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FWF

Der Wissenschaftsfonds.

In accordance with its Funding Guidelines of 1 January 2019
(as last amended), the FWF has issued the following

Application Guidelines for the Clinical Research (KLIF) Programme

Table of contents

1. General Information

1.1. Aim of the programme

The aim is to fund clearly defined research proposals (hereinafter referred to as “projects”) of high academic quality at an international level in the field of clinical research. Research efforts must be initiated by academic researchers, and business organisations must not have a direct commercial interest in the results. They must involve human patients and/or healthy subjects and aim to generate new scientific insights and knowledge about clinical pictures, improvements in clinical practice, new therapy concepts or modifications to them, and ways to improve the treatment of patients.

In general, one principal investigator is responsible for planning and carrying out clinical research projects; however, this person can collaborate with national and/or international research partners.

1.2. Submission

There are no submission deadlines for this programme; applications can be submitted at any time. Applications must be submitted online at https://elane.fwf.ac.at.

Once the application has been submitted online, a PDF cover sheet will be generated. This cover sheet bearing the original signatures and stamped by the research institution must be sent to the FWF by conventional mail. The application shall not be considered officially submitted until the FWF receives the signed and stamped cover sheet (see also Section 2.2.3).

1.3. Who is eligible to apply?

Eligible to apply are researchers working in Austria who possesses excellent research qualifications, sufficient time resources, and has access to the infrastructure necessary to carry out the project submitted. No specific academic title is needed, nor is Austrian citizenship required; however, the project must be carried out in Austria or under the auspices of an Austrian research institution at which the principal investigator works. Applications for clinical research projects may only be submitted by an individual natural person; institutions or companies may not apply.

Please note that the number of ongoing/approved projects in which one researcher can serve as principal investigator is limited to three in the Stand-Alone Projects, International Programmes, Clinical Research, and Arts-Based Research programmes. Further information on restrictions concerning the number of ongoing projects and limits on the submission of applications can be found at Restriction on the number of projects.

For information on submitting an application from abroad, see the FWF website at Applications from abroad.

1.4. What types of projects can be funded?

Funding may be requested for projects in the field of clinical research that are clearly defined, convincingly described in terms of objectives and methods, and limited in time (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. Double funding is not permitted (see Funding guidelines).

Projects must involve human patients or healthy subjects and aim to generate new scientific knowledge and insights that improve clinical practice and patient treatment. Examples include studies on personalised medicine, proof-of-concept studies, the comparison and advancement of diagnostic techniques and/or therapeutic interventions (including surgical procedures), the investigation of new indications for previously approved medications, or non-interventional, epidemiological clinical studies dealing with prevention, prognosis, care, etc.

No restrictions or quotas regarding specific subject areas will be applied in this programme. International and transdisciplinary research approaches are both permitted and explicitly encouraged. The integration of junior clinical researchers as well as gender and age group-specific aspects must be accounted for appropriately in the design of the projects. The working conditions and the working environment, in particular the rules of good clinical practice (GCP), Good Laboratory Practice (GLP), and good manufacturing practice (GMP), must be observed. Each project application must be accompanied by a positive opinion from the relevant ethics commission or evidence of a fundamental approval/endorsement by that commission.

A project may only be submitted within the framework of an existing study in cases where the project exhibits innovative characteristics and its content is not already covered by the original study. The FWF does not provide co-funding or supplementary funding for existing studies.

1.5. What requirements must be met to apply?

Researchers are eligible to apply if their publication record over the last five years has been internationally visible and if their current career stage is commensurate with the career progression expected in their field. The following criteria are decisive in assessing their publication record—documented in the “Publication list” (see Section 2.4.)—and in initiating the review process:

- **Quality assurance:** Most relevant in assessing the applicant’s publication record are those publications that have undergone 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). In the case of journals that are not listed in these databases, or in the case of monographs, edited volumes, contributions to edited volumes, or other publication types, the applicant must provide a link to the publisher’s website, describing the respective quality assurance procedure. If no

description should be available, it is the applicant's responsibility to provide evidence that the publication has been subject to an appropriate quality assurance procedure.

- **International visibility:** Most 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 applicant's publications must be commensurate with the expected career progression and the field concerned. At least two publications must have undergone a quality assurance procedure and must be internationally visible with a substantial and independent contribution on the part of the applicant. At least one first- or last-author publication is required in the life sciences.

