

Guidelines

Clinical Research Units

(for Clinical Research Units to be established in 2009 or later)

These guidelines pertain to proposals for Research Units that focus on translational clinical research with patient-oriented approaches or on understanding disease mechanisms. For Research Units with any other thematic focus, please consult the Guidelines for Research Units (DFG form 1.05e).

I. Funding Objectives

Clinical Research Units promote the development of networks for disease- or patient-oriented (translational) clinical research and the long-term implementation of scientific working groups within clinical institutions. Clinical Research Units allow scientists with outstanding credentials to collaborate closely on special medium-term research projects whose anticipated findings would not be achievable under the DFG's Individual Grants Programme or Priority Programmes. Clinical Research Units pursue clinical investigations, integrate clinical findings, and may conduct clinical pilot studies. Thematically they focus on translational research with patient-oriented approaches and on understanding disease mechanisms.

A Clinical Research Unit generally centres on coordinated research, conducted according to subject-appropriate principles. A Clinical Research Unit thus offers a high degree of flexibility in terms of its structure and objectives.

Clinical Research Units share the following features with other Research Units:

- Clinical Research Units are medium-sized research groups set up by the scientists involved.
- Each Clinical Research Unit consists of a manageable number of projects and other funding modules that all deal with the same subject and that can only be worked on as a group in the proposed manner. To facilitate close collaboration, proposals should generally not encompass more than ten projects.
- The main feature of a Clinical Research Unit is collaboration across projects. Clinical Research Units are led by outstanding scientists with international track records and project experience.
- Clinical Research Units bring together the disciplines relevant to research on the topic at hand.
- The topic chosen by a Clinical Research Unit must be current and relevant. Its underlying concept must be highly innovative and coherent, thus justifying medium-term planning of between six and, in exceptional cases, eight years.

- The criteria for evaluating scientific excellence that apply under the Individual Grants Programme also apply to a Clinical Research Unit and its individual projects.
- Clinical Research Units offer ideal conditions for young scientists.

In addition to meeting the above criteria that apply to all Research Units, **Clinical Research Units** are also expected to:

- improve the situation and quality of clinical research by creating and strengthening research-oriented structures within university hospitals;
- establish or strengthen training structures for clinical research;
- enhance the scientific profile of their main location and institution (the review of a Clinical Research Unit will therefore consider the host university's commitment to the project);
- support the performance-based allocation of resources for clinical research, especially regarding the German states' subsidies for university hospitals and university medical departments, and clearly state this both in the draft proposal and the full proposal (What is the current status? What are the future goals? Are there separate budgets for teaching and clinical operations? If so, how will the budgets be separated?);
- increase cooperation between clinicians and scientists in the foundational disciplines of medicine.

One of the researchers submitting the proposal will assume the position of speaker and represent the Clinical Research Unit in dealings with the DFG and other bodies. The speaker should be a full-time university teacher.

In addition to the speaker, the Clinical Research Unit will also be headed by a research coordinator. Particular requirements apply to this position 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. Once the Clinical Research Unit is established, the research coordinator assumes the scientific and administrative leadership of the group. Because the Clinical Research Unit's main mission is collaborative investigation, it may be necessary and appropriate in some cases to use funds for an activity other than the one for which it was specifically granted. The authority to redirect funds in this manner lies with the speaker and/or research coordinator. In exceptional cases, the Clinical Research Unit's speaker may also serve as its research coordinator. The main applicant for the first funding period is generally the speaker. For the second funding period, the research coordinator serves as the main applicant and the speaker as the co-applicant (see also II.).

II. Types and Duration of Funding

Clinical Research Units consist of researchers who work at university hospitals in close geographic proximity to each other. Involvement of external researchers working at other locations is only possible in well-justified exceptional cases. Close collaboration with foundational disciplines is strongly encouraged.

The hallmark of a Clinical Research Unit is the establishment or enhancement of research-oriented structures in university hospitals. The establishment of a research professorship (salary scale W2 or W3, depending on the person's qualification; plus performance-based bonuses, depending on publications and third-party funds raised) at the main hospital **must** therefore be part of the proposal, unless the holder of an existing research professorship will assume the scientific leadership of the Clinical Research Unit. Such a research professorship, pre-financed or co-financed by the DFG, can accelerate new appointments or enable structural measures such as the establishment of departmental structures or new subject areas. As a prerequisite, the department of medicine at proposal time must confirm in writing that it will make the research professorship permanent and support it for at least five years after DFG funding expires (with two research assistants and two technical assistants, plus an appropriate annual allow-

ance for consumables in the amount of € 50,000). The topic of the professorship must coincide with the mission of the Clinical Research Unit; the research coordinator's main focus must be collaboration within the group. For this reason, the department of medicine must exempt the research coordinator, **upon his or her request**, from any clinical obligations.

