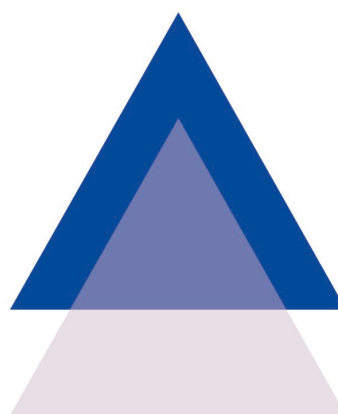
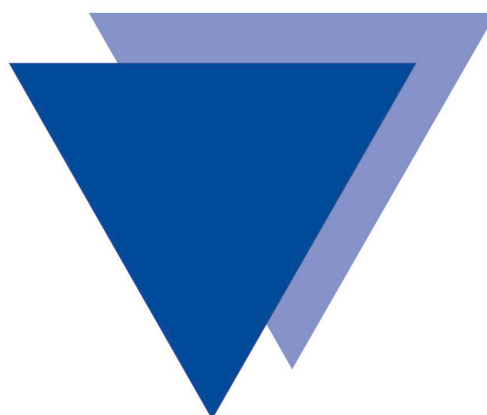


# CALL SPECIFICATIONS

## LBG CLINICAL RESEARCH GROUPS



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# 1 CALL SUMMARY

This first call for proposals for Ludwig Boltzmann Gesellschaft (LBG) Clinical Research Groups (CRG) aims to support larger collaborative research projects with a strong focus on patient-oriented, medically important topics that are scheduled over a medium period (4+4 years). The focus of the funding is on academic clinical research topics – i.e. investigator-driven clinical studies or translational research projects. Key to CRG is thus to strengthen clinical research in general, and to enable more efficient translation of basic research into clinical research and medical innovations. CRG are funded by the Austrian Ministry of Education, Science and Research (BMBWF) as well as the Fonds Zukunft Österreich (FZÖ) and aim to enhance clinical research and help overcome barriers in the processes from bench to bedside.

*Table 1: Details of the call for Clinical Research Groups*

Key Elements	Information
Short description	<ul style="list-style-type: none"> <li>▪ Funding through CRG enables outstanding clinical researchers and physician researchers to collaborate closely on specific research projects in the field of non-commercial clinic research whose anticipated findings could not be achieved within the scope of individual grants.</li> <li>▪ Research within a CRG is further conducted in an interdisciplinary and interorganisational setting.</li> <li>▪ CRG focus on disease- and patient-oriented clinical research with the possibility of integration of translational aspects.</li> <li>▪ Research projects should address in particular investigator-initiated phase I to phase III studies or other clinical studies in connection with clinical pilot or accompanying studies (observational studies, longitudinal studies, epidemiological studies, biobanking, biomarker studies, patient outcome studies, proof of concept studies, etc.).</li> <li>▪ CRG must involve human patients and/or healthy subjects, and aim to generate new scientific insights and knowledge.</li> <li>▪ In addition, CRG have to promote the career of young investigators and strengthen Austria's position in the international clinical research landscape.</li> </ul>
Call type	Two-stage call

Key Elements	Information
<b>Call budget</b>	<p>Total 24 million EUR:</p> <ul style="list-style-type: none"> <li>Austrian Federal Ministry of Education, Science and Research (BMBWF): 16 million EUR</li> <li>Fonds Zukunft Österreich (FZÖ): 8 million EUR</li> </ul>
<b>Max. funded costs/CRG</b>	<ul style="list-style-type: none"> <li>0.5–1.0 million EUR per annum</li> <li>Funding covers personnel, non-personnel expenses, and 25% overhead costs on direct eligible costs.</li> </ul>
<b>Funding rate</b>	Max. 90% of the total costs of the CRG
<b>In-kind contribution</b>	Participating institutions must contribute <b>min. 10% of the total costs</b> of the CRG in-kind (for details please see section 3.5 Eligible costs/funding)
<b>Duration</b>	<ul style="list-style-type: none"> <li>1<sup>st</sup> period: 4 years</li> <li>2<sup>nd</sup> period: 4 years (after successful interim evaluation)</li> </ul>
<b>Eligible Lead Institution</b>	The main applicant of a CRG (Lead Institution) must be an Austrian medical university/faculty with an affiliated university hospital.
<b>Eligible Cooperation Partners</b>	<p>One or more of the following Austrian institutions:</p> <ul style="list-style-type: none"> <li>Public universities</li> <li>Private universities</li> <li>Universities of applied sciences</li> <li>Hospitals (“Krankenanstalten”)</li> <li>(Non-profit) non-university research institutions</li> </ul>
<b>Contact details</b>	<p>Programme Management and Support:</p> <p>Neda Motamedi-Shad, MSc PhD          Nußdorfer Straße 64          1090 Vienna, Austria          Email: <a href="mailto:kfg@lbg.ac.at">kfg@lbg.ac.at</a>          Tel.: +43 1 513 27 50-45</p>
<b>Deadlines</b>	<ul style="list-style-type: none"> <li>Short proposals must be submitted by 17 November 2022.</li> <li>Full proposals (upon invitation only) must be submitted by 20 April 2023.</li> <li>On-site interviews will take place in July 2023.</li> </ul>
<b>Information online</b>	<a href="https://lbg.ac.at/kfg/">https://lbg.ac.at/kfg/</a>
<b>Online submission tool</b>	<a href="https://ecall.ffg.at">https://ecall.ffg.at</a>

## 2 INTRODUCTION

### 2.1 THE LUDWIG BOLTZMANN GESELLSCHAFT (LBG)

The Ludwig Boltzmann Gesellschaft (LBG) is an independent research organisation dedicated to

- i) strong interdisciplinary and transdisciplinary research,
- ii) the generation and implementation of research that addresses important and mainly health-related aspects, and
- iii) the translational nature of its research institutes.

On behalf of the Austrian Federal Ministry of Education, Science and Research (BMBWF) and with additional funds of the Fonds Zukunft Österreich (FZÖ), the LBG recently initiated a new funding scheme for “LBG Clinical Research Groups” (CRG) to support clinical research projects.

