Open Access Policy and Procedures for German Medical Institute Research Infrastructures

Date	Issued by	Approved by
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1. Introduction

The German Medical Institute maintains a portfolio of clinical and translational research infrastructures designed to support high-quality research at national and international level. This policy establishes the framework governing access to these infrastructures, ensuring that access is granted in a transparent, fair and accountable manner while safeguarding patient safety, data protection and operational sustainability. The policy is aligned with national Open Access principles for publicly funded research infrastructures and supports the broader objectives of Open Science, including maximising the impact of public investments and strengthening collaboration between academia, healthcare and industry.

2. Scope of Application and Definition of Research Infrastructures

This policy applies to all research infrastructures operated or hosted by the Institute, including clinical trial units, laboratories, imaging facilities, biobanks, digital platforms and high-performance computing resources, as well as any associated support services. It governs access for both internal users and external stakeholders, including academic institutions, research organisations, public bodies and industry partners.

For the purposes of this policy, research infrastructures are understood as facilities, resources and services used by the research community to generate knowledge and support innovation. These include physical installations, specialised equipment, digital systems, data repositories and technical or scientific support services required for the execution of research activities.

3. Policy Principles

Access to research infrastructures is guided by principles of transparency, equal treatment and scientific excellence. Decisions are based on objective and predefined criteria, ensuring that all applicants are assessed fairly and consistently. The Institute promotes the efficient use of publicly funded resources, while supporting collaboration, innovation and the generation of

measurable scientific and societal impact. Data management practices follow recognised FAIR principles, and all activities are conducted in compliance with ethical standards, regulatory requirements and applicable data protection legislation. Open access is understood as structured and regulated access, and does not imply unrestricted or unconditional use of infrastructure resources.

4. Eligibility and User Categories

Access may be requested by a broad range of users, including Institute-affiliated researchers and clinicians, academic institutions, research organisations, public authorities, non-profit entities and private sector organisations. International research networks and individual researchers may also be considered where appropriate. Industry participation is supported under clearly defined contractual conditions, ensuring alignment with institutional objectives and regulatory requirements.

5. Conditions for Access and Pricing

Access is granted following submission of a complete request demonstrating scientific merit, technical feasibility and compliance with ethical and regulatory requirements. Availability of infrastructure capacity and acceptance of applicable contractual terms are also required.

A structured pricing approach is applied in order to ensure sustainability and compliance with applicable financial regulations. Depending on the nature of the activity and the user category, access may be provided on a full-cost, partial-cost or no-cost basis. Publicly funded research projects and strategic collaborations may benefit from reduced or waived fees, while commercial activities are typically subject to full cost recovery. All pricing is based on a documented costing methodology and ensures appropriate separation between economic and non-economic activities where required.

6. Access Request and Evaluation Process

Requests for access are submitted through a standardised application process and must include a detailed description of the proposed activity, methodological approach, infrastructure requirements, ethical status and expected outcomes. Applications are first reviewed for completeness and then evaluated on the basis of scientific quality, feasibility, regulatory compliance and expected impact.

The evaluation process involves technical assessment by the relevant Infrastructure Lead, verification of compliance by the Department of Research and Innovation and final decision-making by the Research Committee. Decisions are formally documented and communicated to applicants. Where appropriate, conditional approvals may be issued subject to specific requirements. Applicants may request clarification or submit an appeal, which will be reviewed through a formal re-evaluation process.

7. Prioritisation

In cases where demand exceeds available capacity, access is prioritised based on objective criteria, including scientific excellence, strategic relevance, availability of external funding and potential impact. This ensures that infrastructure resources are allocated in a manner that maximises overall value and institutional benefit.

8. Contractual Arrangements and Implementation

Approved access is formalised through a contractual agreement defining the scope of use, responsibilities of the parties, financial conditions, intellectual property provisions, confidentiality obligations and reporting requirements. Operational arrangements, including scheduling, onboarding and safety procedures, are coordinated prior to the commencement of activities.

9. Responsibilities of Users

Users are required to conduct activities strictly in accordance with the approved project and to comply with all institutional policies, safety standards and regulatory obligations. They are expected to maintain accurate records, report any deviations or incidents and appropriately acknowledge the use of the infrastructure in all resulting outputs.

10. Data Management and Dissemination

Research data generated through infrastructure use is managed in accordance with applicable legislation and institutional policies. The Institute promotes responsible data sharing and encourages dissemination of results through open access channels, where legally and ethically permissible. Where necessary, embargo periods may be applied prior to publication.

11. Intellectual Property and Confidentiality

Intellectual property arising from the use of research infrastructures is governed by institutional policies and specific contractual agreements. Provisions may include co-ownership arrangements, licensing rights and defined publication conditions. All confidential information is protected throughout the duration of the project and beyond, in accordance with applicable legal and contractual obligations.

12. Limitations and Restrictions

Access may be limited or restricted due to safety considerations, protection of sensitive data, intellectual property constraints, limited resource availability or technical requirements. Additional restrictions may apply where specialised operation or certified personnel are required. Prioritisation mechanisms are implemented where necessary to ensure fair and efficient allocation of resources.

13. Monitoring and Governance

The Institute maintains a structured monitoring system to oversee the use of research infrastructures and ensure compliance with approved conditions. Key performance indicators are collected, including number of access requests, utilisation rates, external collaborations, scientific outputs and revenue generated from services. Overall governance is ensured by the Research Committee, supported by Infrastructure Leads, the Department of Research and Innovation and the Quality Assurance function.

14. Registration and Visibility

The Institute ensures that its research infrastructures are registered and maintained in the national Research Infrastructure Registry platform. Information is kept up to date to facilitate visibility, accessibility and collaboration at national and international level.

