Der Wissenschaftsfonds.

# Checklist for a complete application (Clinical Research)

The entire application must be submitted in English and it must be submitted via the FWF's electronic application portal https://elane.fwf.ac.at. For a correct application, please observe the information in the application guidelines.

## I. *Elane*: Forms

### Mandatory

- ☐ Application form
- ☐ Form Cost breakdown
- ☐ Form Academic abstract (no more than 3,000 characters) – according to the FWF application guidelines
- ☐ Form Co-authors

### To be filled if necessary

- ☐ Form for National research partners
- ☐ Form Cooperation arrangements – for national and international cooperation partners that are stated to be essential in the project description

## II. *Elane*: Files to upload

### Mandatory upload in a single file

- ☐ ***Proposal.pdf*** - this PDF file must contain the project description as well as annex 1-4 and, if applicable, annex 5. For the project description and annex 1-4, the formatting specifications must be observed (font size 11pt, line spacing 15-20 pt, page margins at least 2cm). The beginning of each paragraph should be clearly recognisable (e.g., by indenting the first line and/or spaces between paragraphs).

  **The project description (on a max. of 20 pages without annexes) must include the following contents:**

  **Scientific aspects:** Decisive for the assessment of the quality of the project

  - ☐ 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 hypotheses or research question(s) of the project
  - ☐ Description of the project's anticipated level of originality or innovation

- ☐ Methods
  - ☐ Description of the methods
  - ☐ 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/subject
- ☐ 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 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.
- ☐ Work plan and timeline
- ☐ Research-related qualifications of the clinicians / researchers involved.
- ☐ All potential ethical, safety-related, or regulatory aspects of the submitted project and how the applicant plans 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 what sex-specific and gender-related issues 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.

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

☐ **Annex 2:** **Financial aspects:** The template from the application guidelines must be used.

The explanations must be presented in a way that is comprehensible to the FWF and the reviewers. Non-transparent information may lead to a reduction in the grant amount. The list and justification of the costs requested must be in accordance with the costs indicated in the *Cost breakdown* form.

- ☐ Information on the research institution and – if applicable – those of the national research partners:
  - ☐ Available personnel – not financed by the FWF
  - ☐ Available infrastructure – Information on the research institution(s) and the project-specific basic equipment available

- ☐ Information on the funding requested:
  - ☐ Personnel
  - ☐ Equipment costs (from an acquisition value of €800.00 incl. VAT/piece)
  - ☐ Material costs
  - ☐ Travel costs
  - ☐ Other costs incl. independent contracts for work and services

☐ **Annex 3**: Clinical trial synopsis on max. 3 pages
- ☐ 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:

☐ **Annex 4:** Academic curriculum vitae and description of previous research achievements (no more than **three pages** per person, incl. **a publicly available link (hyperlink) to a list of all publications, incl. ten of the most important published or accepted academic publications**) of the principal investigator as well as a maximum of four other essential project participants

☐ **Annex 5:** **Optional**: confirmations (collaboration letters, no more than 1 page) of national and international cooperation partners that are stated to be essential in the project description.

## III Attachments:

### Mandatory file to be uploaded (attachment)

☐ Positive opinion from the relevant ethics commission or evidence of a fundamental approval/endorsement

☐ ***Publication_lists.pdf*** – 1 File: A list of all research publications 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 (merged onto the document *publication_list.pdf*).

## If necessary files to be uploaded (attachment):

- ☐ *Cover_Letter.pdf* – Letter accompanying the 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)
- ☐ *Quotes_equipment.pdf* – Quotes for equipment pieces from an acquisition value of EUR 5,000.00 incl. VAT (1 offer per requested equipment piece; in the case of several offers merged into one PDF file)
- ☐ *Quotes_other-costs.pdf* – e.g., costs for the project-specific use of available equipment (project-specific "equipment time") or large research facilities, costs for project-specific work carried out outside the applicant's research institution; in case of several offers merged into one PDF file.

- If the Clinical research project submitted is the continuation of an FWF-funded project:
  - ☐ *Follow.pdf* - report on previous results or a final report, no more than 6 pages
- If the application is the revision of a rejected application (resubmission):
  - ☐ *Overview_revision.pdf* - overview of all changes made in the resubmitted application (For FWF internal use only)

  In the application form must be indicated, whether the response(s) should be passed on to the relevant previous reviewer or all reviewers:

  – If all the reviewers are to receive this response:
  ☐ *Revision.pdf* - overall response to all reviews

  – If these responses are to be passed on only to the reviewers who were previously involved:
  ☐ *Revision_A.pdf* – response to review A
  ☐ *Revision_B.pdf* – response to review B
  etc.