Thematically, the programme focuses on academic approaches to address disease- and patient-oriented clinical or translational research (from bench to bedside and vice versa). CRG should include investigator-initiated clinical studies (phase I to phase III possible) or other clinical studies in connection with clinical pilot or accompanying studies (observational studies, longitudinal studies, epidemiological studies, biobanking, biomarker studies, patient outcome studies, proof of concept studies, etc.). CRG should go beyond individually funded projects by supporting the formation of larger interdisciplinary research consortia of clinical scientist and other scientists. These Call Specifications are based on the [\*“Special Guideline: Clinical Research Groups”\*](#) of the BMBWF, which mainly finances the programme. The LBG is entrusted with the management of the funding programme and acts as a fiduciary of the federal government.

The indicative call budget is 24 million EUR:

- BMBWF: 16 million EUR
- FZÖ: 8 million EUR

### 2.2 AIMS OF THE FUNDING PROGRAMME

In contrast to other countries of the European Union, only scarce funding instruments for non-commercial clinical research existed in Austria up to now. To overcome this funding gap the LBG CRG programme, funded by the BMBWF, was established. The programme aims to promote high-quality scientific training of young clinical researchers through integrating them into clinical research groups working on specific research projects. At the same time, it supports the development of innovative research results in disease- and patient-oriented clinical research.

The overall aims of CRG are:

- To strengthen Austria's standing in the clinical research landscape; to intensify, professionalise, and improve the quality of non-commercial clinical research at Austrian medical universities; and to promote the integration of translational aspects into medical research ("bench to bedside").
- To support the interdisciplinary collaboration between or within medical universities (including their clinical departments), with organisational units of other universities and of non-academic research institutions in order to promote knowledge and technology transfer in the field of health sciences and clinical research.
- To promote young researchers' careers in clinical/translational research and project management.
- To foster gender equality, inclusion, and diversity both in the CRG teams as well as through addressing gender, inclusion, and diversity aspects in research conducted at CRG.
- Moreover, the programme aims to overcome shortages in the Austrian funding landscape by promoting strong collaborative, interdisciplinary and interorganisational research networks.
- With the role of the Mentor, the CRG will be able to promote the career of young clinician scientists<sup>1</sup> by granting off-clinic time to conduct research.
- The funding of CRG should help to improve clinical research by establishing joint research projects at and between university clinics or clinical departments of hospitals or other cooperation partners. It thus should increase cooperation, critical mass, and establish sustainable research competencies, and therefore sharpen the profile of Lead Institutions and of Austria as clinical research location.
- Finally, the funding programme aims to overcome the current inherent competitive disadvantage clinician scientists face when competing for funding with full-time non-clinical researchers.

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<sup>1</sup> Definition: MD-PhDs: "clinically trained health professionals who have undergone additional training in research" (from: Eley, DS. The clinician-scientist track: an approach addressing Australia's need for a pathway to train its future clinical academic workforce. *BMC Med Educ.* 2018;18:227. <https://doi.org/10.1186/s12909-018-1337-5>).

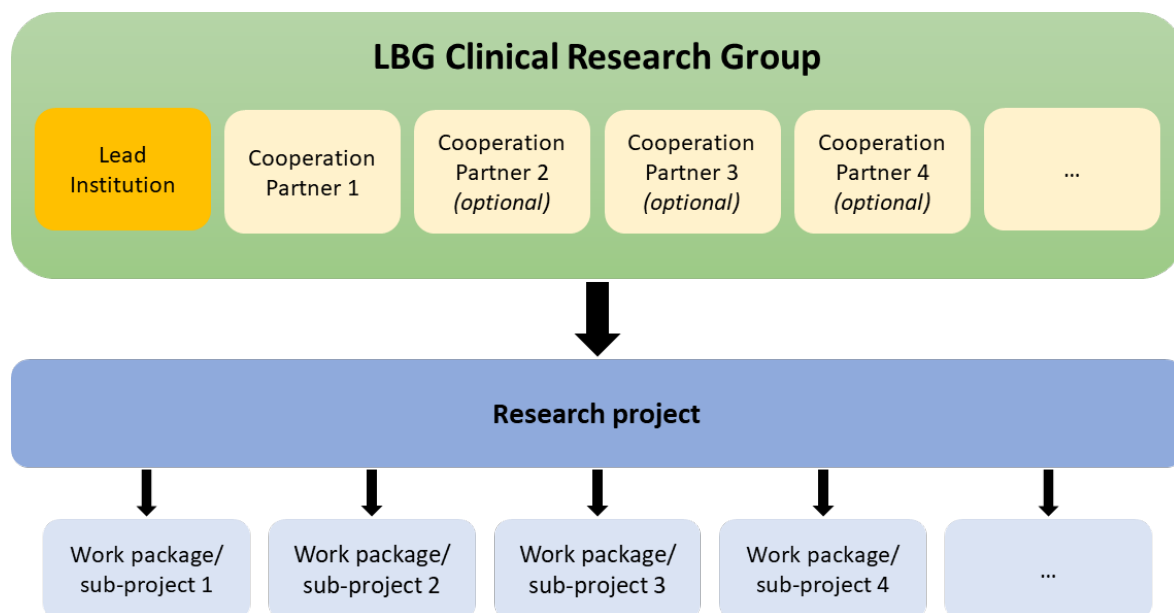
## 3 CALL DETAILS

### 3.1 CLINICAL RESEARCH GROUP

The call is open for submission of proposals for CRG and their research projects. A CRG may consist of a Lead Institution (medical university/medical faculty with an affiliated university hospital) and one or more Cooperation Partners (e.g. public universities (medical or other), private universities (medical or other), universities of applied sciences, hospitals and/or (non-profit) non-university research institutions) (see section 3.3 Consortium/Cooperation Partners for details).

A CRG will conduct a coherent overall research projects that is structured into work packages or sub-projects respectively. Figure 1 illustrates the composition of a CRG and its research project.

*Figure 1: Overview of a potential CRG*



### 3.2 SCOPE OF THE LBG CLINICAL RESEARCH GROUPS

Proposals must include the description of the planned research project as well as a description of the planned work packages/sub-projects that are planned to be conducted by the CRG. The research project including its work packages/sub-projects must meet the following criteria:

- A coherent research project must be presented in the proposal, describing how individual work packages/sub-projects form a larger project, and thereby create benefit.
- Research projects must be innovative and of high quality in the field of disease- and patient-oriented clinical research.



