Bundesministerium
Bildung, Wissenschaft
und Forschung

Special Directive
Clinical Research Groups

(Validity period: Calls for the years 2024 to 2026)

GZ 2024-0.104.765

This document is a translation of the "Sonderrichtlinie Klinische Forschungsgruppen (Laufzeit: Ausschreibungen für die Jahre 2024 bis 2026): GZ 2024-0.104.765" published by the Federal Ministry of Education, Science and Research. Please note that the German version is the legal basis for the funding of the Clinical Research Groups programme.

Vienna, 2024

This guideline is a Special Directive pursuant to the Federal Act on General Matters relating to Article 89 GDPR and Research Organisation (Research Organisation Act - FOG), Federal Law Gazette No. 341/1981 as amended by Federal Law Gazette I No. 75/2020, and § 5 of the General Framework Guidelines for the Granting of Funding from Federal Funds (ARR 2014), Federal Law Gazette II No. 208/2014, issued in agreement with the Federal Minister of Finance.

Imprint

Media owner, publisher and editor:
Federal Ministry of Education, Science and Research
Department V/9
Minoritenplatz 5, 1010 Vienna
Tel.: +43 1 531 20-0

Content

1 Preamble

In contrast to other countries in the European Union, Austria provided only a limited number of funding instruments for non-commercial clinical research until 2022. With the close of funding for medical research from the Austrian National Bank's Jubilee Fund, the funding allocated to clinical research also ended. It was this funding which allowed clinical researchers at the start of their scientific careers to conduct smaller scientific projects independently, making this an important instrument of support for young professionals in clinical research. Although universities take internal measures to enhance the compatibility of clinical and scientific activities and to allocate specific funding for young scientists working in medicine and healthcare, there was, until 2022, however, a lack of funding clearly designed for clinical research, available on a competitive basis, to support and retain physicians at the universities who are interested in pursuing a career in science.

To close the gap with leading countries in this field, such as Germany[1], the Netherlands[2], Sweden[3] and the United Kingdom[4], the programme "Clinical Research Groups (CRG)" was designed in 2022 to overcome the funding gap and encourage high quality, scientific advancement of outstanding young clinical researchers by integrating them into clinical research groups working on a specific research project. This serves to maintain Austria's competitiveness as a location for clinical research, to generate and secure new medical knowledge and innovations, which will benefit patients in the long term, and ultimately create a scientific ecosystem, which attracts academic clinical research and strengthens Austria's attractiveness for the pharmaceutical industry.

In order to ensure sustainability in funding of clinical research groups and in line with international standards, the Federal Ministry of Education, Science and Research (BMBWF) will establish this programme in the long term with this special directive.

This enables the sustainable promotion of young researchers while also supporting the development of innovative research results in disease- or patient-oriented clinical research in the long run. achieves this aim by supporting young scientists while also encouraging innovative outcomes in disease- or patient-oriented clinical research. As the COVID-19 pandemic has shown, clinical research with its associated societal issues plays a vital role when it comes to developing and optimising new diagnostic and therapeutic approaches.

[1] https://www.dfg.de/foerderung/programme/koordinierte_programme/klinische_forschungsgruppen/index.html, last viewed on 15/06/2023.

[2] https://www.zonmw.nl/en/about-zonmw/organisation/, last viewed on 15/06/2023

[3] https://www.vr.se/english.html - search terms clinical or medicine, last viewed on 15/06/2023

[4] Clinical academic research partnerships – UKRI , last viewed on 15/06/2023

Furthermore, the programme meets the particular need for clinical research in Austria and constitutes a funding mechanism of a scale needed for clinical research not available before 2022.

Moreover, the sustainable establishment of the programme will ensure to meet the special demand for Clinical Research in Austria by offering a funding scheme on a scale necessary for clinical research that did not exist before 2022. Therefore, this directive once again enables calls for proposals for the "Clinical Research Groups" funding programme in the period 2024-2026.

2 Definitions

Clinical research	Clinical research is a branch of medicine that deals with experimental testing of therapeutic procedures (e.g. medications) under defined conditions. Clinical research is carried out using clinical studies.
Clinical Research Groups (CRG)	A Clinical Research Group is a group of at least five to a maximum of 12 scientists (FTE) who work together on a project of clinical research. The group includes, at a minimum, the Head, the Mentor, one or more Deputy Heads, one or more Sub-Project Leaders, the researchers and other collaborators, if any.
Clinicians	Physicians active in scientific research or researchers entrusted with medical tasks or patient care.
Lead Institution	The applicant university, which must have a university hospital, and which submits the proposal on behalf of several cooperation partners. If a proposal is submitted by only one university, there is no Lead Institution.
Cooperation partners	Institutions that receive funding jointly with the Lead Institution. All cooperation partners sign the funding contract and are thus contracting parties.

Head	Person with at least four years of research experience after completing MD specialist training or a PhD. She/he plans, organises, coordinates and supervises the structure and implementation of the research project. She/he is also responsible for adherence to quality, time and cost specifications as well as compliance with all applicable legal standards in the sub-projects. She/he usually leads a team of post-docs (working within or outside medicine), clinicians in training, pre-docs, technicians, study nurses, etc., and is responsible for allocating the work packages, coordinating the work steps and leading the team as a whole. This is an experienced researcher with a valid employment contract with the federal government, the respective federal state or university, ideally with a medical position at an university hospital. If the person is employed by the federal government or the federal state, she/he must be assigned to work for the university.
Mentor	She/he is an experienced advisor and provides the experience, knowledge and appropriate network necessary for the success of the specific clinical research project. The Mentor must be an experienced scientist who is either employed by the federal government or federal state and assigned to work for the university, or is directly employed by the university, ideally working as a clinician in a senior position at a university hospital.
Deputy Heads	Persons with at least 2 years of research experience after completing specialist training or a PhD. Junior researchers who can deputise for the Head and support her/him in her/his functions and tasks. The deputy head (but only one person in case there are several deputies) takes over as head in the second funding period.

