FWF Austrian Science Fund

In accordance with its Funding Guidelines dated January 1, 2022 (as amended), the FWF has issued the following Application Guidelines for the program

Clinical Research

effective as of January 1, 2024, version 4

Discovering what matters.

FWF Austrian Science Fund

Contents

Please note: Key terms used in these Application Guidelines are explained in the document Definition of terms.

1 General Information

This document has been prepared in German and English for your convenience. In the event of a dispute, the German version shall prevail.

1.1 Program objective

The aim is to fund clearly defined clinical research proposals in the field of human or veterinary medicine (hereinafter referred to as “projects”) of high academic quality at an international level. Commercial organizations may not have a direct commercial interest in the results. The research must involve human or animal patients and/or healthy test subjects or animals and aim at gaining new clinical findings. The aim of the Clinical Research program is also to strengthen the cooperation between clinicians and basic researchers; to this end, a thematic focus on translational research with patient-oriented approaches and the clarification of the mechanisms of disease is both possible and encouraged.

Clinical Research projects at Austrian research institutions are headed by an individual researcher[1] (hereinafter referred to as the applicant or principal investigator). The principal investigator can collaborate with associated research partners, national, and/or international collaborators as part of the project. In addition to any legal regulations, FWF’s own regulations on international collaborations also apply (see the FWF website for more information).

1.2 What types of projects can be funded?

Funding may be requested for clinical research projects of in the field of human or veterinary medicine that are clearly defined, innovative, have plausibly described objectives and methods, and are limited in duration (no more than 48 months). Aspects of a research project that go beyond the realm of science and scholarship may be mentioned, but they will not play a part in the assessment of whether the project should be funded.

The studies must involve human or animal patients and/or healthy test subjects or animals and aim at gaining scientific knowledge for clinical research. Thematically suitable examples include but are not limited to: studies involving special subpopulations of patients, new therapy concepts or concepts in need of modification, work in the field of personalized medicine, proof-of-principle/proof-of-concept studies, comparison and further development of diagnostic techniques and therapeutic interventions (including surgical procedures), research into the mechanisms of disease, testing of new indications for previously approved drugs, clinical-epidemiological and non-interventional studies in the areas of prevention, prognosis, care, etc..

[1] When the term “researcher” is used in these Application Guidelines, clinicians are included.

Within the framework conditions provided, no further thematic requirements or quotas apply. Clinical relevance and research quality (including the description of a well-balanced study design, statistics/power calculation) are essential. The FWF recommends consulting a clinical trial advisory service to assist in drafting the study protocol. International, interdisciplinary, transdisciplinary, and preclinical/translational approaches are both possible and encouraged.

. The involvement of junior clinical staff as well as gender- and age-group-specific aspects must be taken into consideration when planning the research design, working conditions, and the working environment, and the rules for good clinical practice (GCP), good laboratory practice (GLP), or good manufacturing practice (GMP) must be complied with. A positive opinion or confirmation of fundamental approval from the ethics committee responsible must be provided at the time of submission.[2]

If the project being submitted is part of an existing study, it must be innovative in nature and its content may not be covered by the original study. Co-funding or top-up funding of an existing study is not allowed.

1.3 Submission

There are no submission deadlines for this program; applications can be submitted at any time. All proposals must be submitted online using the elane digital application portal. Project funding is administered through the research institutions (PROFI); this means the application must be approved for submission by both the applicant and the respective research institution (= lead research institution).[3] All forms required for the application must be completed online; other required documents such as the project description incl. annexes and any additional documents must be uploaded in full before the application can be approved for submission by the research institution. For additional information, please see the elane user manual.

1.3.1 Who is eligible to apply?

All Austrian **research institutions** are eligible to apply[4]. The intended project must be carried out in Austria or under the auspices of the applying Austrian research institution. Applications are submitted by the research institution where the project is to be carried out.

The research institution appoints a principal investigator to carry out the project. Neither a specific academic degree nor Austrian citizenship is required to act as principal investigator.

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2 For clinical trials pursuant to the Austrian Medicines Act (*Arzneimittelgesetz*, AMG), the CTIS "Notification of decision according to Article 8 (1) of REG (EU) 536/2014" does not have to be available at the time of submission. This can be submitted later, but must be handed in before the project starts. Fees incurred in this context can be charged to the project, but must already be specified and justified in the project application.

3 Approval for submission by the research institution may be waived by the research institution.

4 Research institutions must be registered in the FWF's research institution portal.

The principal investigator must, however, have appropriate scientific qualifications (see section 1.4) and sufficient time resources to carry out the proposed research. The research institution must provide the necessary infrastructure.

The principal investigator must be employed at the Austrian research institution applying for funding at the time the project is scheduled to begin. Their salary is financed either by the research institution or by the project as a grant-salaried researcher (see section 2.3.1.1). If the principal investigator is employed part-time at the start of the project, project funds can be used to increase the extent of employment to full time.

Researchers who are predominantly working abroad during the project may act as principal investigators if they are employed at the Austrian research institution applying for funding at the time of application and for the entire duration of the project. The extent of employment at the Austrian research institution not funded by the FWF must be at least 25%.[5]

1.3.2 Can multiple applications be submitted simultaneously?

There is no limit to the number of applications that can be submitted by a research institution.

It should be noted, however, that for **principal investigators**, the number of ongoing/approved projects in the Principal Investigator Projects, International, Clinical Research, and Arts-Based Research programs is limited to a maximum of three projects. For further information on restrictions concerning the permissible number of applications and ongoing projects, please see Restriction on the number of projects.