Should an applicant fail to meet one or more of the above criteria, the applicant must include an explanation with the application. In cases of doubt, the decision-making bodies of the FWF shall decide whether the research qualifications are adequate.

1.5.1. Consideration of career breaks

The FWF will take justified career breaks (e.g., parental leave, caring for a family member, or long-term illness) into consideration in assessing the applicant's eligibility to apply. Relevant information can be included in the academic CV and thus also be available to the reviewers.

1.5.2. Inclusion of disabled and chronically ill people

The FWF will also take any exceptions to typical career paths due to disability and/or chronic illness into consideration in assessing the applicant's eligibility to apply. Relevant information can be included in the academic CV and thus also be available to the reviewers.

1.6. What types of funding can be requested?

Project-specific costs are eligible for funding. These include personnel and non-personnel costs that are necessary for carrying out the project and that go beyond the resources provided by the infrastructure of the research institution. The FWF does not finance the infrastructure or basic equipment of research institutions.

For information on requesting funding for the personnel costs of the principal investigator (= applicants who intend their salary to be paid from the grant), see Information on funding the principal investigator's (PI's) salary.

The *National Research Partner* form should be completed for costs arising from the collaboration with national research partners that have to be handled directly between the research institution of the national research partner and the FWF and are not invoiced to the principal investigator.

Please note that exaggerated costs may represent a reason for rejecting an application, even one that is considered excellent in terms of content. The number of reviews necessary for approval depends on the amount of funds requested (see Section 3).

Costs of animals and animal care will generally not be financed within the framework of this programme.

Projects may be co-funded, but in such cases the applicant must submit a declaration defining the nature of the research collaboration. Organisations co-funding a project are not allowed to act as sponsors according to the ICH-GCP regulations. All rights to data and intellectual property must belong to the researchers, except for legal provisions and provisions set forth in the contract of employment.

1.7. International programmes

The application guidelines for clinical research projects as described here apply for applications as part of international research funding programmes (ERA-NET calls, joint projects, etc.) in the field of clinical research, if permitted.

Please note however that these international programmes also have additional application requirements. For further information, see International programmes on the FWF website.

2. Application content and form

2.1. Sections of the application

For an application to be complete, it must contain the following sections:

1) **Academic abstract** in **English** comprising no more than 3,000 characters (incl. spaces; no formulas or special characters). The academic abstract will be used to inform potential reviewers about the project. The abstract must be subdivided into the following sections using the given English terms:
   - Wider research context / theoretical framework
   - Hypotheses / research questions / objectives
   - Approach / methods
   - Level of originality / innovation
   - Primary researchers involved

   Where options are given (indicated by slashes), please choose an option that is appropriate for your project.

2) **Project description**:

A project description on no more than 20 consecutively numbered pages, incl. table of contents, list of abbreviations, headings, figures, captions, tables, footnotes, etc.

The project description must also include the following annexes on additional pages:

- Annex 1: List of literature cited in the application (References) on no more than 5 pages;
- Annex 2: Information on research institution(s) and justification of requested funding;
- Annex 3: Clinical trial synopsis;

- Annex 4: Academic CV and description of previous research achievements (no more than 3 pages per CV);
- Annex 5 (optional): Confirmations ("collaboration letters") of national and international cooperation partners (no more than 1 page per letter);

3) **Attachments to be uploaded individually:**

- Mandatory: positive opinion from the relevant ethics commission or evidence of a fundamental approval/endorsement;
- Mandatory: publication list for the last 5 years, broken down into quality assured and non-quality assured (see also Section 2.4.).
- Where applicable: cover letter; list of reviewers to be excluded; report on results or final report, for follow-up applications (see also Section 3); for resubmissions: overview of all changes made in the resubmitted application and response(s) to reviews; vendor quotes for equipment, etc.

4) **Completed forms**

- Required forms: academic abstract, *application* form, *Cost breakdown* form, *Co-authors* form and *Declaration ethics* form;
- Optional forms: *National research partners* form, *National* / *International cooperation arrangements* form.

2.2. Form requirements and submission of application

2.2.1. Language of application

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

2.2.2. Formatting

The continuous text in the project description, annexes 1-4, and the attachments (except for vendor quotes) must be written in 11 pt. font with 15-20 pt. spacing and at least 2 cm margins. Applicants must comply strictly with all upper limits (e.g., number of pages, attachments, etc.).

