Proposal Preparation Instructions
Proposals to Establish or Renew Clinical Research Units
I  General Instructions

Funding proposals¹ are to be submitted jointly by all researchers involved in the Clinical Research Unit. They are jointly responsible for the scientific conduct of the project. One of the applicants assumes the position of spokesperson and represents the Clinical Research Unit in dealings with the DFG and other bodies. The proposal is submitted by the spokesperson in consultation with the lead medical department(s). Once the Clinical Research Unit has been established, the person designated for the research professorship assumes its scientific and administrative leadership as research coordinator. If the research coordinator holds the research professorship at the time the renewal proposal is presented, he/she is responsible for submitting it. In exceptional cases, the spokesperson of the Clinical Research Unit may also serve as its research coordinator and hold the research professorship.

The proposal process takes place in two stages:

1. In the first stage the participating researchers submit a draft proposal to the DFG Head Office. This approximately 15-page text should outline the Clinical Research Unit’s joint work programme and related objectives and other measures in accordance with the structure and items set out below and include a summary (about 1 to 2 pages) for each of the proposed individual projects.

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   To illustrate and enhance your presentation you may refer to your own and others’ publications. Indicate whenever you are referring to other researchers’ work and explain your own preparatory work. Please list all cited publications in your bibliography. This reference list is not considered your list of publications. Any unpublished work must be included with the proposal. However, note that reviewers are not required to read any of the works you cite. Reviews will only be based on the text of the actual proposal.

   Please note that the DFG may reject any proposals not in compliance with these rules.

   Furthermore, the draft proposal must include information on the project leaders. For each project leader, submit a CV and a list of up to ten of his/her most important publications;

¹ The language in which the funding proposal may be submitted should be agreed upon with the relevant DFG programme division prior to submission.
in addition, submit **one** project-specific list of publications **per** individual project. Follow the Guidelines for Publication Lists.

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Also include:

- a cost estimate,
- a statement by the department of medicine regarding Section II, items 2.10 and 2.12,
- a written declaration regarding all relevant aspects of co-financing (see III. 1. of the programme guidelines) by the entities responsible under state law (university hospital, medical department, in some cases the state).

The draft proposal, which may be submitted at any time, will be sent to reviewers. On the basis of these assessments, a comparative evaluation of the draft proposal will be carried out by review board members. If the draft proposal is approved, the applicant may submit a full funding proposal.

2. The full proposal should particularly describe the proposed research work, the structural aspects, relevant preliminary work and the type and nature of the cooperation between the applicants, in accordance with the structure and items set out below and in a format suitable for peer review. The proposal to establish or renew a Clinical Research Unit can only be submitted by the Research Unit’s spokesperson or research coordinator and only electronically via elan

elan.dfg.de

For the overall description of the Clinical Research Unit and the coordination proposal, please use the relevant template in elan, available in German or English.

www.dfg.de/formulare/53_02_elan

Individual project proposals within the Clinical Research Unit should be submitted in accordance with the instructions on preparing project proposals.

www.dfg.de/formulare/54_01

The proposal must be submitted along with a written declaration regarding all relevant aspects of co-financing (see III. 1 of the programme guidelines) by the entities responsible under state law (university hospital, department of medicine, in some cases the state)
as well as a statement by the medical department regarding items II. 2.10 and 2.12 below.

A review panel evaluates the proposal to establish or renew a Clinical Research Unit, usually at the site of the proposed unit, and develops a funding recommendation for the appropriate decision-making bodies at the DFG.

II Instructions on Preparing the Overall Description of the Clinical Research Unit and the Coordination Proposal

The following structure and items apply to the Clinical Research Unit as a whole.

1. State of the art and preliminary work
   Please explain briefly and precisely the state of the art in your field in its direct relationship to your project. This description should make clear in which context you situate the work of the researchers participating in the Clinical Research Unit and in what areas the Clinical Research Unit intends to make a unique, innovative, promising contribution. This description must be concise and understandable without referring to additional literature.

   What (joint) preliminary work has been done? In what way are the participating researchers/working groups qualified for the project?

