scholarly research available to others, for research re-use or in knowledge transfer activities (e.g. researchers, institutions, the broader public).

The general outline and some text in this policy were adopted from the resources of the LEARN Project (<http://learn-rdm.eu/en/learn-policies-and-data-management-plans/>).

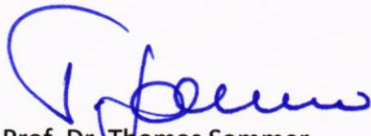
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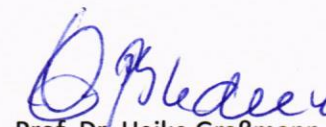
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Berlin, 01.03.2021

MAX-DELBRÜCK-CENTRUM
FÜR MOLEKULARE MEDIZIN
IN DER HELMHOLTZ-GEMEINSCHAFT



Prof. Dr. Thomas Sommer
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7. Appendix

Table: Related documents

Document name	Description	Location
Data Management Plan (DMP)	In progress	
Data protection Guidelines	Data protection guidelines at the MDC	here
Data Protection Policy	In progress	
Process notification	Record of Processing Activities	here
Information security	In progress	
Data Storage, Archival and Deletion	In progress	
Good Scientific Practice	Rules for safeguarding good scientific practice at the Max Delbrück Center for Molecular Medicine (MDC)	here
MDC Publication Policy	Guidelines for standardized presentation of the MDC affiliation in publications	here
Open Access policy	Open Access Policy of the Helmholtz Association, 2016	here
Good Scientific Practice of the DFG	Guidelines for Safeguarding Good Scientific Practice of the German Research Foundation (DFG)	here