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*). Applicants are free to choose the citation conventions or style guide they prefer, but they must apply them/it consistently throughout the application. If available, a DOI address or another persistent identifier should be used for the literature cited.

2.2.3. Submitting the application

The application must be submitted online at https://elane.fwf.ac.at.

To submit the application online, applicants are required to register at the address shown above. All the necessary forms must then be filled out online; additional documents such as the project description are to be uploaded as well. For additional information, see the "Quick reference" guide at https://elane.fwf.ac.at.

1) Required parts of the application:

a) Files:

- *Proposal.pdf* (project description incl. annexes 1-4 and where applicable 5, with PDF bookmarks, at least for the major sections)
- *Positive opinion from the relevant ethics commission or evidence of a fundamental approval/endorsement*
- *Publication_list.pdf* (publication list of all the key project participants for the last 5 years, broken down into quality assured and non-quality assured)

b) Forms:

- *Academic abstract in English*
- *Application form*
- *Cost breakdown*
- *Co-authors (mandatory information)*
- *National research partners (if applicable)*
- *National and international cooperation arrangements (if applicable)*

2) File uploads – if applicable:

- *Cover_Letter.pdf* (= accompanying letter)
- *Negative_list.pdf* (= list of reviewers who should be excluded)
- *Follow.pdf* (=result report or final report of the previous project in case of follow-up applications)
- *Overview_Revision.pdf* (=in the case of resubmission, overview of all changes made in the resubmitted application)
- *Revision.pdf* (=in the case of resubmission, an overall response to all the reviewers or, if preferred, a short response to *each* reviewer saved in a *separate* file: *Revision_A.pdf, Revision_B.pdf* etc.)
- *Quotes_equipment.pdf*
- *Quotes_other_costs.pdf*

Once the application has been submitted, a PDF cover sheet will be automatically generated. This cover sheet must be signed by hand and stamped by the responsible representative of the applicant's research institute before being sent to the FWF by conventional mail. The

application shall not be considered officially submitted until the FWF receives the signed and stamped cover sheet. Alternatively, the signed and stamped cover sheet can be scanned in, signed using the applicant's qualified electronic signature[1] (e.g., mobile phone signature), and sent to the FWF (office@fwf.ac.at) by e-mail. Please note that a scanned, signed and stamped cover sheet is invalid if it does not have a qualified electronic signature.

2.3. Project description and annexes

The project description must comprise no more than 20 pages and include a table of contents as well as the contents described in 2.3.1. Annexes must be attached to the project description in the order indicated in section 2.3.2.

2.3.1. The proposed research and Annexes

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

(2) Clearly defined aims and hypotheses or research question(s) of the project

(3) Description of the project's anticipated level of originality or innovation[2]

(4) Methods

- Description of methods to be applied
- Type of study (classification)
- Precise description of planned intervention(s)
- Relevant criteria for inclusion / exclusion
- Primary and secondary endpoints of the study
- Risk assessment
- Biometric data / statistical analyses (including power calculation), size of sample
- Methods of preventing bias
- Recruiting / availability of patients/subjects

(5) Intended cooperation arrangements (national and/or international) as part of the planned project should be explained. This explanation should specify the people with whom the applicant aims to collaborate, what the subject of the intended cooperation

[1] For example: https://www.digital.austria.gv.at/citizen-card-concept

[2] Examples of projects worthy of funding include, among others:

- Research on new ideas and/or examination of new research questions,
- Application or development of new research methods, new technologies, or original approaches to solving research questions,
- Application or modification of existing methods, technologies, or approaches to new research questions.

Please note that the next logical step or the incremental further development of published data is not considered to be innovative or original.

arrangement(s) will be and what they will contribute to the project. All of the national and/or international cooperation arrangements that were stated to be essential in the project description should be listed on the *cooperation arrangements* form and may be evidenced by a collaboration letter.

(6) Work plan and timeline

(7) Research-related qualifications of the researchers involved

(8) All potential ethical, safety-related, or regulatory aspects[3] of the submitted project and the planned handling of them must be described in a separate section. Also, legal regulations and provisions relevant to the study, in particular the requirements of good clinical practice (GCP), good manufacturing practice (GMP), as well as good laboratory practice (GLP),[4] should be described briefly.