Because the unit's research coordinator will generally not yet have been appointed at proposal time, the formal application to establish a Clinical Research Unit is initially the responsibility of the speaker, who submits it to the DFG via the university's medical department. If the research coordinator has been appointed by the time the renewal proposal is submitted, he/she is the main applicant for the renewal proposal.

When the DFG approves initial financing, it also declares its intent to continue to fund the project for six years (or up to eight years in exceptional cases), contingent on the review of the renewal proposal and an evaluation of the project findings.

Clinical Research Units may have a modular structure. Modules are selected according to subject-specific criteria and may vary between different Clinical Research Units, depending on the topic chosen, the research areas involved, and the structure-building aspect desired. Modules include:

1. Research projects

Clinical Research Units typically have fewer than ten projects, which should be proposed according to the guidelines for the Individual Grants Programme. However, the individual projects are integrated under the umbrella of the Clinical Research Unit's common research topic. In addition to funding for purely scientific projects, Clinical Research Unit proposals may also request funding for pilot studies (e.g. specialised outpatient clinics, resources for building and expanding infrastructure for clinical trials, archiving of patient data).

2. Fixed-term leave

Physicians participating in a Clinical Research Unit can apply to be released from their ordinary duties to be able to dedicate themselves to their research projects for a fixed period of time. Medical assistants are then hired for rotational positions to assume the participating physicians' clinical responsibilities, including highly qualified ones, thus reducing their workload and enabling them to pursue research projects. Each Clinical Research Unit must apply for at least one rotational position. The department of medicine must finance one rotational position in full (or 50% of the budget for rotational positions if more than one is proposed) from its government subsidies for research and education. The DFG funds one additional rotational position (or 50% of all rotational positions). Furthermore, the DFG makes available, upon request, flexible funds in the amount of € 60,000 per year to support especially creative structural measures in hospitals. These rotational positions should be identified as such in the proposal for the umbrella project; they will also be identified accordingly if funding is approved. For more details on rotational positions, please consult DFG form 1.12 (available only in German).

3. Promoting young researchers

Clinical Research Units provide an ideal environment for young scientists. Young researchers are therefore able to apply for funding to establish an independent junior research group within the Clinical Research Unit, following the same guidelines as applicable under the Emmy Noether Programme (see DFG form 1.22e). Please note, however,

that funding for a temporary position as principal investigator is not possible, as funding for project leaders must be provided by the research institution as core support in this structural measure.

4. Flexible funding to compensate for family leave

To allow 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, the proposal for the central project may request flexible funds in the amount of €50,000 for a period of one year. These additional funds are meant to enable the Clinical Research Unit to compensate for any preliminary work or publication shortages due to parental leave. It is not permitted to redirect these funds to other purposes (e.g. equipment purchase or project-related travel).

5. Other staff positions

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. Doctoral positions for medical researchers may be proposed in addition to standard staff funding (grants for research sabbaticals). **They must be funded by the department of medicine following a favourable evaluation.**

6. Fellowship programme

Intensive exchange with long-term visiting researchers from other parts of Germany and abroad, who stay in touch with the group even after they return home, can provide valuable insights and make an important contribution to building a visible focus on the research topic. To enable this it is also possible to apply for funding for a fellowship programme. Outstanding scientists from other locations may then be awarded fellowships for extended periods (e.g. one year). They are funded according to the same procedures used in other DFG programmes for visiting professors (see DFG form 1.161). As a rule, each fellowship is endowed with sufficient funding to cover the costs incurred by the university.

7. Transfer projects

Transfer projects in Clinical Research Units are strongly encouraged wherever appropriate. Such projects involve direct cooperation with industrial partners. Their goal is to bring basic research conducted at universities and industrial research closer together. The following conditions apply:

- There must be firm evidence of mutual benefit, rather than a one-way transfer of knowledge.
- Basic and/or patient-oriented research must remain the prime focus of the university project. The usual review criteria apply.
- Industrial partners must submit their own proposals for their share of the projects, which are also assessed by the review panel.