Work Package / Sub-Project Leader	CRG researchers who lead a work package/sub-project. One or more Work Package / Sub-Project Leaders act as Deputy Heads. The Mentor and the Head may also lead sub-projects.
Junior Researchers	Researchers with at least two years of national/international postdoctoral research experience or experience in conducting their own research project, who can be Sub-Project Leaders or Deputy Heads.
Rotational positions	Rotational positions can be used to request personnel resources to enable clinicians in training who are involved in patient care to participate in a CRG. The rotation allows clinicians 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.
Translational research	Research processes intended to break up the unidirectional flow of knowledge were developed in order to efficiently shorten the time span between medical findings and therapeutic practice. The translation of theory into practice and the development of specific questions from practice are integrated into the research process. This gave rise to the term of "translationality", which emerged in the late 1970s and has since been used in the context of increasing efficiency in research.

Clinical Coordination Centre	A Clinical Coordination Centre is usually located at a medical university and provides physicians and researchers with advice and support in the planning, implementation and evaluation of clinical research projects and clinical studies.
Research equipment	Equipment includes scientific instruments, system components, self-assembly devices (generally assembled from small devices and material) and other durable assets as well as intangible assets such as permits, industrial property rights and associated licences, if their acquisition costs exceed EUR 1,500.00 (incl. VAT, if the research institution is not entitled to deduct input tax) and the equipment is predominantly (more than 50% of the total equipment costs) financed from BMBWF funds.
Large-scale equipment	Large-scale research infrastructure 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.

3 Legal basis

3.1 National legislation

The present guideline is based on the following legislation:

- Federal Act on General Matters relating to Article 89 GDPR and Research Organisation (Research Organisation Act - FOG), Federal Law Gazette No. 341/1981, as amended;
- Federal Act on the Medical Profession (ÄrzteG 1998), Federal Law Gazette I No. 169/1998, as amended;
- Guidelines of the Federal Government pursuant to § 11 (2) FOG on the "Granting and Implementation of Funding";
- Ordinance of the Federal Minister of Finance on "General Framework Guidelines for the Granting of Funding from Federal Funds" (ARR 2014), Federal Law Gazette II No. 208/2014 as amended by Federal Law Gazette II No. 190/2018, which apply subsidiarily;
- Ordinance of the Federal Minister of Health on General and Specialist Medical Training (ÄAO 2015), Federal Law Gazette II No. 147/2015, as amended by Federal Law Gazette II No. 89/2021, on the basis of §§ 10 (5) and 24 (1) of the Act on the Medical Profession (ÄrzteG 1998).

3.2 European legislation

Conformity with EU law: The funding granted under this programme serves to finance the non-economic activities of the funding applicant and therefore does not qualify as state aid within the meaning of Article 107 (1) TFEU.

3.3 Legal entitlement

This Special Guideline does not establish a subjective legal claim to the granting of funding or an obligation to contract on the part of the federal government. Projects will be funded in accordance with the budget available.

4 Objectives and evaluation

4.1 Strategic objectives

The strategic objectives of the Clinical Research Groups (CRG) programme are to

1. Strengthen and enhance Austria's attractiveness as a clinical research location;
2. Allow translational ("bench to bedside") aspects to be integrated into research (especially clinical studies);
3. Strengthen the career prospects of scientists involved;
4. Encourage and develop expertise of young scientists in the fields of clinical research and project management;
5. Promote equality policies and include diversity and gender aspects in research;
6. Intensify, professionalise and improve the quality of clinical research at Austria's medical universities;
7. Ensure interdisciplinary cooperation between university hospitals and other organisational units at universities and non-university research institutions in order to promote knowledge and technology transfer in healthcare and medical research; and to
8. Strengthen the output and impact of clinical research in Austria.

4.2 Differentiation from existing funding programmes

Until 2022, only a limited number of funding instruments for non-commercial disease- and patient-oriented (translational), consortium-based clinical research was available in Austria. In order to ensure sustainability in funding of clinical research groups, this programme will be established on a long-term basis to support clinical research in Austria in the long term. There are several reasons for this:

- As Austrian clinical research is generally conducted at individual sites, the CRG funding programme was designed to promote a paradigm shift towards research consortia. In these groups clinicians with proven expertise will work together on clinically relevant research questions across institutional boundaries in order to generate findings which cannot be achieved with the basic research funding offered by the Austrian Science Fund (FWF) – as its Clinical Research Programme (KLIF) offers exclusively individual funding for small and short-term clinical research projects.
- Research consortia are also possible in a few FWF programmes such as Special Research Programmes (SFBs), Research Groups or doctoral programmes, which may be similar to the present funding programme in terms of duration and level of funding.

However, in contrast to these FWF initiatives, the CRG funding programme incorporates the role of Mentor, thus giving young clinical research staff at (university) hospitals with their strictly hierarchical organisation and huge workload the opportunity ("rotational positions") to engage in disease- and patient-oriented translational research in the daily clinical practice of patient care.

- Funding Clinical Research Groups should also serve to improve clinical research by establishing joint research projects at and between university hospitals and clinical departments and involving other research partners where necessary. This serves to increase cooperation as well as establishing critical mass and sustainable research expertise, and thereby raising the profile of both the main applicant university and of Austria as a place for clinical research.
- Professionally qualified clinicians continue to suffer an intrinsic disadvantage when it comes to competing for basic research funding (e.g., FWF SFBs): as translational researchers, they must compete with "full time" basic researchers who have a greater research output in terms of a linear timeline. Clinicians, in contrast, must divide their time between clinical research and significant levels of patient care. Recognising this problem, Germany launched a special funding programme a few years ago with the aim of establishing clinical research collaborations. The CRG programme therefore continues to address this "market failure" of research funding in Austria. By establishing clinical research groups based on international role models, and simultaneously integrating translational ("bench to bedside") aspects, Austrian healthcare can achieve international connectivity at the highest level.

