



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**



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## 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. Deadlines

There are no submission deadlines for this programme; applications can be submitted at any time.

### 1.3. Who is eligible to apply?

Any researcher working in Austria in a clinical setting or cooperating with a clinic 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?**

Applicants must show that they possess the research qualifications needed to carry out the project by means of a publication record over the last 5 years commensurate with their career stage, which demonstrates their international visibility.

The following criteria are decisive in assessing an applicant's publication record and initiating the review process:

- **Peer review:** All the publications listed (or more than half in the case of the humanities) must have been subject to a quality assurance procedure in line with high international standards, which usually means that journals should be listed in the Web of Science, Scopus, or the Directory of Open Access Journals (DOAJ). For journals not listed in those databases, or monographs, edited volumes or contributions therein, or other publication types, the peer-review procedure must be documented on the publisher's website to which applicants should provide a link. Should no such documentation be available on the website, it is the applicant's responsibility to provide evidence that the publication has been subject to an appropriate quality assurance procedure.
- **Number and quality** of the applicant's publications must be commensurate with his/her career stage. At least two publications must be peer-reviewed and internationally visible publications with a substantial and independent contribution on the part of the applicant.
- **International nature:** Most of the publications listed must be in English.

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.

## 1.6. 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
- 2) **Project description:**
  - Project description of no more than 50,000 characters (incl. spaces) on no more than 20 consecutively numbered pages, incl. table of contents, list of abbreviations, headings, figures, captions, tables, footnotes, etc.;
- 3) **Annexes:**

Please note that annexes are an integral part of the project description and they must be incorporated into the proposal.pdf in the order listed below (see also [Section 2.4](#)):

- Annex 1: Information on research institution(s) and justification of requested funding;
- Annex 2: Clinical trial synopsis;
- Annex 3: List of literature cited in the application (*References*) on no more than 5 pages;
- Annex 4: Academic curriculum vitae (hereinafter referred to as CV) and description of previous research achievements (no more than 3 pages per CV);
- Annex 5: Confirmations (collaboration letters) of national and international cooperation partners (no more than 1 page per letter);

- Additional attachments that must be uploaded individually:
  - positive opinion from the relevant ethics commission or evidence of a fundamental approval/endorsement;
  - publication list for the last 5 years, broken down into peer-reviewed and non-peer-reviewed see also [Section 2.5](#)).
- Where applicable, other attachments may be uploaded individually: 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

### 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 1.5 line (15-20 pt.) spacing and at least 2 cm margins. The beginning of each paragraph should be clearly recognisable (e.g., by indenting the first line and/or spaces between paragraphs). 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 can be uploaded. 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 peer-reviewed and non-peer-reviewed)

#### b) Forms:

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

### 2) Optional file uploads:

- *Cover\_Letter.pdf* (= accompanying letter)
- *Negative\_list.pdf* (= list of reviewers who should be excluded)
- *Follow.pdf* (= report on results or final report of the previous project in the 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 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<sup>1</sup> (e.g., mobile phone signature), and sent to the FWF ([office@fwf.ac.at](mailto: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

The description incl. table of contents of the project on no more than 50,000 characters incl. spaces on no more than 20 pages must include the following contents:

### 2.3.1. Scientific aspects

- Clearly defined aims and hypotheses or research question(s) of the project
- Description of the project's anticipated level of originality or scientific innovation<sup>2</sup>
- Available data / existing (preliminary) work / preclinical studies (where applicable)
- Relevance to international research in the field (international state of research)

### 2.3.2. Methods and research design

- 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
- All potential sex-specific and gender-related aspects<sup>3</sup> in the planned project as well as the planned implementation of these research questions must be described in a

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<sup>1</sup> For example: <https://www.digital.austria.gv.at/citizen-card-concept>

<sup>2</sup> 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.

<sup>3</sup> Positioning and reflecting on the research approaches in the 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

separate section. This aspect should be addressed briefly in the text even if the applicant believes the project does not raise any sex-specific and gender-related issues.

- Intended [cooperation arrangements](#) (national and/or international) as part of the planned project should be explained in the project description. This explanation should specify the people with whom the cooperation arrangement shall take place and the subject of the intended cooperation arrangement(s) or the contribution 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 be evidenced by a collaboration letter.
- Work plan and timeline

### 2.3.3. General rules and provisions

- All potential ethical, safety-related, or regulatory aspects<sup>4</sup> 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),<sup>5</sup> should be described briefly.

### 2.3.4. Human resources

- Research-related qualifications of the researchers involved

## 2.4. Annexes to the project description

Annexes are not included in the maximum character limit for the project description and must be attached to the project description in the specified order.

### 2.4.1. Annex 1: 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
  - Available personnel (not financed by the FWF; usually, the principal investigator and the personnel of the research institutions)
  - Available infrastructure
- Information on the funding requested

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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/>

<sup>4</sup> For instance, the European Commission's [Ethics for Researchers](#) or [The European Code of Conduct for Research Integrity](#) can serve as a guide here.