Industrial partners must bear the costs for their own contributions; agreements regarding the sharing of any profits arising from the research must be established in advance and may not put the university at any disadvantage (a sample agreement of cooperation between research institutions and commercial enterprises is available at

www.dfg.de/forschungsfoerderung/formulare/download/41_026e.pdf). Project findings must be published as appropriate; it is possible to delay publication subject to prior agreement.

8. Coordination funding and position

The Clinical Research Unit's speaker (and subsequently its research coordinator) is responsible for coordinating the group, which also entails public relations and reporting to the DFG. In addition, the speaker (or research coordinator) is responsible for managing the unit's shared funds (for symposiums, visiting researchers, colloquiums, creating and updating websites, travel, publications, public relations, etc.).

To support coordination tasks, special funding may be requested as part of the central project in addition to the expenses listed above. Coordination funding allows the unit to hire a secretary or administrator (provided that his or her coordination tasks have been adequately defined). Alternatively, the speaker or research coordinator may instead apply for an allowance of up to € 10,000 per year, which may be used to hire assistants or other clerical support.

III. Proposal Process

Funding proposals¹ must be submitted jointly by all researchers involved in the Clinical Research Unit. They share responsibility for the scientific implementation of the project. One of the researchers assumes the position of speaker and represents the unit in dealings with the DFG and third parties. Once the Clinical Research Unit has been established, the person designated for the research professorship assumes scientific and administrative leadership of the unit.

The proposal process has two stages:

1. Draft proposal

In the first stage of the proposal process, the researchers involved in the Clinical Research Unit submit a draft proposal to the DFG Head Office. The speaker (usually the department head of the clinical institution that will host the Clinical Research Unit) acts as the main applicant. The draft proposal should enable the review panel to comparatively assess the intended research activities in terms of their scientific quality and structural environment.

The draft proposal should outline the Clinical Research Unit's research programme by addressing the questions listed below in III.3.a) through i) (on approximately 10 pages). It should also include a summary (of about 1 to 2 pages) of each of the proposed individual projects, as well as information on the respective project leaders (CV and a list of original research published in the last five years, identifying any publications relevant to the project) and a rough initial cost estimate. It is especially important to include a written statement by the department of medicine [cf. III.3.e) and g)]. The draft proposal should generally not exceed 25 pages in length, excluding CVs (no more than two pages each) and publication lists (citing the 10 most important, project-relevant publications for each researcher), which should be submitted in a separate volume.

¹ Whether the proposal should be in German or English should be discussed with the appropriate department prior to submission.

a) **Draft proposal format**

Please submit the draft proposal both as hardcopy (15 copies in DIN A4 format, unbound and hole-punched) and as electronic files (e.g. on CD-ROM), preferably in PDF format (or otherwise in RTF format). Files should not be password protected or restricted in any other way. The document security settings should allow the documents to be read, copied and printed.

b) **Submission deadline for draft proposals**

Deadlines for draft proposals are announced on a regular basis (typically once a year). This information is also available on our website at www.dfg.de/en/research_funding/coordinated_programmes/clinical_research_units.

c) **Draft proposal review and decision**

Submitted draft proposals are assessed by peer reviewers and/or elected review board members. On the basis of this review, draft proposals are evaluated by way of comparison by the DFG Senate Commission on Clinical Research. If the evaluation is favourable, a full proposal (see below) may be submitted, which will usually be assessed on site by a group of reviewers. The funding decision is made by the responsible DFG committee on the basis of the reviews and endorsement by the Senate Commission on Clinical Research (with involvement of the Review Board for Medicine).

2. **Full proposal**

The full proposal should follow the format described above in section III.1.a).

It should not exceed 150 pages in length. CVs and publication lists should be submitted in a separate volume (as described above in III.1.).

The full proposal should particularly describe the proposed research work, relevant preliminary work, and the type and nature of the cooperation between the applicants, by addressing the questions listed below in III.3.a) through i) in a format suitable for peer review. Furthermore, the structural aspects mentioned below should be discussed. The descriptions of the individual projects and modules comprising the Clinical Research Unit should follow the guidelines for research grant proposals (DFG form 1.02e). Please number all projects or modules consecutively and include all necessary ethics statements and official permits (see DFG form 1.02e, Proposal Preparation Instructions, II.3.3 through II.3.5). A review panel will evaluate the proposal, usually at the site of the proposed unit, and issue a recommendation to the appropriate decision-making bodies within the DFG.