4.3 Operational objectives and related indicators

No	Operational objectives	Indicators	Target values
1	Strengthening disease- and patient-oriented (translational) clinical research		
1a		Output analyses based on peer review (e.g. publications, citations, presentations, intellectual property rights, documented changes in clinical practice).	Presentation of positive changes
1b		Percentage of proposals assessed as excellent - of which percentage of funded proposals - of which excellent but not funded (approved but not funded)	Perfect match (all proposals assessed as excellent are eligible for funding)
1c		Average number of scientific disciplines involved in a proposal (internal & external cooperation) as an indicator of the degree of cooperation	Target value depending on call

No	Operational objectives	Indicators	Target values
2	Promoting young clinical researchers and their career prospects in science		
2a		Number of training and qualification measures	
2b		Number of rotational positions and Sub-Project Leaders (primarily) active in clinical work as an indicator for the promotion of clinical researchers	
2c		Number of Clinical Research Groups in which a Deputy Head assumes the role of Head after the interim evaluation.	
3	Gender equality goal	Proportion of female (Sub-Project) Leaders as degree of achievement of gender equality goals	1/3 female (Sub-Project) Leaders

4.4 Programme evaluation

The programme must be evaluated by external experts by 31/12/2032 at the latest in order to assess whether the objectives have been achieved. The evaluation must be based on the indicators defined in section 4.3 herein and will be commissioned by the Federal Ministry of Education, Science and Research (BMBWF). In addition, an evaluation will be carried out in 2027 in accordance with the provisions of budgetary law.

5 Subject of funding, funding applicant, duration, type and amount of funding

5.1 Subject of funding

Funding is provided for the implementation of scientific, high-quality clinical research projects that are carried out by outstanding clinical researchers in clinical research groups as part of a medium-term collaboration. The focus of the funding is on academic issues, i.e. investigator-driven clinical studies or translational research projects.

The 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, longitudinal studies, epidemiological studies, biobanking, biomarker studies, patient outcome studies, proof of concept studies, etc.).

5.2 Funding applicant

The following legal entities (institution(s) involved in the project) outside the federal administration may apply for funding if they have the economic and financial capacity as well as the scientific staff with the necessary professional qualifications to implement the Clinical Research Groups addressed by this Special Guideline:

- Universities pursuant to the Universities Act (UG 2002), Federal Law Gazette I No. 120/2002, as amended,
- Private universities pursuant to the Private Universities Act (PUG), Federal Law Gazette I No. 77/2020, as amended,
- Universities of Applied Sciences pursuant to the Universities of Applied Sciences Act (FHStG), Federal Law Gazette No. 340/1993, as amended,
- Hospitals pursuant to § 2 (1) sub-paras (1) and (2) in conjunction with § 1 of the Hospitals and Sanatoriums Act (KAKuG), Federal Law Gazette No 1/1957, as amended,

- Non-university research institutions operating in Austria.

Entities that are not non-profit organisations or do not guarantee immediate publication of the results in a generally accessible format are not eligible to apply.

A Clinical Research Group may consist of one or several of the institutions listed above. One institution, which must incorporate a university hospital, shall take the role of Lead Institution and submit the proposal. However, all the institutions involved (cooperation partners, eligible for funding) must sign the proposal so that all the funding recipients are parties to the funding agreement. A Clinical Research Group must address several sub-projects, with the majority of the sub-projects based at universities. Cooperation with non-university research institutions and other hospitals is possible in principle. Involving external researchers at other sites or abroad is permissible, although they are not eligible to receive funding. Companies may also be involved where this is deemed necessary and effective for carrying out a project. However, a company may not act as a funding recipient or be granted any funding.

5.3 Members of the Clinical Research Group

A Clinical Research Group consists of a Mentor, a Head, one or more Deputy Heads, Sub-Project Leaders, the researchers, and any other staff.

Researchers are employed by the respective institutions represented in the clinical research group.A Mentor must be appointed for each Clinical Research Group whose role it is to ensure that the group is incorporated into the structure and strategic planning of the Lead Institution. The Mentor is an experienced scientist and ideally fulfils this role for the entire duration of the project. A Head must also be appointed who is responsible for the coordination and organisation of the Clinical Research Group. Both must be employed by the federal government, the respective federal stateor the university and should ideally be working as doctors at a university hospital. Where one or both are employed by the federal government or the federal state, they must be assigned to work for the university.

To encourage young scientists and create career opportunities in clinical research, a maximum of two Deputy Heads of the Clinical Research Group must be appointed who also work at the Lead Institution, ideally as a doctor. One of the Deputy Heads will take over as Head of the Clinical Research Group after a period of four years (end of the first four-year funding period). At the start of the project, the Deputy Heads need not have the same scientific and clinical experience as the Head, but should gain the relevant experience over the course of their work on the project.

The Head is responsible for the scientific and administrative management of the Clinical Research Group, and (together with the Mentor) is responsible for the coordination and submission of the proposal and compliance with the reporting obligations. The Head must have relevant expertise and project management experience. Proof that these requirements and qualifications have been met must be shown in the proposal and verified by the reviewers.

Once fully established, the Clinical Research Group will consist of five to a maximum of 12 scientific and non-scientific project members or full-time equivalents.

5.4 Type of funding, funding amount

Funding is granted in the form of non-repayable grants and may range from 0.52 million euros to 1.04 million euros per year per project. The amount of funding depends on the funding requirements of the project. The funding represents peer-review research funding for the participating university research institution in accordance with § 27 2002 of the Universities Act (UG). The maximum funding intensity is 90%.

5.5 Duration of funding

A maximum project duration of 4 years must be specified in the call for proposals. After three years, the funding recipients must submit an interim report (according to section 8.8.1). The formal check of the interim reports is carried out by the Ludwig Boltzmann Gesellschaft (LBG), while their content is reviewed by external reviewers. The Scientific Expert Commission uses the reviews as a basis for their assessment and, in the event of a positive result, will recommend a one-time extension of the funding period by a maximum of 4 years to the responsible Federal Minister for Education, Science and Research. The maximum funding period, including extension, is thus 8 years. Any remaining funds that have not been used by the end of the first funding period can be transferred to the second funding period in case of an extension of the funding period up to a maximum of 15% of the funding amount.