- The number of work packages/sub-projects has to be justified depending on the nature and content of the research project . However, more than 50% of the proposed work packages/sub-projects must be carried out at medical universities/faculties.
- Work packages/sub-projects shall include development and/or improvement of diagnostic and/or therapeutic methods, and produce new medical knowledge and innovation for the benefit of patients' health.
- Research projects should address in particular investigator-initiated clinical trials (eligible are phase I to phase III) or other clinical studies in combination with clinical pilot or accompanying studies (observational studies, longitudinal studies, epidemiological studies, biobanking, biomarker studies, patient outcome studies, proof of concept studies, etc.) that are integrated into a research project. The project shall be led by academic research questions.
- Research projects must meet the [standards of good clinical practice](#), i.e. key principles such as adherence to ethical principles, risk minimisation, subject's rights, safety and well-being, adequate drug information, scientifically sound protocols, IRB/IEC review and approval, protocol adherence, involvement of qualified physicians, etc. They thus contain a sound study design with descriptions of i.e. the research approach, purpose of the trial/study, study protocol, randomisation, statistical power, etc.
- The research project teams within the consortium shall be interdisciplinary and demonstrate a synergistic collaborative attitude between clinical and non-clinical team members (see section 3.3 Consortium/Cooperation Partners).
- Proposals must include a plan to promote career development of young researchers/clinicians and address gender equality issues both within teams as well as in the research project.
- A description of the planned mentoring concept has to be included. This must contain a description of intended measures (training, qualification, supervision). Innovative and new methodological approaches are preferred.

### 3.3 CONSORTIUM/COOPERATION PARTNERS

The main applicant of a CRG (i.e. the Lead Institution) must be an Austrian medical university/faculty with an affiliated university hospital.

Cooperation Partners of a CRG can involve one or more of the following Austrian institutions:

- Public universities (medical or other universities),
- Private universities (medical or other universities),
- Universities of applied sciences,
- Hospitals ("Krankenanstalten"), and/or
- (Non-profit) non-university research institutions operating in Austria.

The Lead Institution and all Cooperation Partners participating in the consortium are hereafter referred to as CRG partners and must authorise the application within the e-submission system.

The following parties may participate but may not receive funding:

- Subcontractors: They are not participants within the definition of the CRG. They provide defined tasks for CRG partners which are listed under the cost category “third party costs” and are not entitled to exploit the CRG results.
- Other participants: The inclusion of international/external research institutions and researchers and industry partners is possible; however, those partners are not eligible for funding.

### 3.4 STAFF WITHIN THE CRG

- In total, the CRG should comprise a minimum of five and a maximum of 15 directly funded individuals (full-time equivalents; no in-kind personnel).
- The consortium must consist of at least two different organisations.<sup>2</sup>
- Different disciplines<sup>3</sup> must be represented in the proposal as CRG partners in the consortium.
- Cross-organisational approach: work package/sub-project teams should ideally consist of staff from different organisations in order to foster cross-sectoral learning.

A CRG comprises the following personnel (hereafter referred to as CRG staff):

- One Mentor,
- A Head,
- One or more Work Package/Sub-Project Leaders, of which one or more Deputy Heads have to be appointed, as well as
- Researchers and other staff members, if any.

Mentor:

The Mentor is nominated by and employed at the Lead Institution and is mainly responsible for the integration of the CRG into the framework of the Lead Institution. The Mentor is an experienced scientist/clinician and is either employed by the federal government and assigned to work for a medical university, or is directly employed by the university; ideally in a medical leadership position at a university hospital. The Mentor should maintain this role throughout the entire duration of the CRG. The Mentor, together with the Head, manages the coordination and submission of the CRG proposal. The Mentor ensures that young clinical research staff have the necessary freedom (keyword “rotational positions”) in order to make disease- and patient-oriented translational research possible in everyday clinical practice, which primarily serves patient care. The Mentor can, but is not obliged

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<sup>2</sup> In well-founded cases, an individual application by a university is also possible. In such cases, greater emphasis should be placed on cooperation between different clinical departments and on interdisciplinarity between researchers.

<sup>3</sup> 4-digit code as defined in: [Statistik Austria. Erhebung über Forschung und Experimentelle Entwicklung 2021. Österreichische Systematik der Wissenschaftszweige 2012; 2021.](#)

to, carry out own research within the CRG mentoring duties, and may also lead work packages/sub-projects. The Mentor agrees to assist the CRG and its young professionals in their professional and personal career development. As such, the Mentor agrees to perform the following mentoring duties:

- Enabling and fostering the integration of the CRG into the Lead Institution.
- Assisting in carrying out research work of the CRG.
- Assisting in building networks and collaborations.
- Providing strategic assistance in young researchers' career planning.

Head:

The Head is responsible for the coordination and organisation of the CRG. Moreover, the Head is responsible for the scientific and administrative management of the CRG, and (together with the Mentor) is responsible for the coordination and submission of the proposals (short proposal and full proposal) and compliance with the reporting obligations (in case of funding).

The Head undertakes the strategic and operational planning and implementation of the entire consortium, including the planning, organisation, coordination, and supervision of the setup and implementation of the research project and its work packages/sub-projects. In doing so, they are also responsible for adherence to quality, time, and cost specifications as well as compliance with all applicable legal standards in the work packages/sub-projects. The Head typically leads teams of postdocs (working within or outside medicine), doctors in training, PhD students, technicians, study nurses, etc. The Head is responsible allocating the work packages/sub-projects, coordinating the work steps and leading the team as a whole. The Head may lead work packages/sub-projects.

The Head must be an experienced researcher employed at the Lead Institution. Moreover, they must be employed by the federal government or at a medical university/faculty, and should ideally be working as a clinical or physician scientist at a university hospital. If the Head is employed by the federal government, they must be assigned to work for a medical university/faculty. The Head assumes the responsibility to adhere to the call requirements as well as any legal aspects. They are required to dedicate at least 25% of their time to the CRG.

The Head must have relevant expertise and project management experience. The requirements and qualifications of the Head have to be demonstrated in the proposal and will be verified by the reviewers of the Scientific Expert Commission.