(9) A separate section must describe what sex-specific and gender-related issues[5] the planned project may potentially give rise to, and how the applicant intends to deal with them. These must be addressed briefly in the text even if the applicant believes the project does not raise any sex-specific and gender-related issues.

2.3.2. Annex 1: List of references

- List of literature cited in the application on no more than 5 pages

2.3.3. Annex 2: Financial aspects

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

- Information on the research institution and those of the national research partners
  - Existing personnel (not financed by the FWF; usually, the principal investigator and the personnel of the research institutions)
  - Existing infrastructure
- Information on the funding requested
  - Explain briefly why the personnel requested is needed (type(s) of requested position(s), job descriptions, extent of employment, and duration of involvement in the project);
  - Explain briefly why the non-personnel cost applied for are justified (equipment, materials, travel, and other costs). If funding for equipment is requested, applicants

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

[4] The rules of good clinical practice (ICH-GCP) and notes on how to write a study protocol can be found at http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002874.pdf

[5] Positioning and reflecting on the research approaches planned for the project in terms of sex-specific and gender-related issues, for instance: 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 checking the relevance of sex-specific and gender-related issues to a project, see https://www.fwf.ac.at/en/about-the-fwf/gender-issues/fix-the-knowledge/fix-the-knowledge-detail/)

must explain why this does not constitute part of the basic equipment of the given research environment – see Section 2.5.3.

2.3.4. Annex 3: Clinical Trial Synopsis

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

The clinical trial synopsis (max. 9000 characters, 3 pages) shall be presented with the following points:

- Title of Clinical Trial
- Graphical Overview
- Applicant
- Clinical Trial Type (f.e. Double Blind, Observational a.s.o.)
- Objectives
- Intervention
- Key Inclusion and Exclusion Criteria
- Primary and Secondary Endpoint(s)
- Sample Size, Statistical Analyses, Power Calculation
- Trial Duration
- Participating Centres

2.3.5. 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 four other project participants) should be described on no more than three pages per person.

2.3.5.1. Required contents for academic CVs

- Name and contact details of the person, address of the research institution, and relevant websites. **It is also required to provide a publicly available link (hyperlink) to a list of all publications**; the use of ORCID is expressly recommended for this purpose.
- List of academic milestones and relevant positions held to date (with a brief explanation of any career gaps, if applicable).
- Main areas of research and short statement of the most important research results achieved to date.

2.3.5.2. Required description of previous research achievements

- 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, if available,

either a DOI address or another persistent identifier must be indicated. In accordance with the San Francisco Declaration on Research Assessment (DORA), journal-based metrics like the journal impact factor should not be included.

- Additional research achievements: **list of no more than ten of the most important research achievements apart from academic publications** (such as awards, conference papers, keynote speeches, important research projects, research data, software, codes, preprints, exhibitions, knowledge transfers, science communication, licenses, or patents).

2.3.6. Annex 5: Collaboration letters (optional)

- Confirmations (each no more than 1 page) of national and international cooperation partners that the project description clearly identifies as essential for the project.

2.4. Mandatory appendix: Publication list

A list of all research publications[6] over the last five years (broken down into "quality assured publications" and "other publications") of all participants for whom an academic curriculum vitae is enclosed, as well as for all project members for whom personnel costs are requested (publication_list.pdf). This list – which will not be forwarded to the reviewers – is used to assess applicants' eligibility and helps the FWF to speed up the process of finding reviewers who do not have a conflict of interest.

2.5. Eligible project-specific costs

The only projected costs eligible for funding are those in the following cost categories.

2.5.1. Personnel costs

Only those personnel may be applied for who are needed in addition to the existing personnel resources for the realization of the project and only to the extent required for the project.

The available legal categories of employment are contracts of employment for full-time or part-time employees and marginal employment. A part-time (50%) contract of employment for "student assistants," which equates to 20 hours per week, may be requested for researchers who have not yet completed a master's or diploma degree programme in the relevant subject area.

The current FWF salary scale ("Personnel costs and salary scale" or, for graduates of medicine in Austria, "Personnel costs and salary scale – Graduates of medical studies"), indicates the salaries that may be requested. The FWF grants an annual salary adjustment to compensate for inflation, which is applied automatically to all existing contracts of

[6] 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." reference can be used.

employment in Stand-Alone projects. Please note that for doctoral students, contracts of employment of no more than 75% (which equates to 30 hours per week) may be requested.