The funding period may be extended by a maximum of one year on a cost-neutral basis if work on the project has been delayed through no fault of the funding recipient, if the project is still eligible for funding and if no additional eligible costs are incurred. The decision to extend the funding must be made no later than six months before the end of the funding period.

5.6 Incentive effect and start of the project

Funding may only be granted if it has an incentive effect, i.e. if the project cannot, or cannot adequately, be carried out without federal funding.

As a rule, funding is only permissible if the work has not yet begun prior to the funding being granted, or has only begun with the written consent of the BMBWF or the funding agency. Funding may also be granted ex post without these requirements being met, if this is justified by the specific nature of the funded activity. In this case funding may only be granted for costs incurred after submission of the proposal (§ 23 (1) ARR 2014).

6 Funding requirements

6.1 Overall funding

The financial viability of the project must be ensured taking the funding into account. The funding applicant must provide relevant evidence by submitting appropriate documentation (cost and financing plans, time and work schedules) as part of the proposal.

6.2 Reasonable in-kind contributions

The funding recipient must contribute an appropriate share of own resources (personnel, financial and material resources, labour) to the project. The amount and extent of these resources must be specified in the detailed cost plan provided as part of the proposal. The adequacy of these resources must be examined and justified on a project-specific basis in the course of the review. The contribution must, however, account for at least 10% of the project sum.

6.3 Avoidance of multiple funding

The applicant must disclose the following information before federal funding can be granted:

- any public funding, including EU funding, granted to the applicant and all persons and institutions involved in the Clinical Research Group for the same activity in the three years preceding the submission of the proposal, albeit for different purposes, and
- any funding requested by the applicant and all persons and institutions involved in the Clinical Research Group for the same activity from another budget-managing body of the federal government or another legal entity (including other federal, regional or local authorities and the European Union); this shall include funding which has already been approved, funding for which the final decision has not yet been made and funding for which the applicant intends to apply.

For this purpose, the funding applicants are subject to a duty of notification under penalty until the completion of the project, which shall also include any funding for which will be applied subsequently.

The funding applicant shall provide the details required to gather this information. The LBG shall, in advance, specify appropriate and effective methods for verifying the information provided by the funding applicant in order to prevent multiple funding. This is to be ensured in any case by the following measures:

1. When submitting and during the implementation of a research project, applicants are obliged to inform the LBG immediately if applications for funding are submitted to other funding organisations in connection with the Clinical Research Group or if further funding is or has been promised or granted by these organisations. The LBG, as the processing centre, will check whether this is a case of multiple funding and will decide on how to proceed. If the projects overlap, the processing centre must stop processing the funding application, reduce the funding amount or demand repayment of funds already allocated. The processing centre has to establish a standard operating procedure (SOP) for this purpose.
2. This shall also include a search in the transparency portal. For this purpose, LBG is authorised to conduct searches in the transparency portal pursuant to § 32 (5) of the Transparency Database Act (TDBG 2012), Federal Law Gazette I No. 99/2012, as amended, both in its own and in the assigned thematic category pursuant to § 22 (1) and (2) TDBG 2012.
3. Moreover, comparisons with other thematically relevant national funding organisations (e.g. FFG, FWF, WWTF) have to be conducted constantly, at least once a year, in order to prevent multiple funding.
4. The LBG must set up a whistleblower channel through which any suspicions of possible misconduct can be reported anonymously in a secure system. LBG must review incoming reports confidentially and take appropriate measures in accordance with SOP 6.3.1.
5. The LBG must in advance notify other potential funding providers of any suspicion of undesirable multiple funding. In case of confirmation of multiple funding, no funding shall be granted. Funding may, however, be granted if

- the proposal is modified or conditions and requirements are included in the funding agreement in such a way that undesirable multiple funding can be excluded,
- the funded activity can be expected to be properly implemented and accounted for, and the other funding requirements are met.

6.4 Qualification of the funding applicant

Funding is granted under the precondition that, on the basis of the information and evidence provided in the proposal and in the absence of any indication to the contrary,

- sound management can be assumed,
- the funded activities can be expected to be carried out appropriately, in particular due to the applicant meeting the relevant professional, economic and organisational requirements,
- there are no legal grounds for exclusion, and
- the Special Guideline does not stipulate other reasons for exclusion.

7 Eligible costs

7.1 Eligible costs

Eligible costs shall include all personnel and material costs that are incurred directly, actually and additionally (to the normal operating costs) for the duration of the funded project, that are economically reasonable and that were incurred after the receipt of the proposal.

Eligible costs:

- Personnel costs for project staff and personnel costs for release from clinical work ("rotational positions"). The personnel costs of Mentors and Heads are not eligible for funding. (The Head may, however, take a rotational position; in this case, the personnel costs of the Head will not be reimbursed, but the corresponding personnel costs incurred by release from clinical work will be eligible for funding). The personnel costs are the wage and salary costs actually incurred according to the company's internal payroll accounting.
- Costs for consulting services provided by the Clinical Trials Coordination Centre or a comparable institution for the planning, coordination and implementation of clinical trials. If such services are provided by external parties, at least three offers must be obtained prior to placing the contract.[5]
- Material costs, acquisition costs for research equipment and IT equipment and costs for the use of core facilities; the material costs category includes project-related consumables, assets, publication costs (especially open access fees and repository fees) and licence fees on a pro rata basis.
- Costs of third-party services (incl. contracts for work and services[6]),
- Travel and accommodation costs of project staff,
- Overhead costs shall be allocated as a flat rate surcharge of 25% of the direct costs. Costs covered by this surcharge cannot also be recognised as direct costs. This provision shall be deemed to cover all costs of an overhead nature that cannot be charged as individual costs, such as in particular:
    - General office, controlling, accounting, payroll accounting, management work
    - Tax consultancy, auditing, legal advice
    - IT and communication expenditure
    - Office supplies, 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

[5] The provisions of the Federal Procurement Act (BVergG 2018) shall apply.