Work Package/Sub-Project Leader(s):

- One or more Work Package/Sub-Project Leaders participate in the consortium by heading one or more of the CRG work packages/sub-projects.
- A Work Package/Sub-Project Leader is required to dedicate at least 20% of their time to the CRG.
- At least 1/3 of all Heads (including the Head, the Deputy Head(s), and the Work Package/Sub-Project Leader(s)) must be female.

The group of Work Package/Sub-Project Leaders shall be a balanced mix of experienced and junior clinical, physician, or other scientists to support the training of the next generation of investigators. Pairs of Work Package/Sub-Project Leaders (e.g. Work Package/Sub-Project Leaders with different expertise, from different disciplines, etc.) can team up to lead a work package/sub-project together. Work Package/Sub-Project Leaders must have a proven track record, and in case PhD students are employed in the respective work packages/sub-projects, Work Package/Sub-Project Leaders must fulfil the academic requirements to supervise PhD students (according to their universities' regulations).

#### Deputy Head(s):

In order to promote young scientists and career opportunities in clinical research, at least one Deputy Head must be appointed. The Deputy Head is a junior researcher (ideally a junior clinical or physician scientist) who must be employed at the Lead Institution. One or more Work Package/Sub-Project Leaders act as the Deputy Head(s) who can cover the Head and support them in their functions and tasks. In case the extension period of the CRG is provided after a successful interim evaluation (after the first funding period of four years, see below), one of the Deputy Heads will take over the role of the Head during the second funding period. The Deputy Heads are not required to have the same advanced scientific, clinical, and project management experience as the Head from the outset of the CRG, but should acquire the necessary expertise by supporting and strongly collaborating with the Head during the first funding period.

Team members of a CRG may include (researchers and supporting personnel):

- Senior Personnel: highly qualified scientists
- Postdocs: or equivalent qualification, including Senior Postdocs
- PhD Students: or equivalent qualification
- Students: Bachelor's or Master's students
- Technicians: technical staff, data analysts
- Study nurses

### 3.5 ELIGIBLE COSTS/FUNDING

Funding may be used for all CRG-related costs (after signing of the funding contract).

#### Personnel:

- Funding for personnel can also include funding for so-called “rotational positions”<sup>4</sup> in order to enable clinicians who perform tasks in patient care to work in a CRG. As part of the “rotational position”, clinicians (including those still in training) are released from clinical duties for a defined period of time (typically not more than one year) to partake in one or more work packages/sub-projects of the CRG. Funding can be used for temporary substitutes who will be appointed to do their clinical work.
- No more than two “rotational positions” (two FTE) per year are permitted for the entire CRG.
- The salaries of the Mentor and the Head as well as of the Work Package/Sub-Project Leader(s) are not eligible for funding. The Head or Work Package/Sub-Project Leader(s) may, however, take a “rotational position”. In this case, the personnel costs of the Head will not be reimbursed as part of the CRG funding, but the corresponding personnel costs incurred by the release from clinical work will be eligible for funding. The personnel costs are the wage and salary costs actually incurred according to the institution’s internal payroll accounting.
- Each person employed as part of the CRG needs to be employed according to the collective agreement (“Kollektivvertrag”) of the Austrian universities or – for staff employed at non-university institutions – [according to the standards of the Austrian Science Fund \(FWF\)](#).

#### Training:

Core to the programme is the promotion of young scientists’ careers. Therefore, in addition to funding “rotational positions” for research purposes, the proposals should also include a plan for training of young clinical researchers to develop skills as clinical or physician scientists. This may include the participation in doctoral programmes and mentoring programmes.

#### Consulting services:

Consulting services for planning, coordinating, and executing clinical studies may be covered by the grant. However, if the consulting service is performed by external third parties, at least three offers must be obtained prior to placing the contract.

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<sup>4</sup> “Rotational positions” can be used to request personnel resources to enable doctors in training who are involved in patient care to participate in a CRG. The rotation allows doctors to be released from medical work in whole or in part for a limited period of time so that they can work on their own dedicated research project as part of the CRG.

#### Material costs:

This cost category includes costs for CRG-related consumables, low-value assets, inventory withdrawals, and proportional licence fees.

- Costs for CRG-related consumables, study medication or medicinal products, goods, small equipment, IT hardware, fees for ethics committees and approval by the national competent authority, and fees for services by core facilities may be covered by the grant.
- Publication costs (including Open Access fees and repository fees), licensing fees, and data access and management fees may also be applied for.
- Inventory withdrawals must be valued using a legally recognised inventory accounting method (e.g. FIFO, specific identification, weighted average).
- Funded purchases become the property of the research institution upon payment.

#### Equipment:

- Smaller equipment may be purchased within the scope of the grant. Acquisitions must follow the institutional guidelines for procurement.
- The purchase of large equipment is not eligible for funding. Large-scale equipment is defined as research infrastructures whose establishment and expansion accounts for a substantial part of the institution's research budget, which is correspondingly large and extensive, and is shared by many research groups.
- *Pro-rata* depreciation rates over the CRG duration for equipment necessary to the research project may be funded.
- For more details please refer to the [\*"Special Guideline: Clinical Research Groups"\*](#) for details regarding investments and depreciation.
- An explanation should be given as to why equipment needs to be purchased and is not accessible via a core facility or by means of collaboration.

#### Third party services:

- In contrast to the costs of materials, the service aspect must be predominant in this cost category.
- Insurances of study participants.
- Research project services charged between CRG partners are not eligible for funding as a matter of principle.

#### Travel and accommodation costs:

Expenses for travel and accommodation for scientific meetings and conferences, fieldwork, and expeditions may be funded under the current federal salary scheme or regulations defined in the collective salary agreement, and according to the travel fee regulation.<sup>5</sup>

- Evidence must be provided that the travel costs charged are clearly related to the research project. Eligibility is restricted to travel costs incurred by CRG staff.
- Travel costs (daily allowances, accommodation costs, travel costs, conference fees) are eligible for funding if they can be claimed as business expenditure pursuant to the provisions applicable to the employees.
- Cost refunds paid instead of daily allowances shall be limited to the respective amount of the daily allowance. Reimbursement for the use of a private vehicle shall be in accordance with the statutory mileage allowance. The mileage allowance is used to cover parking fees, toll fees (including motorway vignette), and fuel.
- The funding recipient must, as a matter of principle, choose the most economical means of transport.