2.5.2. Grant-salaried principal investigators

The FWF defines a grant-salaried principal investigator as a principal investigator whose salary is to be paid from the funding provided for the project. Female applicants are also eligible to apply for funding for professional development and to support mobility.

A detailed description of the requirements and application procedure can be found in the Information on funding the principal investigator's (PI's) salary.

2.5.3. Equipment costs

Equipment may only be requested if it is specifically required for the project and if it is not part of the institution's existing infrastructure. "Infrastructure" is considered to include all equipment (and components for the equipment) that must be available in a modern research institution to conduct basic research in the relevant discipline at an internationally competitive level. Please note that if such equipment or components are requested nonetheless, doubts may be raised whether it is possible to conduct leading-edge basic research in such an environment (and indeed how it was possible to carry out the preliminary work related to the project in the first place). This may have an impact on the funding decision.

In this context, "equipment" includes scientific instruments, system components, self-constructed devices (generally assembled from smaller pieces of equipment and materials), and other tangible fixed assets as well as intangible assets such as licenses, industrial property rights, and licenses derived from such rights, whose acquisition cost per item exceeds the amount specified in Article 13 of the Austrian Income Tax Act 1988 as last amended, Federal Law Gazette No. 400/1988, which is currently EUR 800.00 (incl. VAT, unless the research institution is entitled to deduct VAT). A vendor quote from a company (PDF scan) must be uploaded with the application for each piece of equipment whose acquisition cost (including VAT) exceeds EUR 5,000.00.

For items of equipment which are required specifically for the project and whose acquisition cost (including VAT) is EUR 24,000.00 or higher, applicants must confirm with their signatures on the application form (*affirmation of applicant)* that they have verified that no comparable equipment that could be used or shared is available within a reasonable distance, and that the possibility of (co-)financing by third parties has been explored. Applicants must also ensure that they are aware of any possible costs that could arise from the use, maintenance, and repairs of the equipment.

The principal investigator is to instruct his/her research institution to order the equipment and effect payment accordingly. In all equipment purchases, the research institution's procurement guidelines are to be observed. Each item of equipment is to be recorded in the institution's inventory and the acquisition costs are to be reimbursed from the respective project budget in accordance with the relevant agreement between the research institution and the FWF.

2.5.4. Material costs

"Materials" encompasses consumables and small pieces of equipment (cost per item is below EUR 800.00 incl. VAT).

The calculation of requested funds for project-specific material costs should be justified with reference to the timelines, work plans, and experiment plans. In making the calculation, experience from previous projects should be considered.

2.5.5. Travel costs

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

Travel expenses for researchers from other Austrian and foreign research institutions can only be granted in exceptional cases and require detailed justification.

The calculation of travel and accommodation costs should generally be based on the federal regulations governing travel costs (RGV). The current RGV rates for travel abroad can be found in the following document.

For longer stays, a transparent and appropriate budget should be prepared; in general, this budget will be lower than the costs calculated based on RGV rates.

Applicants must not request funding for the presentation of project results at conferences; the costs associated with attending such conferences should be covered by the "general project costs".

2.5.6. Costs as part of national and international cooperation arrangements

In contrast to national research partners (see Section 1.6), costs arising within the context of a research collaboration with an external research institution are to be borne by that research institution.

Within the context of cooperation arrangements, funds may only be transferred to a cooperation partner (whether or not they are based abroad) if they are clearly limited contracts or services and directly necessary for carrying out the Austrian project. These costs must be substantiated by a vendor quote, and funding for them can be requested under "Other costs".
This does not apply to cooperation arrangements with scientists or scholars from developing countries.