[6] Cf. § 1151 Austrian Civil Code (ABGB); according to the Austrian Federal Economic Chamber (WKÖ), a contract for work and services shall be deemed to exist if a person undertakes to produce a certain result for another person. Wirtschaftskammer Österreich (29/12/2017), "Werkvertrag (arbeitsrechtlich), Begriff - persönliche Unabhängigkeit – Abgrenzungen", available at https://www.wko.at/service/arbeitsrecht-sozialrecht/Werkvertrag_(arbeitsrechtlich).html, last viewed on 28/02/2022.

- Technical literature
- Insurance, tax
- General education and training

Personnel and travel expenses are only eligible to the extent that they are in accordance with the salary scheme of the federal government or the respective federal state or are based on relevant provisions laid down by law or collective agreement and are in compliance with the Travel Fee Regulation (Reisegebührenvorschrift 1955, Federal Law Gazette No. 133/1955, as amended by Federal Law Gazette I No. 153/2020) for comparable federal employees.

The equipment shall be ordered and pre-financed by the research institution on the instructions of the Head or the Sub-Project Leader. The procurement guidelines of the relevant research institution must be observed. The equipment shall be inventoried at the research institution and the acquisition costs reimbursed from the project budget in accordance with the funding contract or the corresponding agreement concluded between the research institution and the LBG. Large-scale equipment is not part of the financing agreement. Consequently, the acquisition of large-scale equipment is not eligible for funding.

Invoices shall meet the requirements specified by VAT law.

Contracts for work and services shall contain a detailed description of the scope of work performed.

The LBG must specify the eligible costs in the call documents or in a cost guideline to be published on the LBG website.

7.2 Funding for purchases

If the payback period of a fixed asset (§ 285 ABGB) acquired for the performance of the work exceeds the period of performance, funding will be limited to the portion of the cost corresponding to the depreciation for the period of performance (according to the Income Tax Act EstG 1988, Federal Law Gazette No. 400/1988, as amended).

The equipment becomes the property of the research institution upon payment. An obligation to operate the equipment may be specified in the funding agreements.

If the funding recipient uses the funding granted (including all federal funding) exclusively or predominantly to acquire an asset whose price (value) exceeds the limit set for low-value fixed assets under the applicable income tax regulations by a factor of four, the funding recipient must immediately inform the funding provider when the purpose of use ceases to apply or changes significantly. In this case the funding recipient must, at the request of the funding

provider, pay appropriate compensation or make the item in question available to the funding provider for further use or transfer it to the ownership of the federal government.

The fair market value of the asset at the time of the cessation or change of use shall be payable as appropriate compensation, which shall be determined by the BMBWF. If the item was not exclusively acquired from federal funding, an aliquot share of the market value corresponding to the federal funding shall be payable. If the funding is provided by several budget-managing bodies, they must work out a coordinated approach (§ 13 ARR 2014).

7.3 Non-eligible costs

Eligible costs do not include:

- Costs that are not essential for successful project completion and goal achievement.
- The value added tax payable on eligible costs is not eligible for funding.
  If, however, this value added tax can be proven to be actually and definitively borne by the funding recipient, i.e. if the latter is not entitled to deduct input tax, then value added tax can be taken into account as an eligible cost element. Value added tax that can be reclaimed in any way is not eligible for funding even if the recipient does not actually get it back. If the tax authority considers a funding as remuneration for services provided by the funding recipient to the funding provider taxable according to the Value Added Tax Act (MWSTG 1994, Federal Law Gazette No. 663) and the funding recipient is therefore liable to pay value added tax, the remuneration shall be treated as a gross amount. Any additional, separate compensation of value added tax by the funding provider – on whatever legal grounds – shall thus be excluded.
- Federal funding may not be used to create reserves or provisions under the Income Tax Act (EstG 1988, Federal Law Gazette No. 400/1988, as amended) or the Austrian Business Code (UGB, dRGBl. S 219/1897, as amended).

8 Funding procedure

8.1 Funding administration

The Ludwig Boltzmann Gesellschaft (LBG), Austrian Association for the Promotion of Scientific Research, registered in the Central Register of Associations (§ 18 of the Associations Act (VerG 2002), Federal Law Gazette I No. 66/2002), ZVR No. 875209001, Nussdorfer Str. 64, 1090 Vienna, Tel. 01 5132750, is responsible for the administration of this funding programme.

The LBG performs the tasks assigned to it as a funding agency on behalf and for the account of the federal government. The LBG shall make reference to this in the funding agreements.

8.2 Scientific Expert Commission and reviewers

The LBG shall set up a Scientific Expert Commission for strategic and operational support in programme development and the review process. The members will be nominated by the BMBWF on the basis of a proposal by the LBG.

The Scientific Expert Commission shall be composed of high-ranking, international scientists with a track record in their fields. Its task is to advise on strategic programme development, to ensure the quality of the evaluation procedure and to formulate funding recommendations based on the short proposals, and subsequently based on the written individual assessments of the proposals provided by external international reviewers. The Scientific Expert Commission is also tasked with formulating recommendations for extension or closure based on the interim evaluations provided by external, internationally renowned reviewers. The reviewers must meet the same standards as the members of the Scientific Expert Commission, i.e. they should be internationally recognised experts in their discipline and work abroad.

Both the members of the Commission and the reviewers must refrain from any activity that might represent a conflict of interest according to § 7 of the General Administrative Procedure Act (AVG 1991). This shall even apply to activities which might give rise to an appearance of bias to third parties.

8.3 Call for short proposals

The LBG invites applications for funding (short proposals) in a competitive process. The evaluation and decision criteria for the proposals as well as the submission deadline shall be announced with the call. The call for proposals must be published on the LBG website. The call must include the following points as a minimum:

- Strategic and operative objectives of the call
- Eligible organisations
- Procedure and timetable of the submission, review and selection process
- Conditions for submitting projects
- Duration and maximum funding amount
- Subject of funding and reporting obligations
- Criteria for the selection of proposals
- Information and contact details of the LBG
- Reference to this Special Guideline

8.4 Submission of short proposals

In the first stage of the procedure, short proposals must be submitted to the LBG by the specified deadline. The short proposals must contain the following information:

- Title of the Clinical Research Group
- Applicant institutions (incl. organisational units involved)
- Prospective Lead Institution
- Overview of the key persons and the planned sub-projects as well as other members of the CRG known at the time of preparation of the short proposal
- Outline of the project including the central clinical/medical research questions
- Overview of the cost and financing plan, including in-kind contributions
- Date and original signatures of the persons authorised to sign on behalf of the funding applicants, as well as the signatures of the future Mentor and Head.

