Regulations for the Use of the Core Unit Research Data Management (cRDM)

at the IZKF, University Hospital Würzburg (UKW)

Effective: January 2025
~~~ Only the German version is legally binding ~~~

1. General Information

The **Core Unit Research Data Management (cRDM)** is a central facility of the Medical Faculty of Würzburg and the Interdisciplinary Center for Clinical Research (IZKF).
Its mission is to provide a **sustainable, FAIR- and GDPR-compliant research data management (RDM) infrastructure** for clinical and pre-clinical research at the University Hospital Würzburg (UKW) and the Julius-Maximilians-University (JMU).

The cRDM supports researchers in **organizing, documenting, analyzing, and publishing** their data in accordance with the **FAIR principles** — *Findability, Accessibility, Interoperability, and Reusability* — and institutional IT and data protection policies.
These regulations define the conditions for use, user obligations, and cost principles for all cRDM services.

2. Services of the Core Unit Research Data Management

The cRDM provides researchers with the following services and infrastructures:

- **Consultation and RDM Planning**
  Development of project-specific Research Data Management Plans (DMPs) and metadata concepts in compliance with DFG and NFDI guidelines.
- **FAIR Onboarding and Structured Questionnaires**
  Guided onboarding via digital questionnaires integrated into individual DMPs, assessing data types, storage, documentation, metadata standards, infrastructures, and repository planning.
- **Infrastructure and Collaboration Tools**
  - *Nextcloud:* secure data storage, versioning, and sharing
  - *OnlyOffice:* collaborative document editing
  - *Labfolder (ELN):* structured experimental documentation and metadata templates
  - *HPC / JupyterHub:* computational analysis environment

- **Metadata and Standardization Support**
  Alignment with community standards (e.g., Dublin Core, Darwin Core, REMBI, FHIR, bioschemas).
- **FAIR-Compliant Publication Support**
  Guidance for repository selection (e.g., ArrayExpress, IDR, HDP), DOI/PID assignment, and data citation.
- **Training and Capacity Building**
  Workshops, user meetings, and targeted support for researchers and consortia.

3. Administration and Contacts

Scientific leadership:
Prof. Dr. Philip Tovote (Systems Neurobiology, Institute for Clinical Neurobiology)
Prof. Dr. Katrin Heinze (Rudolf-Virchow-Zentrum for Integrative and Translational Bioimaging)

Operational management and coordination:
Dr. Johannes Balkenhol, Dr. Nina Schukraft, Hamidreza Alimohammadi

✉ Email: coreunitrdm@uni-wuerzburg.de
🌐 Website: https://www.med.uni-wuerzburg.de/fdm/

4. Access and Registration

All members of the Medical Faculty, UKW, and JMU are eligible to use cRDM services. Access requests must be submitted via the **electronic cRDM Inquiry Form** on the cRDM website.

After registration, users are invited to an onboarding meeting where project-specific needs, technical access (Nextcloud, Labfolder, HPC/JupyterHub), and DMP development are discussed.
External researchers and collaborating consortia may obtain access upon agreement with the cRDM management.

5. Onboarding and Data Management Plans (DMPs)

Each use case is accompanied by an individualized **Research Data Management Plan (DMP)**.
The DMP is developed jointly by the researchers and cRDM data stewards using a **structured digital questionnaire** that follows the full RDM lifecycle, addressing:

- **Basic information:** project title, funding, consortium, contact persons
- **Data characterization:** types, volumes, formats
- **Storage and infrastructure:** local, cloud, or HPC storage options
- **Documentation and metadata:** standards (e.g., Dublin Core, Darwin Core), ELN templates, file naming conventions
- **Publication and repositories:** timing, repository selection, embargo periods, and licensing
- **Compliance and data protection:** GDPR, institutional policies, NFDI affiliation

This questionnaire serves as both a **needs assessment** and **awareness-building tool**, enabling researchers to identify available infrastructures and FAIR compliance gaps, while informing the cRDM team about required support measures.

6. User Categories

User groups are classified according to institutional affiliation and funding context:

- **Internal users:** Researchers of the Medical Faculty, UKW, and JMU
- **Consortium users:** Researchers within DFG- or IZKF-funded projects
- **External users:** Collaborating institutions and partners

7. Use of Infrastructure

Access to Nextcloud, OnlyOffice, Labfolder, and JupyterHub is granted after successful onboarding and DMP registration.
Each user receives individual login credentials and must adhere to institutional IT and data security policies.

The cRDM ensures **role-based access control, version tracking, and regular backups** in cooperation with the Rechenzentrum (RZ, JMU) and the SMI (UKW).

8. Data Handling and Storage Policy

Users are responsible for the correctness, completeness, and legal compliance of uploaded data.
Data containing personal or patient information must only be handled in **approved GDPR-compliant environments** (e.g., FEX, HDP).
Temporary storage on local devices is discouraged.

Data retention and publication timelines are defined within the individual DMP.
Unauthorized data access or sharing is strictly prohibited.

9. Compliance and Legal Framework

All users must adhere to:

- The **General Data Protection Regulation (GDPR)**
- **Good Scientific Practice** (DFG Guidelines)
- The **FAIR Data Principles**

Data management must comply with institutional IT security and backup policies, the **NFDI** recommendations, and any specific consortium or funder requirements.
The cRDM reserves the right to revoke access in cases of non-compliance or data misuse.

10. Training and Awareness

The cRDM provides continuous training for users at all levels:

- FAIR-RDM and ELN onboarding
- Data management workshops and office hours
- Customized sessions for consortia and early-career researchers

Participation in **introductory FAIR-RDM training** is mandatory for all new users.

11. Acknowledgment in Publications

When data, workflows, or infrastructure from the cRDM are used in scientific publications, users must include the following acknowledgment:

"We thank the Core Unit Research Data Management (cRDM) of the Medical Faculty, University of Würzburg, for support in data management, FAIR planning, and infrastructure provision."

In cases of substantial intellectual contribution, cRDM members should be included as **co-authors**.
A PDF copy of the publication must be provided to the cRDM management.

12. Liability

Users and their respective institutes are liable for any damage caused by improper use or negligence in data handling or infrastructure access.
The cRDM is not responsible for data loss resulting from user-side errors or local storage failures.

13. User Fees and Financing Model

The cRDM follows a **hybrid financing model** ensuring sustainability through institutional base funding, project-based cost recovery, and targeted development funds.

Annual user contributions follow a **tiered cost-sharing model**:

Tier	Typical Users	Scope	Internal (€)	External (€)
Bronze	< 15 users	100 GB storage, basic support	0–1,000	1,000–1,500
Silver	15–25 users	+ OnlyOffice collaboration	3,000–4,000	4,000–5,000
Gold	> 25 users	+ Nextcloud Enterprise & monitoring	7,000–8,000	8,000–9,000
Consortia	DFG/EU projects	Full infrastructure access	~10,000	—

Fees cover **system maintenance, secure storage, hosting (RZ/SMI), and enterprise licenses**.