<sup>5</sup> 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](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002874.pdf)

- Concise justifications for the personnel requested (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, 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 2.6.3](#).

#### **2.4.2. Annex 2: 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

#### **2.4.3. Annex 3: List of references**

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

#### **2.4.4. 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](#)) and should be described on no more than three pages per person.

##### *2.4.4.1. 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 to a list of all published 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 scientific/scholarly results achieved to date.

#### 2.4.4.2. 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, either a [DOI address](#) or another [persistent identifier](#) should 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 scientific/scholarly 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.

#### 2.4.5. Annex 5: Collaboration letters

- Confirmations (each no more than 1 page) of national and international cooperation partners that are stated to be essential in the project description

### 2.5. Mandatory appendix: Publication list

A list of all published publications<sup>6</sup> of the last five years (divided into peer reviewed and non-peer-reviewed) of all participants for whom a scientific curriculum vitae is enclosed, as well as for all essential project members for whom personnel costs are requested (Publication\_list.pdf).

This list helps the FWF to determine if there are any potential conflicts of interest with reviewers and thus speeds up the process of identifying reviewers. This list will not be forwarded to the reviewers.

### 2.6. Eligible project-specific costs

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

#### 2.6.1. Personnel costs

The application should include all persons, in addition to the staff already available, who will be needed to carry out the project and will work exclusively to the extent agreed on for this project.

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<sup>6</sup> Publication lists must include: all authors, complete titles, journal, year, and page numbers. For each publication, 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.

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

### 2.6.2. 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](#).

### 2.6.3. 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 should 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 how it was possible to carry out the preliminary work related to the project. 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 400.00 (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.

#### **2.6.4. Material costs**

“Materials” encompasses consumables and small pieces of equipment (cost per item is below EUR 400.00 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. Experience from previous projects should be considered in making the calculation.

#### **2.6.5. 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 congresses; the costs associated with attending such conferences should be covered by the “general project costs”.

#### **2.6.6. 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 (also abroad) if they are clearly limited contracts or services and directly

necessary for carrying out the Austrian project. This does not apply to [cooperation arrangements with scientists or scholars from developing countries](#).

### 2.6.7. 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 economical);
- Costs for the preparation, archiving, open access, and reuse of research data in repositories in accordance with the [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 (project-specific “equipment time”) or large research facilities; in any case, vendor quotes should be provided. Where the costs exceed EUR 10,000 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 overhead, costs of research premises, etc.;
  - Costs for project-specific work carried out outside the applicant’s research institution (e.g., for analysis work performed elsewhere, interviews, sample collection, preparation of thin slices, etc.); vendor quotes should 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.

### 2.6.8. General project costs

For reasons of simplicity, general project costs refer to all those costs that are generally permitted but cannot be requested individually. 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 should 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.

Applicants can apply up to three years after the completion of the project for additional funds for publications resulting from projects supported by the FWF as part of its [peer-reviewed publications](#) programme.

## 2.7. 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 GDPR
- 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.

## 2.8. Additional attachments

In addition to the project description and the forms, the following attachments should 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 should be uploaded in the language of the application (no more than 6 pages);
- For the attachments needed in the case of revising a rejected application (resubmission), see [Section 2.9](#);
- Vendor quotes for the requested equipment for pieces of equipment whose acquisition cost (including VAT) is €5,000 or higher (one quote from one company for each piece of requested equipment; can be submitted in German);



- Vendor quotes for any relevant items requested under “Other costs” (e.g., use of research facilities).

It should be noted that any annexes or attachments in addition to the ones mentioned above shall not be considered in further stages of the process (such as letters of recommendation, publications not yet published).

## 2.9. Revising a rejected application (“resubmission”)

A resubmission is defined as the revision of an application which has already been rejected with the same or similar research questions, regardless of the programme category. 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 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.

- If the project submitted is a resubmission of a rejected application, the applicant should indicate this at the beginning of the project description (e.g., in a footnote).
- 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 to the relevant previous reviewer or all reviewers (see also 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 should be excluded for the resubmission.
- If all the reviewers are to receive this response, the applicant must submit a document containing an overall response.  
If these responses 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. In the case of resubmissions of applications that have been rejected for the standardised reasons C3, C4, and C5, the changes need to be substantial (based on the comments in the reviews). If such changes are not made, the application will be returned without review by the decision-making bodies of the FWF.

### 3. Processing 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 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.

#### **Funding amount requested:**

Up to EUR 400,000.00 at least 2 reviews

Up to EUR 600,000.00 at least 3 reviews

Up to EUR 800,000.00 at least 4 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*

Incomplete applications or those which do not comply with the FWF's regulations or which contain formal errors (in particular, those which exceed the permitted length) will not be processed further by the FWF 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 decision-making bodies of the FWF will return these proposals without review. Similarly, the decision-making bodies of the FWF will return without review applications that have been previously rejected by the FWF and resubmitted without appropriate revisions.