All necessary documents/application documents will be made available to applicants for downloading on the call website.

The LBG invites selected applicants to submit full proposals based on the recommendations of the Scientific Expert Committee. An invitation to the full proposal phase will be based on the complete and excellent fulfilment of the following criteria:

- Original and innovative focus of the submitted proposal
- Compliance with objectives, purposes and topics requested in the call for proposals
- Precise and appropriate formulation of the research questions
- Suitable methods chosen
- Feasibility of research project is demonstrated plausibly
- Adequacy of project structure and design
- Balanced team composition

- Proof of professional qualifications of team members
- Career development opportunities for junior researchers
- Fulfilment of gender criteria

Any exclusion and information on exclusion from the selection process will be provided in writing by stating reasons.

8.5 Full proposal

Full proposals requested by the LBG based on the recommendation of the Scientific Expert Commission must be submitted to the LBG in writing. The proposals must be submitted in electronic form (by e-mail or via the LBG submission platform) and in English, so as to allow them to be reviewed by international scientific experts. The project description, including the table of contents, must contain the information listed below. Attachments are permitted.

The full proposal must contain the following information:

- Title of the Clinical Research Group
- Applicant institutions (incl. organisational units involved)
- University that will act as the Lead Institution
- Key persons and other members of the CRG known at the time of preparation of the proposal
- Detailed description of the project and the clinical/medical research questions, taking into account the current state of research
- Time schedule and work packages
- Detailed cost and financing plan, including in-kind contributions
- References of CRG members: scientific CV and qualifications relevant to the project (up to 10 "*most important*" publications in specialist journals).
- Ethical and legal aspects: a positive ethics vote or basic approval by the relevant ethics committee must be provided (or submitted by the deferral deadlines to be specified in the Call Specifications).
- Legally binding declaration confirming that the information provided, in particular the information concerning the total funding available, is correct and complete.
- Date and original signatures of the persons authorised to sign on behalf of the funding applicants, as well as the signatures of the future Mentor and Head.

8.6 Selection procedure

The selection procedure of the proposals (second stage of selection) is carried out in five steps:

- Formal check by the LBG
- Check for compliance with financial & thematic requirements by the LBG
- Technical assessment / review of proposals:
  Assessment of eligibility for funding according to the relevant call text and of the thematic cohesion of individual sub-projects of the proposal as well as assessment or rating by external reviewers. The proposal is the primary object of the review. The research project should be assessed using peer review and other procedures based on objective parameters that can be validated. The selected research topics should, wherever possible, be assessed using objective input and output parameters that can be validated, e.g. using bibliometric analyses. The scientific quality and degree of innovation of the research project, including methodological aspects, should be given special consideration during the review process.
- Hearing of the designated Heads, Mentors and, if applicable, the Sub-Project Leaders (max. 4 persons) of the Clinical Research Groups by the Scientific Expert Commission.
- Recommendations for funding:
  Formulation of funding recommendations by the Scientific Expert Commission based on the review results and the hearing

If a proposal is incomplete, the applicant should be granted a reasonable period of time to correct any deficiencies that can be remedied. If no improvement is achieved, the proposal will be excluded from the further procedure for formal reasons. Incomplete proposals shall be deemed to have been duly submitted if the required information or missing documents are provided within the call deadline.

All persons entrusted with checking and reviewing the proposals are subject to a strict duty of confidentiality and must sign a declaration confirming that there is no conflict of interest.

8.7 Decision

The decision to approve or reject a proposal is made by the Federal Minister of Education, Science and Research on the basis of the ranked funding recommendation of the Scientific Expert Commission.

Any rejection shall be made in writing, stating the reasons.

8.8 Funding agreement

If the proposal is approved, the LBG must send a written funding offer to the applicant. The funding agreement (pursuant to § 24 ARR 2014) shall come into existence upon written acceptance of the offer by the funding applicant. The applicant must be informed that the funding offer, including the associated requirements and conditions, must be accepted within four weeks, failing which the offer shall be deemed to be withdrawn.

In its capacity as the funding agency, the LBG must draw up a model funding agreement based on the model funding agreement of the Federal Ministry of Finance (section 24 (4) ARR 2014). The funding agreement shall contain the following points in particular:

- Legal basis
- Name of the funding provider and the funded institution(s) (including name and date of birth of the Head of the CRG).
- Start and duration of the funding period
- Type and amount of funding granted
- Project title, description of the subject of funding
- Regulations with regard to liability issues, eligible and non-eligible costs
- Reporting obligations (incl. deadlines)
- Conditions for payment of the funding and payment schedule
- Control and assistance with evaluations
- Provisions on suspension and repayment of funding
- Information on data use and publications
- Other contractual provisions
- Special funding conditions that correspond to the nature of the specific project and also ensure that federal funds are only used to the extent that is absolutely necessary to achieve the desired result.

8.8.1 Reporting obligations

The funding recipient shall submit an annual (interim) report on the use of funds, consisting of a factual report and numerical evidence (interim accounts). After three years, the recipient shall submit an interim report in English, which serves as a basis for the interim evaluation in the fourth year. A final report shall be submitted two months after completion of the project. The documents must comply with the international standards of clinical research.

The reports on the use of funds must be in German or English and shall include as a minimum:

All reports/reports on the use of funds

- Factual report: The factual report must in particular show the use of funding granted from federal and EU funds, and provide evidence of the implementation of the funded project and the results obtained.
- Numerical evidence: Numerical evidence must be provided by submitting a breakdown of all income and expenditure related to the funded project and substantiated with receipts (same structure as in the cost plan of the proposal). The LBG shall reserve the right either to request submission of the receipts or to inspect the receipts at the funding recipient's premises. § 24 (2) (5) ARR shall apply mutatis mutandis to the submission of receipts. Numerical evidence must also include the in-kind contributions as well as any funds received from other legal entities.