#### Overhead costs:

A flat rate surcharge of 25% of the direct costs are included as overhead costs in the total funding (per participating institution within a CRG). This fixed rate covers all general and administrative costs, which cannot be charged as direct costs, in particular:

- General office, controlling, accounting, payroll accounting, management work
- Tax consultancy, auditing, legal advice
- IT (other than IT hardware), communication expenditure
- Office supplies and printed matter
- Workplace equipment (office furniture, IT, etc.)
- Building depreciation, maintenance, repair
- Rent and lease, operating costs
- Cleaning, disposal
- Licence fees (if related to basic business equipment)
- Packaging and transport costs
- Technical literature
- Insurance (other than patient insurances), tax
- General education and training

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<sup>5</sup> Reisegebührenvorschrift 1955, BGBl. Nr. 133/1955, i. d. F. BGBl. I Nr. 153/2020.

In-kind contributions:

At least 10% of the total costs (direct and indirect) must be contributed in-kind by the consortium. Contributions can be personnel costs, direct financial contributions by the institution, non-personnel costs (material, equipment, etc.), and access to and use of existing infrastructure. None of the costs covered by the overheads may be contributed in-kind. In addition, neither third party funding nor contributions from companies will be considered as in-kind contributions.

Non-eligible costs:

- Cost not directly required for the successful completion of the project are not eligible for funding.
- Value-added tax payable on eligible costs is not eligible for funding. However, if it can be proven that this VAT is actually and finally borne by the beneficiary, i.e. that the beneficiary is not entitled to deduct input tax; it can be taken into account as an eligible cost component. VAT that can be reclaimed in any way whatsoever is not eligible for funding even if it is not actually recovered by the grant recipient.
- Please refer to chapter 7 of the [\*“Special Guideline: Clinical Research Groups”\*](#) for details regarding VAT and building reserves or accruals.
- **Funding is not available for studies involving direct commercial interest and does not cover costs for registration of intellectual property rights.**

### 3.6 GENDER ASPECTS

Where applicable, include a description whether and to what extent the sex and/or gender

- of researchers,
- of persons under study,
- of individuals affected by the implementation of research results,
- of animals under study,
- regarding samples taken from humans or animals, and
- in other respects

is relevant to the research project (methods, work package(s)/sub-project(s), objectives, etc.).

At least 1/3 of all Heads (including the Head, the Deputy Head(s), and the Work Package/Sub-Project Leader(s)) must be female.

### 3.7 GOOD SCIENTIFIC PRACTICE, ETHICAL AND LEGAL ASPECTS

Applicants must comply with all legal requirements and safety provisions that apply to the CRG and obtain all necessary authorisations (e.g. from ethics committees, national competent authority



regarding CTR, MDR or IVDR, the national competent authorities regarding animal use for research purposes, etc.).

#### Good Clinical Practice:

For experiments involving humans, including identifiable samples taken from humans and identifiable data, a statement by the local ethics committee must always be submitted. Where an intervention is part of the study, a declaration of compliance with Good Clinical Practice and on the legal sponsor function must also be included where applicable. If the approval from the competent authority and/or the respective ethics committee is required for the planned CRG this must be clearly stated at the short-proposal stage, and the approval must be submitted online with the full proposal.

#### Animal Testing:

Applicants agree to comply with the provisions of the [Animal Testing Act 2012](#). Animal experiments must be described in the research project, including an explanation of how the 3Rs principle (Replacement, Reduction, and Refinement) is to be implemented. For the evaluation and presentation of experiments with laboratory animals, the LBG expects established international standards to be considered, such as the [ARRIVE guidelines](#). If you require funding for the acquisition, breeding, and keeping of experimental animals, the costs must be itemised and explained. If the approval from the competent authority is required for the planned CRG this must be clearly stated at the short proposal stage and the approval must be submitted online with the full proposal.

#### Good Scientific Practice:

Applicants must comply with the [Guidelines for Good Scientific Practice](#) of the Austrian Agency for Research Integrity (OeAWI). If there is reason to believe that an applicant has failed to comply with these standards, the Lead Institution has to carry out a plausibility check. Depending on the circumstances, the Lead Institution is responsible to arrange for the OeAWI to carry out an investigation and has to keep the LBG informed. The LBG reserves the right to suspend, in part or in whole, any procedures related to applications or ongoing CRG until this check or investigation has been concluded.

#### Conflict of Interest:

No members of a CRG shall be acting in any capacity within the private sector or otherwise, as this may constitute a conflict of interest. The applicants will disclose any active engagements on their part that may directly or indirectly qualify as a conflict of interest.

### 3.8 OPEN SCIENCE AND DATA MANAGEMENT

Applicants are expected to comply with best practice in open science. In particular, applicants shall:

- Make their peer-reviewed publications, which have resulted in whole or in part from funding under the CRG programme, openly accessible on the internet in compliance with [plan S](#) (that is, in line with the open access requirements of the FWF and the Horizon Europe programme). Following the [FWF open access policy](#) is considered to be in compliance with the CRG programme.
- Register the clinical studies according to the applicable law in the respective study registries and report the respective outcomes therein.
- Manage their research data responsibly, following the [FAIR principles](#), and provide the data “as open as possible and as closed as necessary”. In order to do so, successful applicants shall develop a Data Management Plan (DMP) in which they outline the measures taken to ensure the FAIRness of data, including openness of research data whenever legally possible or reasons for legitimate cases of data retention. A detailed DMP has to be submitted by end of month 4 after the start of the CRG at the latest. Following the [FWF open data policy](#) is considered to be in compliance with the CRG programme. The LBG will provide a template for such a DMP.

Relevant costs for open access publications and data management (including open data) costs are eligible for coverage by the grant.

## 4 SUBMISSION PROCEDURE

The technical processing of the submission of applications is carried out in cooperation with the Austrian Research Promotion Agency (FFG) using the [FFG's submission system eCall](#).

Proposals can only be submitted electronically via eCall in accordance with the submission deadlines.