1.4 What are the requirements for applicants?

1.4.1 General requirements

The principal investigator's publication record over the last five years must be internationally visible and commensurate with the expected career path in their field. The following criteria apply for the assessment of an applicant's publication record and initiation of the review process:

- **Quality assurance:** Most relevant in assessing the applicant's publication record are those publications that have been subject to a quality assurance procedure in line with international standards (peer review or an equivalent procedure; in the natural and life sciences, peer review is expected). Journals must usually be listed in Web of Science, Scopus, or the Directory of Open Access Journals (DOAJ). For journals not listed in those databases, or for monographs, edited volumes, contributions to edited volumes, or other publication types, the applicant must provide a link to the publisher's website

[5] Proof of employment must be submitted to the FWF with the application.

which contains a description of the applicable quality assurance procedure. Should no such description be available on the website, it is the applicant's responsibility to provide evidence that the publication has been subject to a quality assurance procedure in accordance with the standards of the field.

- **International visibility:** The majority of the applicant's publications must have a wider than national reach. In the natural sciences, life sciences, and social sciences, most of the publications listed must be in English.

- **Number/scope and quality** of the publications must be commensurate with the researcher's expectable career path and the respective discipline. At least two publications must be quality-assured and internationally visible publications with a substantial and independent contribution by the applicant. At least one publication with first, last, or corresponding authorship is required, with the exception of publications in journals (or disciplines) that rank authors alphabetically. If any such publications are included in the required document *PI_publication.pdf* (see section 2.2.4), the applicant's contribution must be specified.

If there is any uncertainty about general application requirements or about accounting for career interruptions (see sections 1.4.3 and 1.4.4), the FWF recommends that the applicant contact the FWF Office or the FWF Equal Opportunities and Diversity in Research Funding unit in good time before submitting the application to confirm that all requirements are met and that any career interruptions can be accounted for. In cases of doubt, the appropriate decision-making bodies of the FWF shall decide on applicants' eligibility.

1.4.2 Equal opportunities, diversity, and inclusion

The FWF Strategy for Equal Opportunities and Diversity of Researchers applies. This means that breaks or delays in applicants' research careers that have led to publication gaps, unorthodox career paths, or limited international research experience can be accounted for. For further details on accounting for career breaks, please refer to the information sheet on career interruptions.

1.4.3 Consideration of career breaks

The FWF will take justified, documentable career breaks (e.g. due to pregnancy, childcare,[6] caregiving obligations,[7] military or civilian service, flight, and asylum) into consideration when assessing eligibility to apply.

6 Childcare includes parental leave periods, if applicable.

7 Immediate family members and/or persons living in the same household: Spouses, registered partners, parents, children, adopted, step, and foster children, siblings, parents-in-law, and children-in-law.

1.4.4 Inclusion of the disabled and chronically ill

The FWF will also take any exceptions to and interruptions of typical career paths due to disability and/or long-term illness into consideration in determining whether the principal investigator meets the application requirements.

1.4.5 Data protection notice

When assessing eligibility, all personal data provided to the FWF by an applicant on a voluntary basis that relates to the information provided in sections 1.4.3 and 1.4.4 shall be taken into account exclusively to the applicant's benefit (compensation of disadvantages). Relevant information (without sensitive or personal data) can be included in an individual's academic CV, making it available to the reviewers. A general explanation, including the duration of the interruption or delay, is sufficient. Please complete the required form and give your explicit consent to data processing on the last page. If you wish to submit further supporting documents in addition to those listed in the form, please submit them directly to the FWF office. These will not be visible to your research institution. This information is only used to check the application requirements and is not made available to reviewers.

1.5 What types of funding can be requested?

Project-specific costs are eligible for funding. These include personnel and non-personnel costs that are needed to carry out the project and that are not included in the infrastructure provided by the research institution. The FWF does not finance the infrastructure or basic equipment of research institutions.

In addition, funding may be requested for project-specific work at the associated research institution(s) where associated research partner(s) work. Associated research partners are researchers working on a project-specific basis at other Austrian research institutions (associated research institutions) and who are making a significant scientific/scholarly contribution to the project. The *Associated research partner* form must be completed for these researchers, if applicable. Funds are disbursed from the lead research institution to the associated research institution(s).[8] Associated research institutions report directly to the FWF to account for funds used at their institution.

For information on applying for personnel costs for the principal investigator's own salary, please see section 2.3.1.1.

Please note that exaggerated cost projections may be grounds for rejection, even if a proposal is otherwise excellent. The number of reviews required before a proposal can be approved is based on the amount of funding requested (see section 3.3).

[8] Associated research institutions must be registered in the FWF's research institution portal. Once a proposal has been approved, the lead research institution must enter into a collaboration agreement with the associated research institution.

Projects may be co-financed, but a statement defining the terms of the co-financing arrangement must be provided. Co-financiers are not permitted to appear as sponsors pursuant to ICH-GCP guidelines. All rights to data and intellectual property remain with the researchers, subject to legal and contractual regulations.

Multiple funding is not permitted (see FWF Funding Guidelines).

1.6 International programs

Clinical research applications submitted for international research funding programs (ERA-NET Calls, Principal Investigator Projects International, etc.), the Application Guidelines for the Clinical Research program apply as described here, if permitted.

Please note, however, that these international programs also have additional application requirements. For more information, please see Principal Investigator Projects International or International – Multilateral Initiatives on the FWF website.

2 Application

2.1 Sections of the application

A complete application must include the following sections:

2.1.1 Academic abstract

The academic abstract must be written in English, may not exceed 3,000 characters (including spaces, no formulas or special characters), and is used to inform potential reviewers about the project. The abstract must use the English headings provided below and be entered into the elane form provided for this purpose.

- Wider research context / theoretical framework
- Hypotheses / research questions / objectives
- Approach / methods
- Level of originality / innovation
- Primary researchers involved

Where alternatives are indicated between slashes, please select the alternative that applies to your project.