2.5.7. Other eligible costs

- Independent contracts for work and services (costs for work of clearly defined scope and content carried out by individuals, provided that they are justified in terms of research and are economical);

- Costs for the preparation, archiving, open access, and reuse of research data in repositories in accordance with the FWF´s Open Access Policy of the FWF;
- Costs for monitoring and other study-related activities; vendor quotes are to be uploaded;
- Costs for patient insurance;
- Costs that cannot be included under personnel, equipment, materials, or travel costs, for example:
  - Coverage of costs for the use of research facilities, e.g., costs for the project-specific use of available equipment (i.e., project-specific "equipment time") or of large research facilities; if the costs exceed EUR 5,000.00 including VAT, vendor quotes must be provided; please upload a PDF scan. Where the costs exceed EUR 10,000.00 not including VAT (over the entire term of the project), each vendor quote must be accompanied by the corresponding calculation basis. This calculation must include information on the nature and scope of the services for which project-specific costs are incurred (according to internal charging procedures, e.g., based on usage days or hours, or based on the number and type of measurements/analyses performed, etc.) and may not contain any infrastructure-related costs like equipment depreciation, supplementary charges for overheads, costs of research premises, etc.;
  - Costs for project-specific work carried out outside the applicant's research institution (e.g., for analyses carried out elsewhere, interviews, sample collection, preparation of thin slices, etc.); in case the costs exceed EUR 5,000.00 including VAT, vendor quotes must be uploaded;
  - Costs for the disposal of project-specific hazardous waste.

Costs of animals and animal care will generally not be financed within the framework of this programme.

2.5.8. General project costs

For reasons of simplicity, general project costs refer to all those costs that are generally permitted but cannot be requested separately. These include, for example, costs for conference travel, dissemination activities as well as smaller, unforeseen costs necessary for the project. General project costs should not be understood in the sense of "overhead costs" of the research institution.

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. No justification for general costs is needed in the project description.

Up to three years after the completion of the project, applicants can apply for additional funds for publications resulting from projects supported by the FWF as part of its peer-reviewed publications programme.

2.6. Forms

All required forms must be completed in their entirety. For the application to be legally binding, the FWF requires the cover sheet generated automatically at the end of the submission process including the original signatures and stamps:

- Affirmation of applicant,
- Declaration of consent by the applicant's research institution,
- Declaration ethics
- Consent of the applicant relating to GDRP
- Affirmation of the national research partner, where applicable,
- Declaration of consent by the research institution of the national research partner, where applicable.

Co-authors form: All persons who have made substantial research-related contributions to the conception and writing of the application should be named as co-authors. A brief description of the nature of each contribution should be included; where there are no co-authors, applicants should state this explicitly on the form.

2.7. Additional attachments

In addition to the project description incl. annexes and the forms, the following attachments must be uploaded, where applicable:

- Positive opinion from the relevant ethics commission or evidence of a fundamental approval/endorsement (mandatory);
- Cover letter;
- List of reviewers who should be excluded;
- If the clinical research project submitted is the continuation of an FWF-funded project, a report on previous results or a final report and a list of publications resulting from the project must be uploaded in the language of the application (no more than 6 pages);
- For the attachments needed when a rejected application is revised and resubmitted, see Section 2.8;
- Vendor quotes for requested pieces of equipment whose acquisition cost (including VAT) is EUR 5,000.00 or higher. (Please provide one quote from one company for each piece of requested equipment. These quotes may be submitted in German).
- Vendor quotes for any relevant items requested under "Other costs" if the costs exceed EUR 5,000.00 including VAT (e.g., use of research facilities).

It should be noted that any annexes or attachments in addition to the ones mentioned above will not be considered in further stages of the application process (such as letters of recommendation, "forthcoming" publications etc.).

2.8. Revising a rejected application ("resubmission")

A resubmission is defined as the revision of a rejected application which – regardless of the programme category – deals with the same or similar research questions. Where an applicant submits an application on the same or very similar research questions, yet does not consider it to be a resubmission but an entirely new project, the applicant must submit a separate accompanying letter to the FWF Office explaining how the research questions have in fact changed. 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 decision-making bodies of the FWF shall decide.

- An accompanying letter containing an overview of all changes made in the resubmitted application must be submitted to the FWF. This overview will not be passed on to the reviewers.
- Response(s) to reviews: the applicant can decide whether the response(s) should be passed on only to the previous reviewer concerned or to all reviewers (see Section 3). These response(s) should address the suggestions and criticism expressed in each review of the previous application and point out the changes made on that basis. Such responses are not necessary in the case of reviews written by persons who are to be excluded from the review process for the resubmitted application. However, such exclusions must be justified and will also be counted toward the list of reviewers who are to be excluded for the resubmission.