The reports on the use of funds form the basis for payment of federal funding.

Interim report

After three years, the funding recipient must document the use of funds by submitting an interim report in English, which serves as a basis for the interim evaluation in the fourth year. The interim report shall be submitted in the form of a single document and include the following sections:

- Brief report on the project status: completed and upcoming work packages and project goals
- Brief interim report on the scientific results achieved
- Statistical information on the project and scientific output of the project

Final report

An overall document consisting of the following sections:

- Brief scientific report including a presentation of the project goals achieved and a summary of the results concerning the research questions of the proposal
- Manuscripts for publications on the project submitted to journals and/or (pre-)published publications in journals
- Media reports
- Statistical information on the project and scientific output of the project

Further texts and images for public relations purposes must be provided at the LBG's request.

The formal check of the reports is carried out by the LBG, while the content of the interim report is assessed by external reviewers. The Scientific Expert Commission uses this review to make recommendations for continuation. The content of the final report is assessed in a final evaluation. The financial audit is carried out by the LBG. The factual reports are to be made available both as hard copy and on a storage medium in Word format or as a PDF file.

If the use of personal data is required to prove the appropriate use of the funding, the applicant must be obligated in the funding agreement to provide the relevant personal data.

In line with an open access policy, abstracts of the final reports will be published on the LBG project website.

8.8.2 Payment

The funding may not be disbursed until it is required by the funding recipient for payments incurred as part of the funded project for the funding purpose and may be paid only to the funding recipient or other natural persons, legal entities or partnerships expressly specified in the funding agreement.

Funding for an activity extending over a longer period of time may in principle be paid in fixed instalments subject to the condition that further instalments will not be paid until relevant evidence of the proper use of the previous instalment has been provided. At least 10% of the total funding amount granted must in any event be retained until the final report on the use of funds has been approved.

The reports on the use of funds may only be accepted after the LBG has examined, in particular

- whether the activities (eligible costs) are attributable to the project,
- whether the ratio between cost and performance is reasonable and
- whether the requirements and/or conditions specified in the funding agreement have been fulfilled.

The payment of funding may be suspended if and as long as the prevailing circumstances are deemed to prevent the proper implementation of the project.

It must be agreed with the funding applicant that the funding granted may be reduced to the extent permissible under § 15 (2) ARR 2014 or according to the provisions of EU law,

- if, after the date of the proposal, she or he receives funding from another federal body or legal entity (including other federal, regional or local authorities) for the same activity, albeit for a different purpose, which was not known at the time the funding was granted, or

- if she or he makes or can make a larger in-kind contributions than originally agreed, unless the budget-managing body or the funding agency deems it expedient to modify the agreement. They may refrain from reducing the funding if the contributions mentioned above are necessary to perform the originally agreed funded activity. If the funding has already been disbursed, a claim for repayment can be made.

If funding amounts cannot be used for payments related to the funding purpose immediately after they have been transferred to the funding recipient, the latter shall be obliged to place them in a separate account at an appropriate credit institution (or, in the case of universities, in a separate internal order) with the best possible interest rate, and the accruing interest shall be offset against the funding.

Following proper implementation and accounting of the funded activity, the funding recipient shall immediately repay any funds that have not been used, applying an interest rate of 2% above the applicable base rate per annum as from the day of disbursement of the funding. In the event of default in repayment, § 25 (4) ARR 2014 shall apply.

8.9 General terms and conditions of funding

The BMBWF or the funding agency may only grant funding if the following general funding conditions are met. In particular, funding applicants shall:

- accept the draft agreement, including the associated conditions and requirements, within a period of 4 weeks in writing, failing which the draft agreement shall be deemed to be withdrawn,
- commence the activity in accordance with the agreed timetable, otherwise without undue delay after the funding has been granted, perform the activity expeditiously and complete it within the agreed period of time, or within a reasonable period of time,
- notify the BMBWF or the LBG without delay and on their own initiative of all events that delay or prevent the implementation of the funded activity or would require modifications from the proposal or the agreed terms and conditions, and comply with their notification obligations without delay,
- grant officials or representatives of the federal government and the European Union the right to inspect their books and accounts as well as other documents required for monitoring the implementation of the activity on site on their own premises and the premises of third parties, or submit such documents at their request. Funding recipients shall provide or arrange for the provision of any information required by such officials or representatives and appoint a suitable contact person for this purpose.

Any decision concerning the context between these documents and the funded activity shall be at the discretion of the official carrying out the inspection.

- retain and preserve all books and accounts as well as all documents mentioned above for a period of ten years from the end of the year in which the full funding amount has been disbursed starting from the commencement of the activity at the latest; if EU law stipulates longer periods, these shall apply.
- have the option to use suitable image and data media for storage if these ensure complete, consistent, authentic, true and verifiable reproduction until the end of the retention period. In this case funding recipients shall be obliged to provide, at their own expense, any auxiliary devices necessary for reading the books, accounts and other documents and, if required, provide permanent copies that can be read without the use of auxiliary devices and provide such permanent copies on storage media,
- obtain several comparative offers when awarding contracts for supplies and services, without prejudice to the provisions of the Federal Public Procurement Act (BVergG 2006, Federal Law Gazette I No. 17), insofar as this is expedient with regard to the amount of the estimated contract value,
- use federal funds in compliance with the principles of economy, efficiency and expedience and observe these principles in all their operations, in particular in the case of overall funding,
- not use federal funds to create reserves or provisions under the Income Tax Act (EStG 1988, Federal Law Gazette No. 400) or the Austrian Business Code (UGB, dRGBl S 219/1897),
- render account of the implementation of the activity by submitting reports on the use of funds (§§ 40 to 42 ARR 2014) within deadlines to be agreed,
- not dispose of claims under any funding agreement by way of assignment, transfer or pledge or in any other way,
- commit to fulfil the repayment obligation pursuant to § 25 ARR 2014,
- provide sufficient security for the repayment of subsidised loans and, in principle, also for any repayment and compensation obligations (§§ 25 and 30 ARR 2014),
- comply with the Equal Treatment Act (GlBG, Federal Law Gazette I No. 66/2004), the Equal Opportunities for People with Disabilities Act (BGStG, Federal Law Gazette I No. 82/2005) and the prohibition of discrimination specified in § 7b of the Disabled Persons Employment Act (BEinstG, Federal Law Gazette No. 22/1970), as amended, and
- undertake to cooperate comprehensively with designated or for this reason appointed bodies, federal officials or representatives of funding institutions with regard to an evaluation of the project and the Special Guideline; this obligation shall remain in force even after the end of the funding agreement.