2.1.2 Project description

Project descriptions are limited to 20 consecutively numbered pages, including the table of contents (required), and where applicable, a list of abbreviations, headings, figures, captions, tables, footnotes, etc.

The project description must also include Annexes 1-4 and if applicable 5 on additional pages:

- Annex 1: List of literature cited in the application (*References*) on no more than 5 pages
- Annex 2: Details of the lead research institution and any associated research institutions and a plausible justification of the funding requested
- Annex 3: Clinical trial synopsis
- Annex 4: CVs and descriptions of previous research achievements
- Annex 5 (optional): Collaboration letters from national and international cooperation partners (max. 1 page per letter)

The project description, including these annexes, must be uploaded as a single file titled *Proposal.pdf*. The FWF will send this document to the reviewers.

2.1.3 Additional documents

- Required:
  - Positive opinion from the relevant ethics commission or confirmation of fundamental approval (exception for clinical trials pursuant to the AMG[9])
  - Two publications written by the applicant must be named, documenting that the applicant fulfills the general requirements to act as principal investigator (publication record, see section 1.4.1)
  - Publication lists for internal FWF use to assess principal investigator's eligibility to apply and to check for conflicts of interest with potential reviewers (see section 2.2.4)
- Where applicable:
  - Results or final project report: If the project submitted is the continuation of an FWF-funded project (follow-up application), a report on previous results or a final project report and a list of publications resulting from the project must be uploaded in the language of the application (max. 6 pages)

[9] For clinical trials pursuant to the Austrian Medicines Act (*Arzneimittelgesetz*, AMG), the CTIS "Notification of decision according to Article 8 (1) of REG (EU) 536/2014" does not have to be available at the time of submission. This can be submitted later, but must be handed in before the project starts. Fees incurred in this context can be charged to the project, but must already be specified and justified in the project application.

- Additional documents in the case of resubmission: If the application is a revised version of a previously rejected application (see section 2.4), a response to the reviews and an overview of all changes made in the resubmitted application must be uploaded *(Overview_revision)*.
- Cover letter accompanying the application (optional)
- List of max. 3 researchers (optional) - including, if applicable, reviewers of a rejected proposal - who are to be excluded from the review process (see section 3.2), with a brief justification

Any additional documents (e.g., recommendations for potential reviewers, letters of recommendation, forthcoming publications) will not be considered in further stages of the application process.

2.1.4 Forms to be completed

- Required: *Research institution* form, *Contact* form, *Ethics commission approval* form, *Cost breakdown* form, *Academic abstract* form, and *Co-authors* form
- Where applicable: *Associated research partner* form, *Other cooperation* form

2.2 Application content and format

2.2.1 Language of application

To allow applications to be reviewed by international experts, all applications must be submitted in English.

2.2.2 Project description: Scope and formatting requirements

The project description may not exceed 20 pages. It must contain a table of contents with page numbers. Optional components such as a list of abbreviations or figures, captions, tables, footnotes, etc. are to be included in the 20-page limit.

The continuous text in the project description, Annexes 1–4, the publication lists, and the additional documents specified in section 2.1.3 where applicable, must be written, without exception, in 11 pt. font with 1.5 line (15-20 pt.) spacing and at least 2 cm margins. A standard, easily legible font must be used for the body text. The formatting requirements (font type and size, line spacing, and margins) of the project description also apply for the additional files, except for documents not prepared by the applicant, such as collaboration letters.

Citations in the text and the list of works cited (*References*) in the application must be in line with the conventions of the respective discipline, preferably according to a widely used style

guide (e.g., Chicago Manual of Style, APA Publication Manual). The choice of citation conventions or style guide is up to the applicant, but must be implemented consistently throughout the application. If available, a DOI address (DOI = Digital Object Identifier) or another persistent identifier should be provided for the literature cited.

2.2.3 Project description and annexes

The project description may not exceed 20 pages and must include a table of contents as well as the following sections, each designated by headings:

1) Table of contents

2) State of the art of relevant international research (including own preliminary work / preclinical data, if applicable) and relation of the project to this context

3) Clearly defined aims and hypothesis/hypotheses or clinical / research question(s)

4) Description of the project´s anticipated level of originality or clinical/scientific innovation

5) Methodology
   - Research methodology
   - Type of study
   - Exact description of the planned intervention(s)
   - Relevant inclusion/exclusion criteria
   - Primary and secondary endpoints of the study
   - Risk assessment
   - Biometrics / statistical analyses (including power calculation), sample size
   - Bias avoidance measures
   - Recruitment / availability of patients / test subjects

6) Work plan and timeline

7) Associated research partners (if applicable): Description of the contributions of the associated research partners (see section 1.6) to the proposed research; associated research partners must be named in the *Associated research partner* form.

   National and/or international collaboration partners (if applicable): Please specify the intended collaboration partners and the subject of the intended collaboration(s) or the planned contribution to the project. **All** national and/or international cooperation arrangements that were stated to be essential in the project description must be listed on the ***Other cooperation* form** (one form must be completed for each collaboration partner) and may be confirmed by a collaboration letter.

8) Research-related qualifications of the researchers involved

9) All potential ethical, safety, and regulatory aspects[10] of the proposal, such as any legal rules and regulations relevant to the study, especially the requirements of good clinical practice (GCP), good manufacturing practice (GMP) and good laboratory practice (GLP), and how applicants plan to deal with them must be described in a separate section.

10) Any potential sex-specific and gender-related aspects[11] of the proposal must be detailed. To what extent are sex-specific and gender-related aspects considered in the proposal? How will they be integrated into the research approach? These questions must be briefly addressed, even if the applicant does not feel that the project involves any such aspects.