If all the reviewers are to receive the response(s), the applicant must submit a single document containing an overall response. If the response(s) are to be passed on only to the reviewers who were previously involved, the applicant should include a short response to each review in a separate document.

Resubmissions must show changes. If an application has been rejected for the standardised reasons C3, C4, and 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.

There is no deadline within which a resubmission of a rejected application must be submitted, but any relevant application requirements must be considered. Submission of a resubmission follows the application procedure described in 2.2.3., meaning that it is submitted as a new independent application and not as an additional application to the previously rejected application.

3. Processing of and decision on the application

The FWF Office undertakes a formal check of the application. A detailed description of the decision-making process, the criteria for selecting international reviewers, detailed rules concerning conflicts of interest and the composition of expert juries and boards can be found in the General Principles of the Decision-Making Procedure.

The **review process** generally takes about six months. When it is completed, the FWF Board considers the reviews and decides whether the proposal should be supported. The applicant will be informed in writing of the FWF's decision.

The number of reviews required for a funding approval depends on the amount of funding requested. For requests of up to EUR 400,000.00, at least two reviews are needed; for each additional EUR 200,000.00, at least one further review is required (e.g., up to EUR 600,000.00, at least 3 reviews, and so on).

Please note that experience has shown that the average processing time increases significantly with an increase in the number of required reviewers.

Requests for changes and returning applications without review

The FWF will not process incomplete applications, those which do not comply with the FWF's regulations or which contain formal errors (in particular, if the maximum length permitted is exceeded), unless and until the applicant has rectified the problems within a reasonable period of time (generally three weeks). If the problems have not been resolved within this period of time, the FWF's decision-making bodies will return these proposals without review. Similarly, applications will not be reviewed if they have been previously rejected by the FWF and resubmitted without appropriate revisions.

All applications that conform with the FWF's regulations will be sent out for review. The reviewers (generally persons working outside of Austria) will be selected by the members of the FWF Board and confirmed by the FWF's decision-making bodies,

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

The most common reasons why applications are returned without review are (a) that the applicant's track record of publications does not meet the requirements (see Section 1.5.) and (b) that the application does not address specific hypotheses or research questions (see Section 2.3.1.).

Reasons for rejection

The reasons for rejecting a project will be analysed and assigned one of five categories (C1–C5). The result will be sent to applicants along with the reviews. A detailed description of the categories can be found in the General Principles of the Decision-Making Procedure.

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 generally not be contacted for a second review. However, please note that all resubmissions are also evaluated by new reviewers.

Proposal bans

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

Applications that have been submitted 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.

It is only ever topics that are temporarily banned according to these rules, and not applicants.

Exclusion of reviewers

As mentioned in Section 2.7., an additional document may be uploaded giving a list of up to three reviewers who the applicant believes may have a conflict of interest and whom he therefore does not wish to review the application. A detailed description of the FWF’s policy on conflicts of interest can be found in the General Principles of the Decision-Making Procedure document.

The applicant must give reasons for why they wish to exclude certain reviewers. If the reasons given hold up to scrutiny, the FWF will generally fulfil such requests and will exclude those reviewers from the review process.

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

4. Compliance with legal requirements and standards of research integrity

Applicants must comply with all legal requirements and safety provisions (e.g.,the Federal Disabilities Act) that apply to their Stand-Alone project and obtain all the necessary permits (e.g., from the Ethics Commission, the Commission for Animal Experimentation, the Federal Monuments Authority Austria, or the relevant foreign authorities).

Applicants must also comply with the Guidelines for Good Scientific Practice of the Austrian Agency for Research Integrity (ÖAWI) when submitting the application and carrying out the project. If there is reason to believe that an applicant has failed to comply with these standards, the FWF will arrange for the ombudsperson of the respective research institution or the Austrian Agency for Research Integrity (ÖAWI) to carry out an investigation. The FWF reserves the right to suspend, in part or in whole, any procedures related to applications or ongoing projects until the investigation has been concluded. For more detailed information, see FWF procedure in cases of suspected scientific misconduct.

5. Publication of project data and results

The FWF would like to point out that should the project be approved, the FWF will publish on its website a summary of the project in German and English for public relations purposes – which must be sent to the FWF by the applicant when returning the grant agreement – as well as the amount of funding granted and, on project completion, summaries of the final report of the project. The principal investigator should ensure that these summaries are

written in such a way as to safeguard legitimate interests of secrecy for reasons of national defence and patent law, and that trade secrets are appropriately protected.

