FWF Austrian Science Fund

# Checklist for a complete application (Clinical Research)

The complete application must be submitted in English, using the FWF's online application portal elane. To make sure you have completed your application correctly, please consult the Application Guidelines.

## I. *elane*: Forms

### Required forms:

- *Research institution* form
- *Contact form*
- *Application form*
- *Statement on ethics commission approval* form
- *Cost breakdown* form
- *Academic abstract* form (max. 3,000 characters) - pursuant to FWF guidelines (see section 2.1.1 of the Application Guidelines
- *Co-authors* form

### Where applicable

- *Associated research partner* form: One form for each associated research partner
- *Other cooperation* form Must be completed for all national and international collaboration partners listed in the project description; one form for each collaboration partner

## II. elane: File uploads

### Required upload (in one file)

- ***Proposal.pdf*** – This PDF file must include the project description, Annexes 1–4, and, if applicable, Annex 5. Formatting requirements apply to the project description and Annexes 1–4 (font size 11 pt. with 15–20 pt. line spacing and margins of at least 2 cm).

The project description (max. 20 pages) must include the following components:

- Table of contents
- State of the art of relevant international research (including own preliminary work / preclinical data, if applicable) and relation of the project to this context
- Clearly defined aims and hypothesis/hypotheses or clinical / research question(s)
- Description of the expected level of novelty or clinical / academic innovation of the project
- Methodology
  - Research methodology
  - Type of study
  - Exact description of the planned intervention(s)
  - Relevant inclusion / exclusion criteria

    - Primary and secondary endpoints of the study
    - Risk assessment
    - Biometrics / statistical analyses (including power calculation), sample size
    - Bias avoidance measures
    - Recruitment / availability of patients / test subjects
  - Associated research partners (if applicable): Description of the contributions of the associated research partners to the proposed research; associated research partners must be named in the *Associated research partner* form.
    National and/or international collaboration partners (if applicable): Please specify the intended collaboration partners and the subject of the intended collaboration(s) or the planned contribution to the project. **All** national and/or international cooperation arrangements that were named as essential must be listed on the ***Other cooperation*** **form** (one form must be completed for each collaboration partner) and may be confirmed by a collaboration letter.
  - Work plan and timeline
  - Research-related qualifications of the researchers involved
  - All potential ethical, safety-related, and regulatory aspects of the proposal and how applicants plan to deal with them must be described in a separate section. These questions should be addressed briefly in the text even if the applicant believes the project does not raise any ethical issues.
  - A separate section must describe any potential sex-specific and gender-related aspects of the proposal. How will they be integrated into the research approach? These questions must be briefly addressed, even if the applicant does not feel that the project involves any such aspects.
- Annex 1: List of **literature cited in the application** (*References*) on no more than 5 pages
- Annex 2: **Financial aspects:** Please use the template provided in the Application Guidelines (Appendix A). The information provided must be presented plausibly and understandably for the FWF and the reviewers. Implausible information may lead to reductions in the funding amount. The list and justification for the requested funding must correspond with the costs indicated in the *Cost breakdown* form.
  - Details of the applicant’s research institution and of national research partners
    - Description of
      - Existing personnel (not financed by the FWF, usually the principle investigator and project participants at the research institutions)
      - Existing infrastructure
  - Information on the funding requested:
    List and justification for
    - Personnel costs
    - Equipment costs

  - Material costs
  - Travel costs
  - Other costs (including independent contractor agreements for work and services)
- Annex 3: **Clinical trial synopsis** on max. 3 pages
  - Title of clinical trial
  - Graphical overview
  - Applicant
  - Clinical trial type (e.g. double blind, observational etc.)
  - Objectives
  - Intervention
  - Key inclusion and exclusion criteria
  - Primary and secondary endpoint(s)
  - Sample size, statistical analyses, power calculation
  - Trial duration
  - Participating centers
- Annex 4: **Academic CVs** and description of the previous research achievements of the principal investigator and of max. 3 other key project participants (max. 3 pages per person)
- Annex 5 (optional): **Collaboration letters** (max. 1 page each) of national and international collaboration partners that the project description clearly identifies as essential for the project.

# III Additional documents:

## Required uploads:

- ***Ethics commission approval.pdf*** **:** A positive opinion or confirmation of fundamental approval from the ethics commission[1]
- ***PI_publication.pdf:*** Two publications written by the applicant must be named, documenting that the applicant fulfills the general requirements to apply (see template *PI_publication*). The FWF will determine eligibility to apply based on these publications.
- ***Publication_list.pdf:*** A list of all research publications over the last five years (categorized into “quality-assured publications” and “other publications”) by all participants for whom a CV has been submitted, as well as for all project staff members for whom personnel costs are requested, in *one* PDF document

## Other file uploads, if applicable:

- ***Cover_letter.pdf*** – Accompanying cover letter; optional

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

- ***Negative_list.pdf*** – List with names of reviewers who are to be excluded from the review of the application for various reasons (max. 3 names; optional)
- If the application is a continuation of an FWF-funded project:
  - ***Follow.pdf*** – Results or final project report on the previous project, max. 6 pages
- If the application is a revision of a previously rejected application (resubmission):
  - ***Overview_revision.pdf*** – Overview of all changes made in the resubmitted application (for FWF internal use only)
  - ***Revision.pdf*** - response to all reviews of the previously rejected application, even if one of the reviewers of the rejected application is to be excluded from reviewing the resubmission