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Guidelines

Clinical Research Units

- Valid for proposals based on draft proposals submitted to the DFG prior to 31 December 2022 -

Disclaimer: The English translation of this document is provided for informational purposes. In the event of a discrepancy between the English and the German versions, the German text takes precedence.



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I Programme Information

1 Objective

Funding for a Clinical Research Unit enables outstanding researchers to collaborate

closely on specific medium-term projects whose anticipated findings could not be

achieved within the scope of individual grants programmes. The thematic focus of a Clin-

ical Research Unit is on basic, disease-oriented or patient-oriented clinical research. Fur-

thermore, measures tailored specifically to the Clinical Research Unit are pursued in

order to promote researchers in early career phases and also equity and diversity.

All other research topics are covered by the "Guidelines for Research Units" (DFG

form 50.04).

www.dfg.de/formulare/50_04

Funding should also contribute to improving clinical research by creating and strength-

ening research-oriented structures within university hospitals, establishing or enhancing

training structures, enhancing the scientific profiles of the departments of medicine, and

increasing cooperation between clinicians and scientists in the foundational disciplines

of medicine.

A Clinical Research Unit typically has fewer than ten projects which are coordinated to

enable work on a common research topic.

2 Proposals

2.1 Eligibility

A proposal for a Clinical Research Unit is prepared jointly by several researchers and

submitted by the spokesperson. Researchers must work at a university or non-university

research institution in Germany and have completed their academic training (usually with

a doctorate). Projects should aim to achieve an appropriate level of participation of fe-

male researchers corresponding to their general representation in the relevant subject

area.

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A Clinical Research Unit is primarily run by university hospitals at **one** location. Cooperation with non-university research institutions is possible if the majority of research projects are based at universities. The involvement of external scientists at other locations

or abroad is only possible in justified exceptional cases.

Researchers who work at an institution that is not non-profit, or one that does not allow immediate publication of research findings in a generally accessible form, are not eligible

to apply.

2.2 Format and deadline

Applicants must first submit a draft proposal to the DFG Head Office, which is then forwarded to reviewers. If successful, the DFG will invite the applicants to submit an establishment proposal. Draft proposals and establishment proposals may be submitted at

any time. For more detailed information on preparing your proposal, please consult the

instructions for proposals to establish or renew Clinical Research Units.

www.dfg.de/formulare/54_09

Proposals for the individual projects within the Clinical Research Unit should be submit-

ted according to the instructions for project proposals.

www.dfg.de/formulare/54_01

3 Duration

For draft proposals and proposals based on draft proposals submitted after 1 Octo-

ber 2018, note the following:

The total funding duration is generally eight years. The first funding period is generally

four years. Further funding requires the submission and approval of a renewal proposal.

4 Participants

The Clinical Research Unit consists of the leaders of the individual projects. One of the

project leaders assumes the role of **spokesperson** and agrees to coordinate the pro-

posal. They represent the Clinical Research Unit toward the DFG and third parties and

are required to submit reports to the DFG. The spokesperson should be a full-time uni-

versity teacher.

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In addition to the spokesperson, the Clinical Research Unit will also be headed by a **research coordinator**. Once the Clinical Research Unit is established, the person appointed to the research professorship assumes its scientific and administrative leadership as research coordinator. The person appointed to the research professorship must meet particular requirements with regard to his/her scientific track record, experience in leading projects (including projects with third-party funding), and integration and leadership skills. These criteria will be considered during the review process. The spokesperson or the research coordinator is responsible for managing the unit's common central-project funds, especially those for coordination.

In well justified exceptional cases and after consulting with the DFG Head Office first, the spokesperson of the Clinical Research Unit may also serve as its research coordinator and hold the research professorship.

II Proposal Modules

To apply for funding in the Clinical Research Units Programme, the **project leader** may submit the modules listed below for the individual research projects. For more details, please see the respective guidelines for each module.

1 Basic Module

Use the basic module to request funding for direct project costs, project-specific staff, and instrumentation necessary to carry out the research project. In addition to funding for purely scientific projects, Clinical Research Unit proposals may also request funding for pilot studies and other necessary patient-oriented research costs (e.g. specialised outpatient clinics, resources for building and expanding infrastructure for clinical trials, archiving of patient data).

www.dfg.de/formulare/52_01

2 Replacements

If your project requires that you be released from teaching or administrative duties, you can use this module to request funding for a replacement to take over these responsibilities.

www.dfg.de/formulare/52_03



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The following modules can be submitted by the project leaders for the individual projects in conjunction with the modules above, or by the spokesperson or research coordinator for the entire Clinical Research Unit within the coordination proposal:

3 Temporary Substitutes for Clinicians

If this project requires that clinicians conduct research, you can use this module to re-

quest funding for temporary substitutes to take over their patient-care responsibilities.