A renewal proposal should describe shared goals that have been accomplished by the group and any joint events held (seminars, lectures, workshops, symposiums, etc.). It must also explain why any new projects are being proposed or why any previously funded projects should be discontinued. A final report must be presented for any projects that are terminated early. In addition, the renewal proposal must include the responsible state agency's pledge to provide matching funding for the second funding period, as well as renewed guarantees to lift the time limit on the research professorship at the beginning of the **third year** of the Clinical Research Unit's duration, and to provide the necessary core support after DFG funding expires (see below). After the research professorship has been made permanent it must be funded by the university's medical department (from the beginning of the fourth year of DFG funding).

3. Proposal content

The draft proposal and the full proposal should provide a summary of the research programme and its intended structure, mention relevant preliminary work, position the project within a domestic and international context, and describe the type and nature of the cooperation between the applicants. In addition it should list the titles of the projects and the researchers who will handle them. For the draft proposal, a two-page outline should be

provided for each project. Please include CVs and lists of research published within the last five years for all participating project leaders, as well as a list of third-party funds received within the last three years.

In addition, the draft as well as the full proposal for the Clinical Research Unit as a whole should address the following questions:

- a) What is the specific relevance/ topicality of the joint research project, and what are the objectives? Is the collaboration based on an innovative and coherent concept? Can the stated objectives only be achieved through the proposed cooperation? Do you intend to involve all of the relevant disciplines necessary to investigate the topic?
- b) What key results do you expect in the short to medium term? What long-term results are anticipated?
- c) What qualifications/expertise do the participating researchers and working groups bring to the project? What preliminary work contributes to the project? If applicable, why is a working group from another European country or a private business involved, and how is this of particular importance to the Clinical Research Unit as a whole?
- d) What are the expected benefits of collaboration within the group, particularly between clinicians and basic researchers? How is the collaboration structured?
- e) Do the Clinical Research Unit's topic, the projects chosen and the participating disciplines provide a suitable basis for the department of medicine to further develop its chosen priorities? Please describe the scientific priorities and the research structure at the institution(s) involved in the proposal. The draft proposal should include a statement by the department of medicine confirming that the Clinical Research Unit's topic fits the department's prioritisation.
- f) What are the plans for the appointment of a research coordinator? If a specific person is being proposed for this leadership role, he/she should be involved in the creation of the concept. In this case, his/her special expertise should also be documented in a CV and publication list. In all cases, appointments to research professorships are subject to the respective state's higher education laws. The DFG must also be included in the appointment process, should the research coordinator be selected through an (international) announcement procedure. ***The DFG is strongly committed to equal opportunities in science and research. We are therefore especially interested in qualified candidates who can contribute, through their expertise and leadership skills, to the diversity and excellence of the proposed Clinical Research Unit.***
- g) What are the modalities by which performance-based government subsidies for research and education are allocated at the host university's medical department? Are funds for scientific projects distributed by a research commission? How are overhead expenses shared within the host university? If approved by the DFG, will the Clinical Research Unit be guaranteed space and equipment? Will the teams be close to each other (with the core group's hospital ward and laboratory preferably located in the same building)? Will space be allocated based on performance?

- h) How do you plan to integrate and promote young researchers? Describe any training programmes and special measures to advance young scientists. Is there an option to release research clinicians from patient care obligations (rotation programmes)?
- i) What are the plans for promoting gender equality within the Clinical Research Unit?

4. Auxiliary support versus core support

The majority of the research projects should be university-based. However, cooperation with non-university research institutions is also possible.

Expenses must be shared in such a way that core support - especially office/lab space, equipment, and operating costs - is provided by the university/medical faculty. The extent and nature of the core support provided by the host institution(s) should demonstrate commitment to the Clinical Research Unit. Project-specific costs may be funded by the DFG as auxiliary support, as stipulated in these guidelines and in the guidelines for research grants (DFG form 1.02e).