The funds for the execution of the study will not be released until the necessary permits have been obtained from the relevant authorities, and the study has been registered in a publicly accessibly database for clinical research projects in accordance with the WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects.

In addition, the FWF requires a data management plan (DMP) for all approved projects. This should also be sent to the FWF when returning the grant agreement. The template for the DMP can be viewed and downloaded at https://www.fwf.ac.at/en/research-funding/open-access-policy/research-data-management/.

In presentations and publications of project results, applicants must comply with the relevant requirements on acknowledging the FWF as the funding institution and the FWF's Open Access Policy.

APPENDIX I:
Template Annex 2: Information on the research institution and finances

Note: The information on the research institution and the description of project finances must be presented using the following structure and appended to the project description as Annex 2. The costs must be broken down and adequately justified for each point below. The list and justification of the costs requested must be in accordance with the costs indicated in the *cost breakdown* form.

(a) Details on the research institution of the applicant and of national research partners[7]:

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

(b) Information on the funding requested[8]:

- Explain briefly why the personnel requested is needed for the personnel requested (type(s) of requested position(s), job descriptions, extent of employment, and duration of involvement in the project);
- Explain briefly why the non-personnel cost applied for 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 2.5.3 .

List and justification for

Personnel costs:

Equipment costs:

Material costs:

Travel expenses:

Other costs (including independent contracts for work and services):

[7] In the case of international programmes (joint projects), information on the research site(s) of the foreign project partner(s)

[8] In the case of international programmes (only Joint Projects in Lead Agency procedure): list and justification of the requested funds of the foreign project part(s)

Template Annex 3: Clinical Trial Synopsis

Note: The clinical trial synopsis (max. 3 pages) must be presented using the following structure and appended to the project description as Annex 3.

1) Title of clinical trial:
2) Graphical overview:
3) Applicant:
4) Clinical trial type (f.e. double blind, observational a.s.o.):
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 centres:

APPENDIX II: Notes and questions for reviewers in the Clinical Research funding programme[9]

The FWF actively supports equal opportunities and fair treatment for all applicants. The FWF does not put applicants at a disadvantage for non-research-related reasons (such as age, gender, etc.) and therefore asks all reviewers to apply the same standards. For example, when assessing applicants' qualifications, please disregard their actual age, but consider their academic age instead. Our commitment to equal opportunities also means taking into account 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, unorthodox career paths, or limited international research experience.

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 San Francisco Declaration on Research Assessment (DORA), the FWF also emphasizes that, in assessing research performance, reviewers should refrain from using journal-based metrics such as the Journal Impact Factor.

Please review the present proposal[10], using the following six assessment criteria:
1) innovation and originality, 2) quality of the proposed research, 3) approach and feasibility, 4) researchers' qualifications, 5) ethics and gender, 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 "excellent" to "poor". Please be aware, however, that the FWF's funding decision will be based primarily on referees' written assessments rather than the ratings assigned.

9 Further information on the FWF's corporate policy and mission or the application guidelines for clinical research projects can be found on our website at: (http://www.fwf.ac.at/de/ueber-den-fwf/leitbild/ and https://www.fwf.ac.at/en/research-funding/fwf-programmes/programme-clinical-research-klif

10 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 details see https://www.fwf.ac.at/en/research-funding/fwf-programmes/programme-clinical-research-klif)

Section 1a[11] (forwarded to the applicant in its entirety):

Section 1 and 2 will be forwarded to the applicant in its entirety:

(1) Innovation and originality:

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) Qualifications of the clinicians / researchers involved

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

(5) Ethics and gender:

a. Ethics: Have ethical considerations been addressed satisfactorily?

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

(6) Overall evaluation:

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.

[11] Additional questions in the case of international programmes: International cooperation arrangement(s) – complementarity and integration of contributions to the research.

(2) Section 2: Optional recommendations for the applicant(s)

If you are in favour 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 impact on the FWF's funding decision, especially if they amount to substantive criticism of the project.

(3) Section 3: Confidential remarks to the FWF

Please use this space to make any comments that you do not wish to be conveyed to the applicant(s). Feel free to also give us feedback about the evaluation process and your interactions with us.