- The main proposal may only be submitted if all Cooperation Partners have previously completed and submitted their partner proposals<sup>6</sup> via eCall.
- A proposal is considered to have been submitted if the eCall application has been finalised by clicking the “Submit” (“Einreichung abschicken”) button. On successful submission, a confirmation will be sent by email. It is not possible to resubmit the proposal or parts of it, or to revise the proposal after the submission deadline.
- In case of any questions about eCall please contact the FFG Funding Service: +43 5-7755-0; [foerderservice@ffg.at](mailto:foerderservice@ffg.at).

The call follows a two-step application process: in a first stage, applicants submit a short proposal describing the key objectives and motivation for the proposed work. In the second stage, the applicants of successful short proposals are invited to submit a full proposal and present it in expert-led interviews.

### Short proposal:

1. Abstract (approx. half page/1500 characters)
2. Short CRG description (5 to max. 10 pages)
  - 2.1. Introduction, background, and state of the art (max. 2500 characters)
  - 2.2. Objectives, hypotheses and research questions (max. 2000 characters)
  - 2.3. Overview on the planned research design (general overview of plans for 8 years, a more detailed overview for the first 4 years) (max. 2000 characters)
  - 2.4. Scientific methods, study design and research design (including work package(s)/sub-project(s)) and feasibility (max. 2000 characters)
  - 2.5. Expected results, clinical relevance/impact and novelty (level of innovation)
  - 2.6. Schedule/research project overview
  - 2.7. Interdisciplinary collaborative aspects, role of team members/researchers (max. 1500 characters)

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<sup>6</sup> I.e. Cooperation Partners' signatures/approvals of the short/long proposal.

- 2.8. Measures to advance research careers and description of the role of the Mentor (max. 1500 characters)
  - 2.9. Potential ethical aspects (max. 700 characters)
3. Financial plan
4. Authorisation and affirmation
5. Attachments (CVs of key staff, letter of intent, brief ethical declaration)

**Full proposal** (max. 20 pages in length for sections 1 to 6):

1. Abstract (approx. half a page/1500 characters)
2. Introduction (approx. 4 pages)
  - 2.1. Subject of the research project
  - 2.2. State of the art and key scientific challenges
  - 2.3. Own preliminary data
3. Hypotheses, objectives, and expected outcomes (approx. 3 pages)
  - 3.1. Research questions and hypotheses
  - 3.2. Objectives of the research project (general overview for 8 years, more specific for the first 4 years)
  - 3.3. Expected results
4. Clinical relevance and innovativeness (approx. 3 pages)
  - 4.1. Contribution and relevance of the work to the targeted medical/clinical field
  - 4.2. Innovativeness of the proposed research project
5. Methodological approach (approx. 5-6 pages)
  - 5.1. Research plan (including Gantt chart; general plan for 8 years, more specific plan for the first 4 years)
  - 5.2. Description of the work packages/sub-project(s)
  - 5.3. Research methods and clinical study design (if applicable)
  - 5.4. Description of the patient cohort (inclusion, exclusion criteria, patient recruiting strategies)
  - 5.5. Feasibility, risk management, and mitigation strategy
  - 5.6. Data management (incl. dissemination of results)
  - 5.7. Ethical aspects (approx. 750 characters)

6. Collaboration and Personnel (approx. 4 pages)
  - 6.1. Justification and roles of personnel (incl. project management)
  - 6.2. Interdisciplinary collaborative aspects
  - 6.3. Measures to advance research careers and mentoring
  - 6.4. Research team composition & gender equality (approx. 750 characters)
7. CRG-related publications/key references
8. Additionality: Incentive effect
9. Financial plan
  - 9.1. Explanation of financial plan (approx. 3000 characters)
  - 9.2. Disclosure of thematically related and publicly funded projects, which provide the basis of or feed into the proposed application (max. 500 characters)
10. Authorisation and affirmation
11. Attachments

**Submission and review of full proposals:** The invited applicants may submit full proposals, which contain a detailed research project with a detailed budget. Full proposals will first be checked by the LBG regarding their compliance with the formal specifications outlined above.

## 4.1 SUBMISSION DEADLINES

First stage:

The call for **short proposals** is open from **22 September 2022** until **17 November 2022**.

In **January 2023**, a Scientific Expert Commission will decide which proposals proceed to the full proposal stage.

Second stage:

Successful applicants must submit their **full proposal** until **20 April 2023**.

Selected applicants will be invited to **on-site interviews** at the beginning of **July 2023**.

The final funding decision is expected to be announced in **July 2023**.

The CRG are expected to start in **October 2023**.

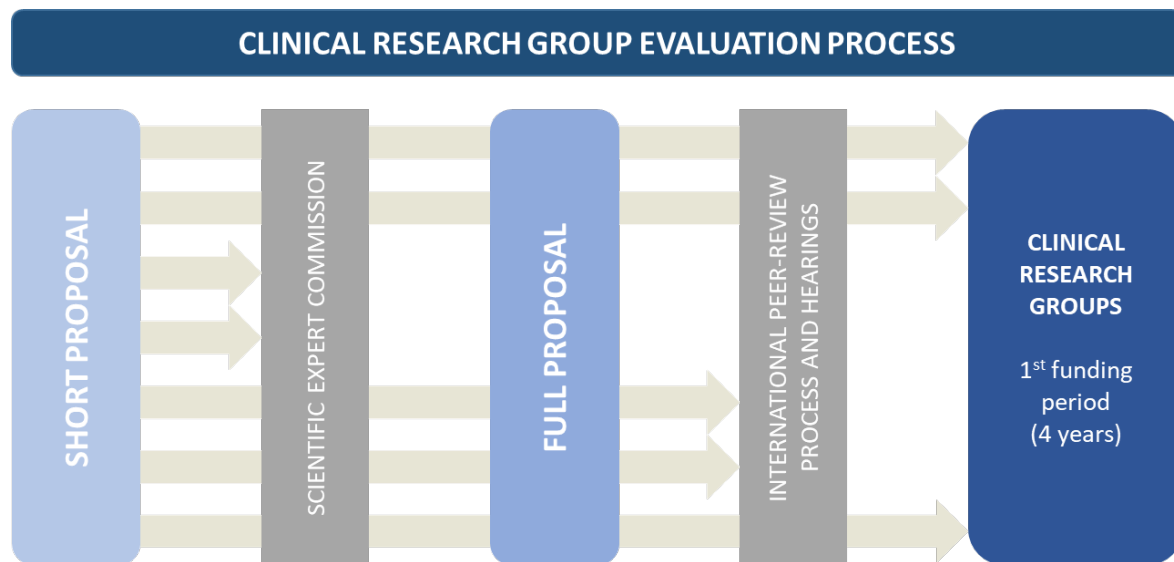
## 4.2 WHICH DOCUMENTS ARE REQUIRED FOR SUBMISSION?