   1.1 For a renewal proposal: Report on the progress to date
   For renewal proposals, please report on your previous work. This report should also be understandable without referring to additional literature.

   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 fourth year of the Clinical Research Unit’s duration, and to provide the necessary core support after
DFG funding expires. After the research professorship has been made permanent it must be funded by the department of medicine (from the beginning of the fourth year of DFG funding for the Clinical Research Unit).

1.2 Project-related publications
Please list the most significant publications that relate directly to the proposed Clinical Research Unit and document your preliminary work. Follow the Guidelines for Publication Lists.

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2. Objectives and joint work programme

2.1 Objectives of the overall project and expected benefits of collaboration within the unit, incl. a description of the group composition and their project-specific qualifications
What common objectives will be pursued by the Clinical Research Unit and to what extent does this require collaboration within the project? 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 work on the topic? What key results do you expect in the short to medium term? What long-term results are anticipated?

2.2 Joint work programme including proposed research methods
Describe the Clinical Research Unit’s joint work programme.

2.3 Research data and knowledge management
What measures are planned to manage the research data and knowledge generated within the Clinical Research Unit? How will this be supported by the institutions participating in the project?

2.4 Potential impact on the research area and local research environment
Describe the Clinical Research Unit’s potential impact on the research area and local research environment.
2.5 Measures to advance research careers
Detail what measures are planned to integrate and promote promising early career researchers within the Clinical Research Unit (e.g. training programmes, special measures, etc.). Are there clinician scientist programmes or opportunities for research clinicians to be released from patient care obligations (through temporary substitute programmes)? Are there plans to offer doctoral programmes for medical scientists?

2.6 National and international cooperation and networking
What national and/or international collaborations are relevant?
If applicable, how will information and communication technology be used within the research work itself, other than for communication between the participants? (Examples may include interactive planning and conduct of experiments, data sharing for division of work or comparative analysis, etc.)

2.7 Collaboration with international cooperation partners
Are international cooperation partners involved in the Clinical Research Unit?

2.8 Description of the spokesperson’s qualifications
Please explain why you would like to assume the role of spokesperson, also with respect to your academic qualifications and personal skills. What experience do you have in managing third-party funded projects?

2.9 Scientific qualifications of the head of the Clinical Research Unit
Describe the plans for appointing the head of the Clinical Research Unit to the research professorship. 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. Should the individual be selected through an (international) announcement procedure following establishment of the Clinical Research Unit, the DFG must also be included in the appointment process. The DFG is strongly committed to gender equality in science and research.
2.10 **How does the Clinical Research Unit contribute to the research profile of the university/department of medicine?**

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.

2.11 **Expected benefits of collaboration between clinicians and basic researchers**

What are the anticipated benefits of collaboration within the unit? How will the collaboration be structured?

2.12 **Modalities of performance-based funding allocations for research and teaching through the department of medicine**

What are the modalities by which performance-based government subsidies for research and education are allocated at the host university’s department of medicine? Are funds for scientific projects distributed by a research commission? 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 clinic and laboratory preferably located in the same building)? Will space be allocated based on performance?

3. **Coordination**

3.1 **Description of how joint objectives and the joint work programme will be implemented in the coordination project**

Describe the coordination project’s joint work programme and how the joint objectives will be achieved and implemented.

3.2 **Requested modules**

The template provided in elan contains a list of funding modules available to facilitate coordination within the Clinical Research Unit. Please provide detailed justification for each module requested in the online form. If you will be applying for gender inclusion funding for spokespersons, please describe what measures are planned and explain how these funds were used during the current funding period.
III Obligations

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

1. agree to adhere to the principles of good scientific practice.²

   The principles of good scientific 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)³ 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:

   - 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;

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² The principles of good scientific 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).

³ DFG Rules of Procedure for Dealing with Scientific Misconduct, DFG form 80.01
- revoking funding decisions (full or partial termination of the grant contract, demanding repayment of funds spent);

- demanding that those concerned either retract the discredited publications or correct the falsified data (in particular by publishing an erratum), or appropriately indicate 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 misconduct.

By accepting funding, the recipients agree 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.