Annex 1: List of literature cited in the application (*References*) on no more than 5 pages

Annex 2: Financial aspects

The template for the description of projected costs can be found in Appendix A.

- Information on the lead research institution and the research institutions of associated research partners
    - Existing project participants (not financed by FWF project funds) (usually the principal investigator and academic project staff at the research institutions)
    - Available infrastructure
- Information on the funding requested
    - Explanation of why the personnel requested is needed (type(s) of requested position(s), job descriptions, extent of employment, and duration of involvement in the project)
    - Concise justifications for non-personnel costs (equipment, materials, travel expenses, and other costs) If funding for equipment is requested, applicants must explain why this does not constitute part of the basic equipment of the given research environment – see section 2.3.2).

Annex 3: Clinical trial synopsis on max. 3 pages

The template for the clinical trial synopsis can be found in Appendix B.

- Title of clinical trial
- Graphical overview
- Applicant

[10] For instance, the European Commission's Ethics for Researchers or The European Code of Conduct for Research Integrity can serve as a guide here.

[11] Positioning and thoughts on the research approaches in the project in terms of sex-specific and gender-related aspects could include: Is the research approach likely to produce sex-specific and gender-related findings? If so, what findings? How and where are these integrated into the research approach? (For information on determining the relevance of sex-specific and gender-related issues please see the FWF website.)

- Clinical trial type (e.g. double blind, observational etc.)
- Objectives
- Intervention
- Key inclusion and exclusion criteria
- Primary and secondary endpoint(s)
- Sample size, statistical analyses, power calculation
- Trial duration
- Participating centers

Annex 4: CVs and description of previous research achievements

The academic CVs and research achievements (for the principal investigator as well as a maximum of 3 other key project participants) should be described on no more than three pages per person. Please note that according to the Agreement on Reforming Research Assessment, metrics such as journal impact factors, Article Influence Scores, h-index and the like may not be listed on academic CVs.

Academic CVs must be structured as follows:

- *Personal data*: Personal details (name, researcher unique identifier(s) such as ORCID, research ID, etc., no photos), address of research institution, and relevant websites. In addition, a publicly accessible link to the list of all published publications is required.

- *Education:* List of academic milestones

- *Position(s)*: List of academically relevant positions (with the extent of employment in the case of part-time employment)

- *Career breaks* (if any): List of career breaks or delays (see also section 1.4.2)

- *Net research experience* (optional): The length of time (in years and months) that has actually been used in net total for research – calculated in such a way as to be equivalent to full-time employment – and broken down into the time before and after completion of the applicant's doctoral degree. This is intended to make it easier for the reviewers to assess the principal investigator's qualifications in term of academic age

- *Research interests*: Description of the main areas of research and the most important research results achieved to date

- *Academic publications*: List of no more than ten of the most important published or accepted academic publications (journal articles, monographs, edited volumes, contributions to edited volumes, proceedings, etc.); for each publication, either a DOI address or another persistent identifier should be indicated, if available.

- *Additional research achievements*: List of no more than ten of the most important research achievements apart from academic publications. Please note that research achievements should be presented individually (e.g., one project = one research

achievement, two projects = two separate research achievements, etc.). Examples of such research achievements include freely accessible research data including software and codes, awards, contributions to conferences, keynote lectures, significant research projects, peer review activities, promotion of junior researchers, exhibitions, interactions with society (including citizen science or transdisciplinary activities), science communication, knowledge transfer, licenses, or patents. If available, a persistent identifier or link to each research achievement must be provided

Annex 5 (optional): Collaboration letters

Collaboration letters (each no more than 1 page) from national and international collaboration partners who are named in the project description as being essential for the implementation of the project and whose role is plausibly described

2.2.4 Publication output

The following two separate uploads are required:

- *PI_publication.pdf*: Two publications written by the applicant must be named, documenting that the applicant fulfills the general requirements to apply (see template *PI_publication*). The FWF will determine eligibility to apply based on these publications.
- *Publication_list.pdf:* A list of all research publications over the last five years[12] (categorized into “quality-assured publications” and “other publications” see section 1.4) by all participants for whom a CV has been submitted, as well as for all project staff members for whom personnel costs are requested, in *one* PDF document; this publication list helps the FWF to determine if there are any potential conflicts of interest with reviewers. It will not be forwarded to the reviewers.

2.3 What project-specific costs can be funded?

When requesting funding, the regulations of the respective research institution and the FWF guidelines apply. The requested funds must be summarized in the elane *Cost breakdown* form.

If the research institution for which funds are requested is entitled to deduct value-added tax (VAT), the funds should be applied for without value-added tax (net). This applies to the lead research institution and, where applicable, to associated research institutions.

[12] Publication lists must include: all authors, complete titles, journal, year, and page numbers. For each publication, if available, either a DOI address or another persistent identifier should be indicated; for publications with more than 20 authors, an “et al.” citation can be used.

VAT is an eligible expense only if the funding recipient is not entitled to deduct it and it is demonstrably and finally borne by the funding recipient. Recoverable VAT is ineligible for funding even if it is not reclaimed or recovered by the funding recipient.

Funding may only be requested for the following cost categories.

2.3.1 Personnel costs

Funding may only be requested for staff needed in addition to existing personnel resources for the realization of the project and only to the extent required for the project.

Full- or part-time employment contracts (*Dienstverträge*, DV) and contracts for marginal employment (*geringfügige Beschäftigung*, GB) are available for project staff. FWF's standard personnel costs apply. When calculating personnel costs, applicants must include a fixed percentual increase determined by the FWF to compensate for wage raises in subsequent years.

Employment contracts for doctoral students may not exceed 75% employment (up to 30 hours per week). A part-time (50%) employment contract of 20 hours/week for student employees may be requested for researchers who have not yet completed a graduate degree program in the relevant subject area.