9 Suspension and repayment of funding

The funding recipient shall be obliged, subject to the assertion of further legal claims, to immediately repay the funding received upon written request by the BMBWF or the LBG. In this case, the claim to any approved funding not yet disbursed shall expire in particular if:

1. the funding recipient has informed officials or agents of the LBG or the federal government incorrectly or incompletely about material circumstances, or
2. the funding recipient has not provided mandatory reports, documentary evidence or required information if a written warning with a corresponding deadline and an express reference to the legal consequences of non-compliance has remained without effect and if the funding recipient has failed to give notice as provided in this guideline, or
3. the funding recipient does not immediately (in any event before an inspection or the notification thereof), and on his/her own initiative, report events that delay or prevent the performance of the funded activity or would require modifications from the proposal or the agreed terms and conditions, or
4. the funding recipient prevents or obstructs planned inspection measures or if the eligibility for funding can no longer be verified within the retention period for documents, or
5. the funding recipient has used the funding in whole or in part contrary to its intended purpose, or
6. the funded project cannot be carried out or has not been carried out in time without the consent of the LBG, or
7. the funding recipient has failed to comply with the prohibition on assignment, transfer, pledging and other disposition pursuant to § 24 (2) (11) ARR, or
8. the Equal Opportunities for People with Disabilities Act (BGStG) or the prohibition of discrimination specified in § 7b of the Disabled Persons Employment Act (BeinstG) has not been complied with, or
9. the funding recipient has not carried out the publication measures required according to section 10 herein (Publication of project results), or
10. suspension and/or repayment is demanded by executive bodies of the European Union, or
11. the funding recipient has not complied with other funding conditions, terms and requirements, in particular those intended to ensure that the purpose of the funding is achieved.

Instead of full repayment as stated above, partial suspension or repayment of funding is possible in individual cases if

- the obligations assumed by the funding recipient can be divided into several parts and the partial performance is in itself eligible for funding,
- the funding recipient is not at fault for the circumstances that led to the demand for repayment; and
- the funding provider can be reasonably expected to continue the funding agreement.

Interest shall be payable on the repayment amount from the date of disbursement of the funding at a rate of 4% per annum, applying compound interest. If this interest rate is below the interest rate specified by the European Union for repayments, the interest rate set by the European Union shall be applied. § 25 (4) ARR 2014 shall apply to the payment of default interest.

In the event of only partial performance through no fault of the funding recipient, the BMBWF/LBG may refrain from extinguishing the claim and from reclaiming the funding attributable to the partial performance carried out if the partial performance is in itself eligible for funding.

The LBG shall be responsible for making the decision to suspend or reclaim funding.

§ 25 (7) ARR 2014 shall also apply.

10 Publication of project results

The funding recipient shall undertake to include the following reference in all publications resulting from the project: “gefördert durch das Bundesministerium für Bildung, Wissenschaft und Forschung” (English: "funded by the Federal Ministry of Education, Science and Research").

The logos of the BMBWF and the LBG must be displayed on all information materials related to the funded projects.

Information materials for events related to the funded projects must include a reference that the event is funded by the BMBWF.

11 Data protection

The funding applicant must be informed in the proposal and in the funding agreement that the BMBWF and the LBG are entitled, in their capacity as joint controllers,

- to use the personal data provided in the course of preparation and implementation of the agreement, if this is necessary for the conclusion and execution of the funding agreement, for control purposes and for the fulfilment of the tasks assigned by law to the budget-managing body;
- to obtain the personal data required for verifying the eligibility for and proper use of the funding (beyond the information provided by the applicant) from other federal authorities, other legal entities granting or managing relevant funding or other third parties, in particular from institutions involved in the funding application, and to transmit such data to these parties, who shall in turn be entitled to process the required personal data, to provide information and to conduct searches in the transparency portal according to § 32 (5) of the Transparency Database Act (TDBG 2012, Federal Law Gazette I No. 99/2012 as amended).

The funding recipient must be informed that data may have to be transmitted or disclosed in particular to officials and agents of the Court of Audit (in particular pursuant to § 3 (2), § 4 (1) and § 13 (3) of the Court of Audit Act (RHG 1948), Federal Law Gazette No 144/1948), the Federal Ministry of Finance (in particular pursuant to §§ 57 to 61 and 47 of the Federal Budget Act (BHG 2013), Federal Law Gazette I No 139/2009 and § 14 ARR 2014) and the EU in accordance with the provisions of EU law.

The funding recipient further confirms that the disclosure of personal data to the BMBWF/LBG is in accordance with the provisions of Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ No. L119 of 04.05.2016 S1 (hereinafter GDPR), and the Federal Act concerning the Protection of Personal Data (Data Protection Act - DSG), original version: Federal Law Gazette I No. 165/1999 as amended.[7]

[7] The funding recipient must be provided with appropriate information on data processing in accordance with Articles 13 and 14 GDPR. If the funding recipient discloses personal data of third parties (e.g. employees, beneficiaries, etc.) to the funding provider, Article 14 GDPR shall apply.

12 Jurisdiction

All legal disputes arising in connection with the granting of funding shall be settled by the court of competent jurisdiction in Vienna. The Republic of Austria reserves the right to take legal action against the funding applicant at their place of general jurisdiction.

13 Period of validity

This Special Guideline enters into force on 01 January 2024 and shall be applied until such time as the last project funded under this Guideline has been completed. Calls for proposals based on this Guideline may be published until latest 30 June 2025

The funding agreements shall be finalised by 30 June 2026, at the latest.