Each Clinical Research Unit must apply for lump-sum funding of **at least one** temporary substitute. The department of medicine must finance the funding for this position. The

DFG will provide lump-sum funding for one additional temporary substitute position (if

more than one such position is proposed, for 50% of all such positions).

www.dfg.de/formulare/52 04

4 Project-Specific Workshops

If you would like to conduct workshops for your projects or for the entire Clinical Research

Unit, you may request funding to help you do so.

Please use this module to request funding for all workshops and colloquiums that you

will conduct within the funding period or for a concluding colloquium. It is not possible to

submit a request for colloquium funds at a later date.

www.dfg.de/formulare/52_06

5 Mercator Fellows

This module enables you to pursue an intensive and long-term exchange with researchers in Germany and abroad. Fellows will partially be on site but will remain in contact

with the Clinical Research Unit even after their stay.

www.dfg.de/formulare/52 05

6 Public Relations

To enable you to present your work to the general lay public, you can request funding

for public relations.

www.dfg.de/formulare/52 07

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The following modules can only be submitted by the spokesperson or the research coordinator on behalf of the entire Clinical Research Unit within the coordination proposal:

7 Professorship

To support the Clinical Research Unit, a professorship may be established with advance and/or partial funding by the DFG. Such funding must enable an early professorial appointment or the implementation of a structural improvement.

The establishment of a research professorship at the site of the Clinical Research Unit **must** be part of the proposal, unless the holder of an existing research professorship will assume the scientific leadership of the Clinical Research Unit. At the time of submitting the proposal, the department of medicine must certify in writing that it will fund the unlimited continuation of the research professorship as of the second funding phase following successful evaluation, and support it for at least five years after DFG funding for the Clinical Research Unit expires (with two research assistants and two technical assistants, plus an appropriate annual allowance for consumables in the amount of €50,000).

The scientific topic of the professorship must be in line with the mission of the Clinical Research Unit. The research professor's main focus must be collaboration within the unit. For this reason, the department of medicine must exempt the research professor, upon the research coordinator's request, from any clinical obligations.

www.dfg.de/formulare/52_10

8 Coordination

This module enables the spokesperson to

- apply for the funds needed to coordinate the various projects and work within the network (coordination funding), and, irrespective of that, to
- apply for gender inclusion funding for individual and subject and/or project-related activities serving to facilitate the spokesperson's new role in conjunction with being in an underrepresented gender at the project management level in the relevant field or discipline.

If the research coordinator of the Clinical Research Unit submits the coordination proposal, the guidelines for this module apply to this person accordingly.

www.dfg.de/formulare/52_12



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9 Network Funds

Use this module to request funds for the entire network.

www.dfg.de/formulare/52_13

10 Start-Up Funding

Through this module, research networks can receive funds to help promising researchers in early career phases pursue independent projects.

www.dfg.de/formulare/52_11

11 Standard Allowance for Equity and Diversity

This module can be used to request funds for targeted and project-specific or, in this case, network-specific measures to promote gender equality for researchers and diversity in research and to make jobs in science and academia more family friendly (including care). These funds may also be used to enable research physicians and other scientists who return from parental leave to lead projects and to submit regular funding proposals for projects within the Clinical Research Unit.

www.dfg.de/formulare/52_14

Up to €15,000 per funding year may be requested as a lump sum for this purpose.

III Special Provisions

1 Co-financing and budgetary commitment

Funding for Clinical Research Units requires co-financing. Co-financing must ensure that after four years of DFG support for the proposed research professorship and a positive interim evaluation, from the fifth year on, the research professorship will be funded in full by the university's department of medicine from the state appropriations for research and education, and will be included in the regular hospital/medical department budget for at least five years after DFG funding for the Clinical Research Unit expires, along with the necessary core support to ensure scientific viability (two research assistants and two technical assistants, plus an appropriate annual allowance for consumables in the amount of €50,000);



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at least one temporary substitute position in the Clinical Research Unit (and, if more than one such position is proposed, 50% of all such positions) will be financed by the department of medicine. If one temporary substitute position is approved, the DFG will fund an additional one.