2.3.1.1 Grant-salaried principal investigators

The FWF understands "grant-salaried" to mean that the principal investigator's salary is financed by the funds of the research project.

Applying for funding (including partial funding) of one's own position is possible for every principal investigator, regardless of whether they are in permanent or long-term employment at the time of application. Principal investigators can apply for a senior postdoc salary rate[13] to fund their own position (pro-rated accordingly in the case of partial funding).

Female principal investigators whose own position is funded to the extent of at least 50% have the additional option of applying for up to €2,000 per year in the category of "Other costs" for personal coaching and further training measures that directly contribute to their career development. Coaching is understood to mean individual counselling and support processes in a professional context. Continuing education activities eligible for funding include courses on scientific – in particular, subject-specific – skills (e.g., courses on methodological skills) and personnel development measures such as those offered at some research institutions (e.g., in teaching, academic writing, writing funding applications [especially in English], personnel management and project management, conflict- and

[13] The senior postdoc rate can only be requested to fund the principal investigator's own position; the postdoc salary rate applies for project staff members at the postdoc level.

problem-solving skills, academic organization, and vocational training and other seminars directly related to career development, e.g., programs for the advancement of women).

2.3.2 Equipment costs

Funding for equipment may only be requested if it is specifically required for the project and if it is not part of the existing infrastructure of the participating research institution(s). “Infrastructure” is defined to include all equipment (and components thereof) that a modern research institution needs to conduct basic research in the relevant discipline at an internationally competitive level. This means that equipment such as computers (laptops, etc.) is considered to be part of the standard infrastructure and no funding will be approved for these items.

Equipment eligible for funding includes:

- Scientific instruments
- System components
- Self-constructed devices (generally assembled from smaller pieces of equipment and materials)
- Other durable goods
- Intangible assets such as concessions, industrial property rights, and licenses derived from such rights

Equipment with an acquisition value in excess of €250,000 can only be financed through depreciation. Only the percentage of costs that are incurred during the project period can be requested and financed. The depreciation rules of the research institution acquiring the equipment apply.

If funding is requested for a piece of equipment which is required specifically for the project, the lead research institution confirms upon completing the online submission that they have verified that no comparable equipment that could be used or shared is available within a reasonable distance, and that third-party (co-)financing options have been explored. The research institution that owns the equipment must also ensure that any possible costs arising from the use, maintenance, and repairs of the equipment are covered.

The principal investigator is to instruct their research institution to order the equipment and effect payment accordingly. The principles of economy, efficiency, and expediency apply to any acquisition. The procurement guidelines of the research institution and the provisions of the Federal Procurement Act 2018 (*Bundesvergabegesetz*) as amended apply.

In order to determine the equipment costs (incl. VAT, unless the research institution is entitled to deduct input tax) to be requested, vendor quotes must be obtained before the application is submitted pursuant to the research institution’s procurement guidelines. Vendor quotes are submitted to the FWF only upon request.

If a specific piece of equipment required for the proposed project is already available at the research institution but is in need of repair, funding for repairs can be requested instead of purchasing costs. Again, the equipment must not be part of the research institution's infrastructure and may not be otherwise in general use at the research institution.

2.3.3 Material costs

"Materials" is defined as consumables and small items of equipment (cost per item less than €1,500 incl. VAT).

The calculation of funds requested for project-specific material costs should be justified based on the project's schedule, work plans, and experimental schedule. Experience from previous projects should be considered in making the calculations.

2.3.4 Travel costs

Funding may be requested for project-specific travel and accommodation, field work, expeditions, etc. The project description must include a detailed itinerary, broken down by project staff members. This plan must indicate which staff members will be travelling, the destination, for what purpose, when (in which year of the project), for how long, and how much the travel will cost

When planning travel in connection with a project, researchers should always carefully consider whether travel is absolutely necessary or whether the relevant information can be exchanged virtually.

If a project requires travel, transportation by train is generally preferred to travel by air as a contribution to environmental sustainability. Funding can be requested for any resulting extra costs such as an additional overnight stay.

Travel expenses for researchers from Austrian and international research institutions other than the lead research institution or associated research institutions can only be granted in exceptional cases. Grounds for the exception must be provided in detail.

Travel and accommodation costs are generally calculated according to the lead or associated research institution's individual travel expenses policies. If no such policies are in place at the research institution, the federal regulations governing travel costs (*Reisegebührenvorschrift des Bundes* 1955, RGV) as amended apply.

2.3.5 Costs as part of national and international cooperation

Unlike when cooperating with associated research partners (see section 1.5), costs arising in the context of a research collaboration with an external research institution are to be borne by that research institution. This does not apply to cooperation arrangements with scientists or scholars from developing countries (see section 2.3.6).

Funds may only be transferred directly to a cooperation partner (in Austria or abroad) upon presentation of an invoice and only if they are in payment for clearly defined commissions or services and immediately necessary to carry out the Austrian project.

2.3.6 Other funding available

- Independent contractor agreements (costs for work of clearly defined scope and content carried out by individuals, provided that they are cost-efficient and justified in the context of the research project)
- Costs for the preparation, archiving, open access, and reuse of research data in repositories in accordance with the FWF's Open-Access Policy for Research Data
- Costs that cannot be included under personnel, equipment, materials, or travel costs, for example:
  - The use of research facilities, e.g., costs for the project-specific use of available equipment (project-specific "equipment usage time") or large research facilities
  - Monitoring and other support measures for studies
  - Patient insurance
  - Remuneration for animal owners (only for applications in the field of veterinary medicine)
  - Costs for animals and animal maintenance
  - Project-specific work carried out outside the researcher's research institution (e.g., for analyses carried out elsewhere, interviews, sample collection, etc.)
  - Disposal of project-specific hazardous waste
  - Cooperation arrangements with researchers in developing countries

The procurement guidelines of the research institution and the provisions of the Federal Procurement Act 2018 (*Bundesvergabegesetz*) as amended apply.