*Table 2: Required documents for submission*

Category	Document type
<b>Call documents</b>	<ul style="list-style-type: none"> <li>▪ Short proposal form (Microsoft Word)</li> <li>▪ Full proposal form (Microsoft Word)</li> </ul>
<b>Mandatory annexes</b>	<ul style="list-style-type: none"> <li>▪ Cost sheet (Excel)</li> <li>▪ CVs of the key researchers (mandatory: Head, Work Package/Sub-Project Leader(s), Mentor)</li> <li>▪ Ethical approvals (no templates)</li> </ul>
<b>Optional attachments</b>	<ul style="list-style-type: none"> <li>▪ Other CRG-relevant additions such as overviews, graphical representations (max. 5 pages, no template)</li> </ul>

## 5 EVALUATION PROCESS AND CRITERIA

Figure 2: Evaluation process in a nutshell



### Short proposals:

A Scientific Expert Commission of up to nine experts will evaluate the short proposals. The research project, the basic concept, the innovativeness of research questions, the quality of the consortium and collaborations, and the basic budget are key elements of the expert evaluation. International research in the same area is used as a benchmark. Based on the review of the Scientific Expert Commission, consortia of successful short proposals are invited to submit a full proposal.

### Full proposals:

At least three reviewers will assess the full proposals in an international peer-review process. The review process concludes with on-site interviews with the Scientific Expert Commission (hearings), involving representatives of the CRG partners. Based on the rating of the peer-review process and of the outcome of the hearing, the Scientific Expert Commission produces a ranking and a recommendation for funding.

Based on the ranked funding recommendation of the Scientific Expert Commission the decision to grant or refuse funding is made by the Federal Minister of Education, Science and Research for funds allocated by the BMBWF (according to the [“Special Guideline: Clinical Research Groups”](#), section 8.7), and by the LBG’s board of directors for funds allocated by the FZÖ (in accordance with the regulations of the FZÖ).

## 5.1 EVALUATION CRITERIA

Short and full proposals will be assessed according to the following criteria:

### A: Scientific excellence and fit to the call

- Fit to the scope, relevance, potential
- Excellence, innovativeness, originality

### B: Competencies of applicants

- Team composition, collaborative/interdisciplinary aspects, gender aspects
- Career development prospects

### C: Quality of planning

- Research design, methods
- Good scientific practice, ethical, and legal aspects
- Financial plan/budget

The evaluation scheme is divided into a scale from 6 (“Excellent”) to 1 (“Insufficient”) (see Table 3).

*Table 3: Evaluation scheme*

Score	Explanation	Description
6	Excellent	The research project meets the criterion very well and fully.
5	Good	The research project meets the criterion well and to a predominant extent.
4	Average	The research project meets the criterion in a sufficient manner.
3	Poor	The research project meets the criterion to an inadequate extent. There are significant weaknesses.
2	Very poor	The research project addresses/meets the criterion to a very inadequate extent. The weaknesses clearly outweigh the few strengths.
1	Insufficient	The research project does not meet the criterion.

## 5.2 ELIGIBILITY CHECK

The funding application (short and full proposals) is checked for formal correctness and completeness.

- The LBG communicates the result of the formal check within two weeks.
- If the formal requirements are not met and the deficiencies cannot be remedied, the funding application will be discarded from the procedure.



- Applicants can remedy rectifiable deficiencies regarding attachments within a reasonable period.
- Only in well-founded cases, applicants may submit ethical and official approvals for the CRG after the deadline for full proposals, but no later than 30 June 2023. In case an extension for the submission of ethical and official approvals is needed, please contact the LBG Programme Manager (see chapter 1 Call summary for contact details).
- If incorrect information is found after the formal check, the grant application may be withdrawn from the procedure at a later stage. The checklist for the formal review can be found in section 5.3 Checklist formal check.

Substantial omission of elements of the proposal or other serious lack of information may result in rejection of the proposal before the review of the Scientific Expert Commission begins. Any such decisions are taken by the LBG based on the criteria Table 4 in section 5.3.

## 5.3 CHECKLIST FORMAL CHECK

*Table 4: Checklist formal check*

Criterion	Requirements checked	Correctable?	Consequence
Completeness of the application	The short or full proposal form must be completed in full; alteration and addition of chapters or headings are not permitted (upload as PDF file)	No	Rejection as result of formal check
Use of correct forms	Short or full proposal form (available at <a href="https://lbg.ac.at/kfg/">https://lbg.ac.at/kfg/</a> )	No	Rejection as result of formal check
Duration	4+4 years (indicated by proposed start and end date; second funding period after successful interim evaluation)	No	Rejection as result of formal check
Language	English	No	Rejection as result of formal check
The applicant is eligible for submission of a proposal	Austrian medical university/faculty with an affiliated university hospital	No	Rejection as result of formal check

Criterion	Requirements checked	Correctable?	Consequence
The Cooperation Partners are eligible for participation	<p>One or more of the following Austrian institutions:</p> <ul style="list-style-type: none"> <li>Public universities</li> <li>Private universities</li> <li>Universities of applied sciences</li> <li>Hospitals ("Krankenanstalten")</li> <li>(Non-profit) non-university research institutions</li> </ul>	No	Rejection as result of formal check
Requirements for consortium/staff	<ul style="list-style-type: none"> <li>Lead Institution</li> <li>Consortia partner(s) institution(s) that are independent from each other<sup>7</sup></li> <li>Mentor and Head must be employed at the Lead Institution</li> <li>Min. 5 and max. 15 directly funded researchers (FTE) in total</li> <li>At least 1/3 of all Heads are female (including the Head, the Deputy Head(s), and the Work Package/Sub-Project Leader(s))</li> </ul>	No	Rejection as result of formal check
Funding amount	Maximum funding for the first funding period is 4 million EUR	No	Rejection as result of formal check
Attachments to proposal form	Mandatory CVs of the Mentor, Head and of the Work Package/Sub-Project Leader(s) attached using the template and not exceeding the four-page limit	Yes	Rectification via online submission tool is possible

<sup>7</sup> In well-founded cases, an individual application by a university is also possible. In such cases, greater emphasis should be placed on cooperation between different clinical departments and on interdisciplinarity between researchers.