5. Co-financing and budgetary commitment

Funding for Clinical Research Units requires that specific funding modules listed under section II be financed by the state subsidy through the medical department/university hospital, and subsequently allocated to the unit, together with the core support and the performance-based allocation. Both the draft proposal and the full proposal must include a written statement by the entities responsible under state law (university hospital, department of medicine and/or or state government), vouching that:

- these costs will be assumed and co-financing will be funded from the respective state government's research and education subsidy to the medical institution;
- after three years of DFG support for the proposed research professorship and a positive interim evaluation, from the fourth year on, the research professorship will be funded in full by the university's medical department from the state subsidy for research and education, and will be included in the regular hospital and/or university budget for at least five years after DFG funding for the Clinical Research Unit expires (usually after six years), 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);
- at least one rotational position in the Clinical Research Unit (and, if more than one such position is proposed, 50% of all rotational positions) will be funded from the subsidy for research and education. If one rotational position is approved, the DFG will fund an additional one. Furthermore, the DFG makes available, upon request, flexible funds in the amount of €60,000 per year to support especially creative structural measures in university hospitals.

No co-financing is expected for any projects outside of the department(s) of medicine.

If funding is approved, the DFG pays out its share of the overall budget for the Clinical Research Unit. Accounting for the unit is expected to identify funds derived from state government subsidies and how they were used in the project. To simplify accounting, expenditure reports must include both those expenses that were covered by the DFG and the overall costs of the Clinical Research Unit (divided into payroll and direct project expenses).

6. Final colloquium

If appropriate, a final colloquium may be held after funding for the Clinical Research Unit concludes (possibly with reviewer participation). If this is planned, such funds should be requested in the renewal proposal after the first three years of funding. A final colloquium cannot substitute for a written final report (see guidelines on final reports of Clinical Research Units, available only in German, DFG form 1.052).

IV. Publication of Data on Applicants and Research Projects

The data necessary for processing your grant proposal will be stored and processed electronically by the DFG. If funding is awarded, your work address (e.g. telephone, fax, e-mail, website), as well as information on the content of your research project (e.g. topic, summary, keywords, international cooperation), will be published in the DFG's project database GEPRIS (<http://www.dfg.de/gepris>) and - in excerpts (grant recipient's name, institution and location) - in the "Programmes and Projects" section of the electronic annual report (<http://www.dfg.de/jahresbericht>). If you do not wish this information to be published electronically, please notify us in writing no later than four weeks after receipt of your award letter.

The DFG expects Clinical Research Units to create and regularly update an appropriate web presence.

V. Obligations

By submitting a grant proposal for a Clinical Research Unit to the DFG, you agree to:

1. Adhere to the **rules of good scientific practice**.²

In cases of scientific misconduct, the DFG may impose sanctions. Scientific misconduct is defined as the misrepresentation of facts in a scientific context, either consciously or due to gross negligence, violation of intellectual property of others, or any other infringement upon others' research activities. The circumstances of each case will be considered on an individual basis.

Depending on the nature and extent of the misconduct exposed, the DFG may impose one or several of the following penalties:

- issue a written reprimand to those involved;
- exclude those found responsible from the right to apply for DFG funds for a period of one to eight years, depending on the severity of the scientific misconduct;
- revoke funding decisions (complete or partial cancellation of the grant, recall the funds granted, reclaim funds spent);

² The rules of good scientific practice are presented in detail in the white paper *Proposals for Safeguarding Good Scientific Practice* (published by Wiley-VCH) and in the usage guidelines for research grants, DFG form 2.01 and 2.02 (available on the Internet at <http://www.dfg.de/forschungsfoerderung/formulare/gesamt.html>). They are based on the recommendations of an international commission on self-regulation in science and on a decision by the DFG's General Assembly, endorsed by the German Rectors' Conference, dated 17 June 1998. According to a decision made by the General Assembly on 4 July 2001, research institutions that have not implemented the rules of good scientific practice or do not abide by them will not be able to apply for or receive DFG funding as of 1 July 2002.

- demand that those concerned either retract the publications containing false data, correct the false data (by publishing an erratum), or include a reference regarding the DFG's retraction of funds in the relevant publication;
 - exclude those found responsible from acting as a reviewer or from membership on DFG committees;
 - deny those responsible the right to vote in DFG elections.
2. Devote the funds granted exclusively to the expeditious realisation of the research project supported by the grant. Therefore the **use and accounting** of funds must conform to the **relevant regulations of the DFG**.
 3. Submit **research progress reports** to the DFG according to the dates specified in the award letter, and document the use of the funds granted.

The DFG expects that the **results** of the research projects carried out with its support be made **available to the public**.