2.3.7 General project costs

The approved grant sum includes 5% general project costs that are permitted for funding but cannot be requested individually using the abovementioned cost categories. They are subject to the FWF's Funding Guidelines and the costs must be eligible for funding. These include, for example, costs for conference travel, dissemination activities, and minor unforeseen costs necessary for the project.

Overhead costs for the research institution are not included in general project costs.

General project costs are to be entered in the appropriate field in the *Cost breakdown* form and calculated as 5% of the total funding requested. General project costs impact the number of reviews required for the proposal (see section 3.3). No justification for general costs is needed in Appendix A.

2.3.8 Publication costs

Publication costs cannot be requested as part of the application process. Information on funding options for publications resulting from the proposed research can be found on the FWF website under the Communication portfolio.

2.4 Resubmitting a previously rejected application

A resubmission is defined as the revision of an application addressing the same or similar research questions as a proposal the FWF has previously rejected, regardless of the program category. If an application is submitted on the same or a very similar research question and if, in the view of the principal investigator, this application is not a resubmission but a completely new project, this must be explained in a separate accompanying letter to the FWF Office. For example, changes in research methods alone are not sufficient for a proposal to qualify as a completely new project. In cases of doubt, the appropriate decision-making bodies of the FWF shall decide.

Resubmissions must show changes from the rejected application. If an application has been rejected for the standardized reason C3, C4, or C5, these changes need to be substantial (based on the comments in the reviews). If no such changes are made, the FWF's decision-making bodies will return the application to the applicant without review.

When resubmitting an application, the following documents must be uploaded:

- An accompanying letter containing an overview of all changes *(Overview_revision)* made in the resubmitted application must be submitted to the FWF. This overview will not be passed on to the reviewers.

- A response to all reviews of the rejected application must be provided, even if one of the reviewers is to be excluded from reviewing the resubmitted application (see section 3.2). This response, consolidated in *one* document, will be forwarded to all reviewers reviewing the resubmission and should address the recommendations and criticisms included in the previous reviews as well as describe the resulting changes made.

While no deadlines for the resubmission of a rejected application apply, the respective application requirements apply. Resubmissions must be submitted as described in section 2, i.e., as a separate, new application and not as a supplementary application to the previously rejected proposal.

2.5 File formats, file names, and online forms

Below please find an overview of all documents and forms to be submitted.

2.5.1 All applications must include the following parts:

a) Files:

- *Proposal.pdf* (project description incl. Annexes 1–4 and where applicable 5, with PDF bookmarks, at least for the major sections)
- *Ethics commission approval.pdf* (Positive opinion from the relevant ethics commission or confirmation of fundamental approval - exception for clinical trials pursuant to the AMG[14])
- *PI_publication.pdf* (Two publications written by the principal investigator must be named, documenting that the applicant fulfills the general requirements to apply)
- *Publication_list.pdf* (publication list of all the key project participants for the last five years, categorized into into “quality assured publications” and “other publications”)

b) Forms:

- *Research institution*
- *Contact form*
- *Application form*
- *Statement on ethics commission approval*
- *Cost breakdown*
- *Academic abstract* (in English)
- *Co-authors*
- *Associated research partners* (if applicable)
- *Other cooperation* (if applicable; for national and international collaboration partners)

2.5.2 File uploads, if applicable

- Cover_letter.pdf (= accompanying letter; optional)
- Negative_list.pdf (= reviewers who should be excluded; optional)
- Follow.pdf (= result report or final project report of the previous project for follow-up applications; will be forwarded to the reviewers)
- Overview_revision.pdf (= for resubmissions, overview of all changes made in the resubmitted application)
- Revision.pdf (= for resubmissions, response to all reviews of the previously rejected application)

[14] For clinical trials pursuant to the Austrian Medicines Act (*Arzneimittelgesetz*, AMG), the CTIS“Notification of decision according to Article 8 (1) of REG (EU) 536/2014” does not have to be available at the time of submission. This can be submitted later, but must be handed in before the project starts. Fees incurred in this context can be charged to the project, but must already be specified and justified in the project application.

3 Processing and Decision-Making

3.1 Submission and requests for changes

All of the documents specified above must be uploaded in full to elane. Once an application has been officially submitted, the research institution and the principal investigator can make no further changes to the application themselves. All applications are checked for completeness and any formal errors by the FWF Office. The FWF's decision-making bodies reserve the right to return applications without review if they do not meet the FWF's formal requirements. The most common reasons why applications are returned without review are (a) that the principal investigator's publication record does not meet the requirements (see section 1.4.1), (b) that the application does not address specific hypotheses or research questions (see section 2.2.3)., and c) that resubmissions have not been sufficiently revised (see section 2.4).

If the FWF Office identifies issues with the application that it considers to be rectifiable, it will notify the research institution and the principal investigator, giving them the opportunity to correct the problems within a reasonable period of time (generally 3 weeks). The requested changes are to be submitted to elane as a supplementary application and approved for submission by the lead research institution if necessary. If the requested changes are not made and submitted as a supplementary application before the specified deadline, the decision-making bodies at the FWF will return the application without review.

Once the review process has begun, no more changes can be made to the application.

3.2 Excluding reviewers

A list of a maximum of three potential reviewers who should not be consulted to review the proposal due to a possible conflict of interest can be uploaded as an additional document. The applicant must briefly explain why these reviewers should be excluded. If the reasons for exclusion are professionally and academically sound, the FWF will generally fulfil such requests and will exclude these reviewers from the review process. A detailed description of the FWF's policy on conflicts of interest can be found in the General Principles of the Decision-Making Procedure.