2 Systematisation and structuring of doctoral training for medical researchers

The proposal must include a statement by the department of medicine describing any plans to systematise and structure doctoral training for medical researchers or to structure scientific training. If doctoral positions for licensed physicians or fellowships for research sabbaticals for medical students are planned within the Clinical Research Unit, this should be outlined in the statement. These positions and fellowships must be funded by the department of medicine following a favourable evaluation.

3 Association of Emmy Noether Groups

Clinical Research Units may associate Emmy Noether Groups that investigate related topics. In this case, the Clinical Research Unit proposal and the Emmy Noether proposal should refer to one another. Decisions on both proposals will be made independently of each other. If both the Clinical Research Unit and the Emmy Noether Group are established, the Emmy Noether Group Leader will participate in the Clinical Research Unit's shared events. The association can also be established afterwards at the CRU spokesperson's discretion.

4 Knowledge transfer projects

Knowledge transfer projects are projects in the pre-competitive area, in which a research question is worked on together with an application partner (either a commercial enterprise or a non-commercial, non-profit institution). Such projects serve to pursue the practical application of scientific findings and the outcomes of basic research (e.g. through prototypes, an exemplary application or concepts for practical use). Projects are also expected to generate fresh impetus for basic scientific research.

The core of the project is a joint work programme, focusing on intensive mutual exchange of scientific knowledge and corresponding application issues.



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Further information on knowledge transfer projects can be found in the relevant proposal preparation instructions.

www.dfg.de/formulare/54_014

IV Obligations

In submitting a draft proposal or proposal to the DFG, you

1. agree to adhere to the principles of good research practice. 1

The principles of good research practice include, among others: maintaining professional standards, maintaining strict honesty with regard to one's own contributions and those of third parties, documenting results and rigorously questioning all findings.

2. recognise the DFG's **Rules of Procedure for Dealing with Scientific Misconduct** (Verfahrensordnung zum Umgang mit wissenschaftlichem Fehlverhalten – VerfOwF)² as legally binding.

In the draft proposal stage, the spokesperson obtains signed Declarations of Obligation of Compliance from all designated individual project leaders

www.dfg.de/formulare/80_02

and keeps these on file for ten years following submission of the draft proposal. Should allegations of scientific misconduct arise, upon request the spokesperson will forward the relevant declaration to the DFG Head Office.

Scientific misconduct is defined as the intentional and grossly negligent statement of falsehoods in a scientific context, the violation of intellectual property rights or impeding another person's research work. The circumstances of each case will be considered on an individual basis. In cases where scientific misconduct has been established, the DFG may impose one or more of the following sanctions in accordance with its Rules of Procedure, depending on the nature and severity of the scientific misconduct:

² DFG Rules of Procedure for Dealing with Scientific Misconduct, DFG form 80.01



The principles of good research practice can be found in detail in the DFG Code of Conduct Guidelines for Safeguarding Good Research Practice and in the Funding Guidelines: General Terms and Conditions of DFG Grants (DFG form 2.00).

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issuing a written reprimand to those involved;

exclusion from the right to apply for DFG funds for a period of one to eight years,

depending on the severity of the scientific misconduct;

revoking funding decisions (full or partial termination of the grant contract, demand-

ing repayment of funds spent);

demanding that those concerned either retract the discredited publications or cor-

rect the falsified data (in particular by publishing an erratum), or appropriately indi-

cate the DFG's retraction of funding in the discredited publications;

exclusion from serving as a reviewer for a period of one to eight years, depending

on the severity of the scientific misconduct;

exclusion from membership in DFG bodies and committees for a period of one to

eight years, depending on the severity of the scientific misconduct;

denying voting rights and eligibility in elections for DFG bodies and committees for

a period of one to eight years, depending on the severity of the scientific miscon-

duct.

By accepting funding, the recipient agrees to

3. use the grant exclusively and in a targeted manner to realise the funded project. The use

and accounting of funds must conform to the relevant regulations of the DFG.

4. submit progress reports on the research according to the dates specified in the award

letter and to present financial accounts to the DFG detailing the use of funds.

The DFG expects that the findings of the projects it funds be made available to the public.

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V Data Protection

Please note the DFG's Data Protection Notice on research funding, which can be viewed and downloaded at www.dfg.de/privacy_policy. If necessary, please also forward this information to those individuals whose data will be processed by the DFG due to their involvement in your project.

www.dfg.de/privacy_policy