## 6 FUNDING PROCEDURE

### 6.1 FUNDING CONTRACT

In case of funding, the formal funding contract will be between the LBG and the participating institutions, and will require the signature of the rectorate (according to §27 of the University Act 2002) or the authorised person(s) of each institution, the Mentor, and the Head. The funding contract needs to be signed by October 2023. Funding will be transferred to the Lead Institution, which is responsible to allocate the funds to the Cooperation Partners. Each partner institution has to establish a project account to which the funds will be transferred to.

### 6.2 REPORTING

In case of funding, the Head, with the assistance of the Mentor, is responsible for the reporting duties. These include:

**Annual reports including a scientific report and a financial report** must be submitted during the entire CRG duration. Corresponding templates are provided by the LBG (the use of the templates is mandatory).

During the fourth research year, but at least 6 months before the end of the first funding period, an **interim report** must be submitted. This report will be the basis for the decision on whether the second funding period of the CRG (for additional 4 years) will be granted. The interim report must include a summary of CRG status (completed work packages and/or sub-projects as well as deliverables of the research project, upcoming work packages/sub-projects, deliverables, and aims), a publishable summary of the accomplished scientific results, quantifiable outputs (publications, public outreach, third party funding, etc.), and a detailed financial report.

Within two months after the end of the second funding period, an extensive **final report** must be submitted. This report must include a scientific report with a description of completed work packages/sub-projects and conclusions, publications/pre-prints, public outreach, and research project outputs as well as a detailed financial report.

The formal review of the reports is carried out by the LBG and the content of the interim report is reviewed in an international peer-review process. Based on this peer-review process, the Scientific Expert Commission makes recommendations for further funding; the content of the final report will also be peer-reviewed. The financial audit is carried out by the LBG. The reports have to be made available both in a single copy as a print version and on data carriers in Word format or as a PDF file.

Additional texts and images for public relations purposes have to be sent to the LBG upon request. In light of the open-access policy, a publicly publishable summary of the final reports will be released on the LBG CRG website.

## 6.3 PAYMENTS

The first instalment will be paid once the requirements have been met and the funding contract has been signed, however, not earlier than one week before the start of the funding period. Payments are made to the bank account specified by the Lead Institution.

Subsequent instalments will be paid in accordance with the progress of the research project:

- After the approval of the interim reports and interim accounts.
- Once additional requirements have been met (where necessary).

*Table 5: Number of reports and instalments for funding period 1 (4 years)*

Instalment no.	% of funding amount	Financial reporting date	Payment date
1	30% at contract conclusion and fulfilment of any additional conditions		October 2023
2	up to 20%	July 2024	October 2024
3	up to 20%	July 2025	October 2025
4	up to 20%	July 2026	October 2026
5 (final)	10%	Within 2 months after funding period 1	Dependent on end date of funding period 1

## 6.4 HOW MAY CONFIDENTIAL PROJECT DATA BE USED?

The LBG processes personal data of funding applicants and funding recipients provided by the persons concerned in the course of the funding application, and data collected by the LBG itself in the course of concluding the funding agreement, as well as data generated by means of the transparency portal query pursuant to section 32(5) TDBG 2012 for the following purposes:

- To process the funding application and assess whether the general and specific funding requirements are met.
- For the conclusion of the grant agreement and, in the case of the conclusion of a grant agreement, for the purpose of fulfilling the respective contractual obligations, in particular for the administration of the grant benefits and the control of the evidence of the grant prerequisites.

- For the fulfilment of legal obligations, in particular reporting obligations and control purposes to avoid double funding, namely § 38 iVm 18, 27, ARR.
- The legal basis of the processing is therefore Art. 6 para. 1 lit.c DSGVO (fulfilment of a legal obligation). For the awarding and administration of grants pursuant to Art. 89 DSGVO, Section 2g of the Federal Act on General Matters Pursuant to Art. 89 DSGVO and the Research Organisation (Research Organisation Act - FOG); Federal Law Gazette No. 341/1981 as amended is to be mentioned as the legal basis in particular.
- Personal data may have to be transmitted or disclosed in particular to bodies and agents of the Court of Audit (in particular pursuant to § 3 para. 2, § 4 para. 1 and § 13 para. 3 of the Court of Audit Act 1948, Federal Law Gazette No. 144), the Federal Ministry of Finance (in particular pursuant to §§ 57 to 61 and 47 of the Federal Budget Act 2013 as well as § 14 of the ARR Ordinance) and the European Union in accordance with the provisions of EU law.
- The provided personal data is passed on in fulfilment of legal obligations to:
  - a. Austrian Federal Ministry of Education, Science and Research.
  - b. To third parties, which may be: the Court of Audit, EU bodies, other federal or provincial funding agencies.
  - c. External experts can also be commissioned to evaluate projects in individual cases. Such experts act as processors in the name and on behalf of LBG, and are obliged to take technical and organisational measures to ensure data security and maintain data confidentiality.
- Project content and results may only be published (e.g. on the website or in social media forums) with the consent of the funding recipients (Art 6 para 1 lit a DSGVO), unless the LBG is under a legal obligation to do so.
- The consent of the persons concerned must also be obtained from the LBG for any other data processing going beyond this provision.
- In order to ensure a level of protection appropriate to the risk with regard to confidentiality, integrity, availability, and the resilience of the systems, the LBG will take technical and organisational measures within the meaning of Art 32 DSGVO that are sufficient and appropriate to ensure the protection of data against accidental or unlawful destruction, against loss, and against access by unauthorised persons.

The detailed regulation is available in the [LBG's privacy policy for clinical research groups](#).