Please note that the FWF does not wish to receive, nor will it consider a list of potential reviewers from applicants.

3.3 Number of reviews required

The number of reviews required for funding approval depends on the amount of funding requested. For funding requests of up to €450,000, at least two reviews are needed; for each additional €200,000, at least one further review is required (e.g., up to €650,000 at least

three reviews, and so on). The average processing time increases significantly with an increase in the number of required reviewers.

3.4 Decision-making process

For detailed information on the decision-making process, the criteria for selecting international reviewers, detailed rules concerning conflicts of interest, and the composition of juries and review panels, please see the General Principles of the Decision-Making Procedure.

The **review process** for Clinical Research Projects usually takes about six months. More detailed information is available online on the FWF Dashboard.

When the review process it is completed, the FWF Board considers the reviews and decides whether the proposal should be funded. The lead research institution and the principal investigator are informed in writing of the FWF's decision.

3.5 Reasons for rejection

The reasons for rejecting an application are assigned to one of five categories (C1–C5) and communicated to the principal investigator and the lead research institution; the principal investigator is also sent anonymized copies of the reviews. A detailed description of the reasons for rejection can be found in the General Principles of the Decision-Making Procedure.

3.6 Reviewing resubmissions

If the application is a **resubmission** of a previously rejected proposal, the FWF will generally contact those reviewers who provided constructive criticism on the previous application. Reviewers who gave entirely positive or negative comments will usually not be contacted for a second review. However, please note that generally all resubmissions are also evaluated by new reviewers.

3.7 Proposal bans

Applications that are rejected for reason C5 will be barred for 12 months (from the date of the official notification of the decision) and cannot be resubmitted during that period.

Applications that have been submitted to the same funding program three times and rejected for reasons C3 or C4 (with the "three times" referring to the original application and two resubmissions) are also barred for 12 months (from the date of decision). Rejections for reasons C1 or C2 do not count towards this total. In general, only topics are banned, not applicants or applying research institutions.

4 Compliance with Legal Requirements and Standards of Research Integrity

4.1 Legal regulations

Please note that the research institution(s) and all individuals involved in the project are obligated to comply with all legal requirements, safety provisions, and any embargo regulations and sanctions (e.g., Federal Disability Equality Act, Federal Equal Treatment Act, Dual-Use Regulation [EU] 2021/821) that apply for the Principal Investigator Project and obtain all the necessary permits (e.g., from the Ethics Committee, the Animal Testing Commission, the National Heritage Agency, or the relevant foreign authorities).

4.2 Academic integrity

The Guidelines for Good Scientific Practice of the Austrian Agency for Research Integrity (OeAWI) apply.

Where a breach of these standards is suspected, the ombud of the respective research institution is responsible for investigating the issue. Research institutions are required to report any cases of suspected serious violations of the standards to the OeAWI. The FWF reserves the right to suspend, in part or in whole, any procedures related to applications or ongoing projects until this check or investigation has been concluded. For more detailed information, please see FWF procedure in cases of suspected violation of the standards of good research practice.

5 Data Protection and Publication of Project Data and Results

5.1 Data protection

Pursuant to Art. 6 (1) item a of the General Data Protection Regulation (GDPR), in conjunction with § 2g of the Austrian Research Organization Act (*Forschungsorganisations-gesetz*, FOG), the FWF processes and publishes personal data (e.g. the title of the submitted project, research institution, academic abstract, PR summaries) necessary for the administration of the funding by the FWF – while safeguarding business and trade secrets – for the purposes of research policy (e.g., presentation of the development of basic research in Austria, economic analyses, funding impact reports, etc.) and for public relations work (publication of excerpts in the FWF annual report, on the FWF website, in press releases, media collaborations, etc.). If necessary, these data are also transmitted to third parties (e.g., for the preparation of research policy studies, on the basis of supervisory duties, in particular §§ 2d and 3a of the Research and Technology Funding Act [*Forschungs- und Technologie-*

förderungsgesetz, FTFG], to bodies and agents of the Federal Ministry of Education, Science and Research and, in particular, pursuant to § 3 [2], § 4 [1], and § 13 [3] of the Court of Audit Act 1948 [*Rechnungshofgesetz* 1948 RHG], to the Austrian Court of Audit as well as to bodies and institutions of the European Union in accordance with European legal provisions). Transmission of data is also based on § 6 (1) item c of the GDPR in conjunction with § 2g of the FOG.

Further information on the data privacy rights of the applicant or applying research institution as well as the contact details of the FWF's data protection officers is available here.

5.2 Publication of project data and results

Please note that if a grant is awarded, a PR summary in German and English will be published on the FWF website, as well as the grant amount and later, PR summaries of the project's findings in German and English. Summaries must be submitted to the FWF when the grant agreement is returned. The principal investigator must ensure that these texts are worded in such a way that legitimate interests of secrecy for reasons of national defense and patent law are safeguarded and business secrets are protected appropriately. Information on writing PR texts can be found on the FWF website.

In addition, the FWF requires a data management plan (DMP) for all approved projects. This plan should also be sent to the FWF when returning the grant agreement. The template for the DMP can be viewed and downloaded on the FWF website.

The guidelines specified in the grant agreement on acknowledging the FWF as the funding institution and the FWF's Open-Access Policy apply for any publication of project results (e.g., academic publications, research data, conference contributions, and media reports).