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

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 by the decision-making bodies of the FWF are (a) that the applicant's track record of publications does not meet the requirements (see [Section 1.5](#)) and (b) that the application is missing specific hypotheses or research questions (see [Section 2.3](#)).

### *Reasons for rejection*

The reasons for rejecting a project will be assigned one of five categories (C1–C5) and 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 (i.e., the original application and the respective resubmissions) are also barred for 12 months (from the date of decision); rejections for reasons C1 or C2 do not count towards this total.

### *Exclusion of reviewers*

Applicants may include a separate document with a list of reviewers who should not be asked to review the application due to possible conflicts of interest. A detailed description of the FWF's rules concerning conflicts of interests can be found in the [General principles of the decision-making procedure](#).

This list may include up to three potential reviewers whom the applicant believes may have conflicts of interests. This selection must be briefly justified. If the reasons for exclusion are professionally and technically sound, 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**

The FWF would like to point out that applicants must comply with all legal requirements and safety provisions (e.g., Federal Disabilities Act) that apply for 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 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 accessible 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: information on the research institution and description of financial aspects

Note: The information on the research institution and the description of financial aspects shall be presented using the following structure and appended as Annex 1 to the project description. The list and justification of the costs requested must be in accordance with the costs indicated in the form *cost breakdown*.

(a) Details on the research institution of the applicant and of national research partners<sup>7</sup>:

- 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<sup>8</sup>:

- Concise justifications for the personnel requested (type(s) of requested position(s), job descriptions, extent of employment, and duration of involvement in the project);
- Concise justifications for non-personnel cost (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 2.6.3](#).

List and justification of the personnel costs applied for:

List and justification of the equipment costs applied for:

List and justification of the material costs applied for:

List and justification of the travel expenses applied for:

List and justification of other costs applied for:

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<sup>7</sup> In the case of international programmes (joint projects), information on the research site(s) of the foreign project partner(s)

<sup>8</sup> 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 2: Clinical Trial Synopsis**

Note: The clinical trial synopsis (max. 9000 characters, 3 pages) shall be presented using the following structure and appended as Annex 2 to the project description.

- 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 Programme<sup>9</sup>

In all of its programmes, the FWF actively supports equal opportunities and equal treatment. The review of an application must not put applicants at a disadvantage for non-research-related reasons such as age, gender, etc. For example, the review of applications should not focus on the applicant's actual age, but on the relation between the applicant's previous research achievements and the length of his/her research career. For the FWF, equal opportunities also means taking into account any unavoidable delays in applicants' research careers that have led to publication gaps, less time spent abroad, etc. (e.g., due to well-founded, extended qualification periods; time spent raising children; long-term illness; caring for relatives; etc.).

In writing your review, please keep in mind that your comments in the first section of the review will be forwarded to the applicant and, where applicable, other reviewers, in an anonymous way.

The FWF would like to point out that the length and the form of the project proposal must fulfil the form requirements<sup>10</sup> of the FWF, and therefore we ask that you keep these restrictions in mind when writing your review.

The FWF is obligated to ensure the best possible use of public-sector funds for basic research according to scientific/scholarly research criteria. We therefore ask you to comment on the following aspects of the application in Section 1a. What are the specific strengths of the project? Does it have weaknesses, and if so, what are they?

### Section 1a<sup>11</sup> (forwarded to the applicant in its entirety):

- 1) Level of originality or scientific innovation of the application
- 2) Clinical/Scientific quality of the proposal
- 3) Approach/methods and feasibility of the proposal

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<sup>9</sup> Further information on the FWF's corporate policy and mission or the application guidelines for Stand-Alone projects can be found on our website at: (<http://www.fwf.ac.at/de/ueber-den-fwf/leitbild/> and <http://www.fwf.ac.at/de/forschungsfoerderung/fwf-programme/einzelprojekte/>)

<sup>10</sup> **Form requirements:** Project description incl. figures and tables, no more than 20 pages; list of literature cited no more than 5 pages; academic CVs and description of previous research achievements of the project participants incl. the 10 most important publications, no more than 3 pages each.

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

- 4) Clinical/Research-related qualifications – based on their academic age – of the researchers involved
  
- 5) Additional aspects:
  - a. Ethical aspects
  - b. Sex-specific and gender-related aspects
  
- 6) Overall evaluation with consideration of the key strengths and weaknesses. Please give a clear recommendation for or against funding a project.

### **Section 1b (optional remarks to the applicant)**

Reviewer's recommendations to the applicants for implementing the project (in the case of approval). The recommendations made here generally should not play a role in the funding decision.

### **Section 2 (confidential remarks to the FWF)**

Other comments intended solely for the FWF.