15. Review of the Policy

This policy and the associated procedures are reviewed periodically and updated as necessary to reflect regulatory, organisational, or strategic developments.

Annex I – Standard Operating Procedure (SOP): Access to Research Infrastructures

1. Purpose

This Standard Operating Procedure describes the process through which access to the Institute's research infrastructures is requested, evaluated, approved, implemented, monitored, and formally closed. The procedure is intended to ensure consistency, transparency, traceability of decisions, and compliance with applicable ethical, legal, regulatory, and quality requirements.

2. Scope

This SOP applies to all research infrastructures operated or hosted by the Institute and to all requests for access submitted by internal or external users for research-related activities.

3. Definitions

For the purpose of this SOP, research infrastructure refers to any facilities, resources and services used by the research community to generate knowledge and support innovation. These include physical installations, specialised equipment, digital systems, data repositories and technical or scientific support services required for the execution of research activities. The applicant is the individual or organisation submitting an access request. The Infrastructure Lead is the person responsible for the operational management of a specific infrastructure. The Research Committee is the body responsible for the final decision on access requests.

4. Responsibilities

Applicants are responsible for submitting complete, accurate, and truthful information and for complying with the conditions of access once approval is granted. The Department of Research & Innovation coordinates the access procedure, performs administrative checks, and serves as the primary point of contact. Infrastructure Leads assess technical feasibility, capacity, and operational implications. The Quality Assurance Department oversees adherence to this SOP and ensures audit readiness. Final approval authority rests with the Research Committee.

5. Procedure Description

Access requests are submitted to the Department of Research & Innovation using the approved Access Request Form. Upon receipt, the Department of Research & Innovation performs an administrative and completeness check within ten working days. Requests that do not meet the basic documentation requirements are returned to the applicant with written feedback. Access is provided within a structured and regulated framework and does not constitute unrestricted or unconditional use of infrastructure resources.

Requests that pass the initial check undergo scientific and technical assessment. This assessment is coordinated by the Department of Research & Innovation and carried out by the relevant Infrastructure Lead, who evaluates feasibility, capacity, safety considerations, and resource requirements. The scientific rationale and methodological soundness of the proposed activity are also reviewed to ensure that the requested use of the infrastructure is appropriate.

In parallel, ethical and regulatory verification is performed, including compliance with data protection legislation (GDPR) and adherence to FAIR data principles (Findable, Accessible, Interoperable and Reusable), where applicable. Also where applicable the approval from Cyprus National Bioethics Committee will be required.

Following completion of all assessments, a consolidated evaluation is submitted to the Research Committee. The Committee reviews the documentation and issues a decision, which may take the form of approval, conditional approval subject to specified requirements, deferral due to capacity or timing constraints, or rejection. All decisions are documented with a brief justification and communicated in writing to the applicant.

Where access is approved, the Department of Research & Innovation coordinates the formalisation of access through an appropriate agreement or contract. This agreement defines the scope of access, responsibilities of the parties, cost recovery arrangements, intellectual property provisions, confidentiality obligations, and reporting requirements. Operational onboarding, scheduling, and any required safety induction are completed before access begins.

The applicable pricing model is determined based on the category of user, type of activity and funding source, in accordance with the Institute's pricing policy.

During the period of access, use of the infrastructure is monitored to ensure compliance with the approved conditions. Any deviations, incidents, or cases of non-compliance are

documented and addressed through corrective actions as appropriate. Upon completion of the approved activity, the applicant notifies the Department of Research & Innovation, and access is formally closed.

Applicants may request clarification on decisions and have the right to submit a formal appeal. Appeals are reviewed by the Research Committee or an appointed independent body, and the outcome is communicated in writing.

Annex II – Access Request Form – Research Infrastructures

This Access Request Form is to be completed by all internal and external users requesting access to the Institute's research infrastructures. The completed form must be submitted to the Department of Research & Innovation. Incomplete forms may not be evaluated.

Section A – Applicant and Institutional Details

Principal Investigator / Responsible Person	
Position and Department	
Institution / Organisation	
Institution Category (Academic / Industry / Public / Non-profit / Other)	
Address	
Email	
Telephone	

Section B – Project Information

Project Title	
Scientific Background and Rationale	
Objectives	
Study Design and Methodology	
Expected Scientific, Clinical, Societal or Economic Impact	
Expected Start Date	
Expected End Date	

Section C – Requested Research Infrastructure

Infrastructure / Facility Requested	
Services or Equipment Required	
Estimated Duration and Frequency of Use	
Personnel or Technical Support Required	

Section D – Ethical and Regulatory Status

Ethics Committee Approval Status	
Ethics Reference Number (if applicable)	
Participant Involvement (Yes/No – describe)	
Informed Consent in Place (Yes/No)	
Other Regulatory Approvals Required	

Section E – Data Management and Protection

Type of Data Involved	
Data Classification (personal / coded / anonymised)	
Legal Basis for Data Processing	
Data Storage Location	
Data Access Control Measures	
Data Retention Period	
Data Sharing Planned (Yes/No – describe)	

Section F – Funding Information

Funding Source	
Grant or Contract Reference	
Budget Coverage for Infrastructure Use	
Intended Use of Infrastructure (Non-economic research activity / Economic activity – please specify)	

Section G – Dissemination and Open Access

Expected Outputs (publications, reports, etc.)	
Commitment to Acknowledge Infrastructure Use	
Open Access Publication Planned (Yes/No)	

Section H – Declarations

Acceptance of Institutional Policies and SOPs	
Acknowledgement of Applicable Pricing and Cost Recovery Conditions	
Conflict of Interest Declaration	
Name and Signature	
Date	