6 Appendices to the Application Guidelines

6.1 Appendix A: Information on the research institute and description of financial aspects

Information on the lead research institution and any associated research institutions and the description of project finances must be presented **in English** using the following structure and appended to the project description as Annex 2. Costs must be broken down and adequately justified for each point below. The list of and justification for the requested funds must correspond to the costs indicated in the *Cost breakdown* form.

a) Details on the applicant's research institution and – if applicable – of associated research partners: [15]

- Existing personnel (not financed by the FWF, usually the principal investigator and research personnel at the research institution(s))
- Existing infrastructure

(b) Information on the funding requested: [16]

- Explain briefly why the personnel requested is needed for the project (number and type of requested positions, job descriptions, extent of employment, and duration of involvement in the project)

- Explain briefly why the non-personnel costs requested are justified (equipment, materials, travel, and other costs). If funding for equipment is requested, applicants must explain why this does not constitute part of the basic equipment of the given research environment - see also section 2.3.2.

Please list of and and provide justifications for the following:

Personnel costs:

Equipment costs:

Material costs:

Travel expenses:

Other costs (including independent contractor agreements):

[15] In the case of Principal Investigator Projects International; information on the research institution(s) of the international project partner(s)

[16] In the case of Principal Investigatgor Projects International for which FWF acts as the Lead Agency: list of and justification for the requested funds for the part(s) of the project conducted abroad

6.2 Appendix B: Clinical trial synopsis

Please note: The clinical trial synopsis (max. 3 pages) is to be written in English using the structure below and attached to the project description as Annex 3.

1) Title of clinical trial
2) Graphical overview
3) Applicant
4) Clinical trial type (e.g. double blind, observational etc.)
5) Objectives
6) Intervention
7) Key inclusion and exclusion criteria
8) Primary and secondary endpoint(s)
9) Sample size, statistical analyses, power calculation
10) Trial duration
11) Participating centers

6.3 Appendix C: Notes and questions for reviewers of Clinical Research projects[17]

The FWF actively supports equal opportunities and equal treatment in all of its programs. The review of a proposal must not put researchers at a disadvantage for non-research-related reasons such as age, gender, etc. For example, instead of considering the applicant's actual age, the review process should focus on the how the length of the individual's research career corresponds to their research achievements to date.

Our commitment to equal opportunities also means considering breaks or delays in applicants' research careers (e.g., due to parental leave; long-term or chronic illness; disability; caring responsibilities; etc.), which may have led to publication gaps, atypical career paths, or limited international research experience. Please also see our information for reviewers on unconscious bias in the decision-making process.

Only the ten most important academic publications and the ten most important additional research achievements of the applicant are to be considered when evaluating the application. As a signatory to the Agreement on Reforming Research Assessment, the FWF also emphasizes that, in assessing research performance, reviewers should refrain from using journal-based metrics such as journal impact factors, Article Influence Scores, or the h-index.

Please review the current proposal[18] based on the following six assessment criteria:
1) innovation and novelty, 2) quality of the proposed research, 3) approach and feasibility,

[17] Further information can be found on our website: FWF's corporate policy and mission statement or the Application Guidelines for Clinical Research.

[18] The project proposal must meet the FWF's formal requirements. Please bear these in mind when writing your review. (Key formal requirements: 20 pages max. for the project description including figures and tables; 5 pages max. for the list of references; 3 pages max. for each academic CV, including a description of previous research achievements and the ten most important publications. For further information see the Application Guidelines for Clinical Research.)

4) researchers' qualifications, 5) ethical, sex-specific, and gender-related aspects, and 6) overall evaluation.

For each of these criteria except 5) we ask you for both written comments and a rating on a scale from "outstanding" to "poor." Please be aware, however, that the FWF's funding decision will be based primarily on reviewers' written assessments rather than the ratings assigned.

Please keep in mind that sections 1 and 2 will be forwarded to the applicant in full and in anonymous form. If the proposal is approved, the research institution may have access to the anonymized reviews submitted to the applicant.

Section 1:[19]

1. Innovation and novelty

Is the proposed research innovative? Does it make an original contribution to its field?

2. Quality of the proposed research

Are the research questions formulated clearly? Are they timely, challenging, and likely to lead to relevant insights?

3. Approach and feasibility

Is the research design well-conceived, clearly formulated, and suitable for answering the research question(s)? Is there a well-organized work plan? Have the methods been chosen well and does the proposal describe them in sufficient detail?

4. Research-related qualifications of the researchers involved

How well are the researchers qualified to carry out the proposed research? How would you assess the academic qualifications the applicant, their team and collaboration partners? In evaluating their qualifications, please consider their career stage, taking unorthodox career paths and circumstances that may have slowed down their progress (e.g., parental leave, long-term or chronic illness, disability, caregiving responsibilities) into account.

5. Ethical, sex and gender

Ethics: Have ethical considerations been addressed satisfactorily?

Sex-specific and gender-related aspects: Applicants are required to address any relevant sex-specific and/or gender-related elements inherent in research questions and/or research design. Please assess whether the treatment of these components is adequate.

6. Overall evaluation

[19] Additional questions for international programs: International collaboration(s) – How well integrated are the parts of the project in Austria and in the partner country/countries? How would you rate the complementarity of the scientific contributions of the scientists in Austria and abroad?

What is your overall impression of the proposal? Specifically, what would you consider its key strengths and weaknesses? Please give reasons for your answers, taking as much space as you need.

Section 2: Optional recommendations for the applicant

If you are in favor of the project being funded, you may want to add to the formal assessment in section 1 by making further and perhaps more informal comments or suggestions here. However, please note that these remarks, too, may also have an impact on the FWF's funding decision, especially if they amount to substantive criticism of the project.

Section 3: Confidential remarks to the FWF

Please use this space to make any comments that you do not want submitted to the applicant. Feel free to also give us feedback about the evaluation process and your interactions with us.