Peer review handbook

Grant for planning of clinical study in therapy research 2023

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Foreword

Welcome as an expert reviewer for the Swedish Research Council's peer review process in Clinical Therapy Research for 2023 and our call for Grant for planning of clinical study in therapy research. The evaluation of research applications constitutes the foundation for the work of the Swedish Research Council and your assignment as member of one of our review panels is an important position of trust. Your work is very important and I hope you realize how much we and all the scientists that are applying for funding this year appreciate your efforts.

The aim of this handbook is to assist you in your forthcoming work and describes the review process step by step with a purpose to make it easy to find the information relevant for the tasks. It contains important practical instructions on the assessment of applications as well as how final statements to applicants shall be written. In addition, you can find information on the Swedish Research Council's general guidelines and on our conflict of interest policy and gender equality strategy.

Please read both the instructions and the links carefully, so that you are well prepared for your review work.

Thank you for your efforts and welcome as a reviewer for the Swedish Research Council.

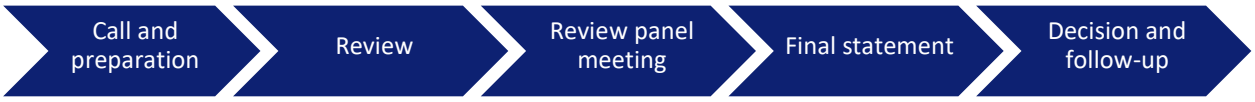
Jonas Oldgren

Secretary General, Clinical Research

Introduction

The purpose of the grant is to create opportunities for a constellation of researchers within academia and health and medical care to plan ahead with other actors for a future application for a grant for a clinical study in therapy research.

The handbook is designed to reflect the review process step by step. The intention is to make it easier for you as a panel member to find the information you need for tasks to be carried out.



General starting points and principles

The following guidelines and principles strictly apply during all steps in the review work.

Peer review

The Swedish Research Council should give support to basic research of the highest scientific quality within all fields of science. The fundamental principle for assessing scientific quality is the peer review of applications carried out by the review panels. In order to provide a basis for the scientific review, the board of the Research Council has formulated guidelines for peer review based on eight principles. Take part of the guidelines for peer review.

Conflict of interest

In order to avoid any situation involving a conflict of interest, the Swedish Research Council has established strict guidelines that you must be acquainted with. Take part of the Swedish Research Council's conflict of interest policy and guidelines for conflict of interest.

Anyone who has a conflict of interest should not participate in the handling, assessment or discussion of the application or the applicant during any part of the process. In order to prevent the occurrence of conflict situations an application should not be reviewed in the review panel:

- if a member of the panels is an applicant or a participating researcher
- if a related party to a member of the panel is an applicant (not participating researcher)

You are obliged to report any conflict of interest in relation to the applications you will be reviewing. In the event of any doubt, please confer with the chair and the Research Council personnel.

Gender equality

One of the operational goals of the Swedish Research Council is to ensure that women and men have the same success rates and receive the same average grant amount, taking into account the nature of the research and the type of grant. Review panels should consider the gender equality goal and work out the success rate in its proposal, as well as consider and if necessary comment on the outcome. When ranking applications of equal quality, applicants from the under-represented gender should be prioritised.

Sex and gender perspectives

As of 2018, the Swedish Research Council's instruction from the government include that we must work to ensure that gender and gender perspectives are included in the research we fund, when applicable. How gender and gender perspectives are handled in research, when relevant, is included in the assessment of the scientific quality of the applications.

Handling of ethical considerations in the application and review

The Swedish Research Council requires that research conducted with our support follows good research practice and that it complies with applicable law in Sweden. When the applicant (PI) and the administrating organisation sign the terms for an awarded grant, they confirm their responsibility for this.

Handling of ethics consists of two parts and is included in the assessment of the scientific quality and the feasibility of the applications.

Deviations in the application

If you think that an application deviates from the Swedish Research Council's guidelines in a way that is not clearly covered by the scientific review work, you should notify us of this as soon as possible. This could for example concern ethical issues or deviations from good research practice.

Confidentiality

Throughout the review process, applications and the review of applications should be treated confidentially:

- You must not spread the documents that you have access to in your work as a member
- You must delete the documents after the assignment has been completed.
- Third parties should not be informed of what was discussed at the meeting, or of the views of any other reviewers in the ongoing review process.
- All communications between applicants and the Swedish Research Council concerning the review process or the decisions should be carried out via the Research Council’s research officer responsible.

Review work in Prisma

All the review work is carried out in the web-based system Prisma. If you have any questions concerning the system and cannot find the answer in Prisma’s User Manual, please contact the research officer responsible.

Roles in the review process

Chair and vice chair

The chair leads and coordinates the work of the panel. The vice chair's task is to stand in for the chair of the review panel in situations where she or he cannot or should not take part, such as when the chair has a conflict of interest.

Panel member

The panel members review, grade and rank the applications and discuss them at the review panel meeting.

Observer

An observer from the committee for clinical therapy research is appointed to the review panel to oversee and uphold the quality of the review process. The observers provide feedback to the committee for clinical therapy research and the Secretary General after each review period.

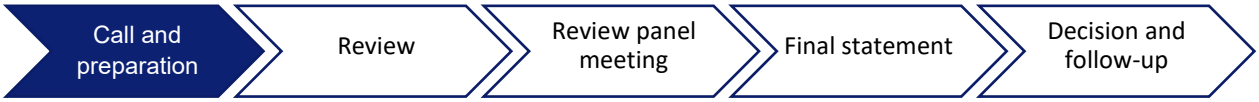
Swedish Research Council personnel

The research officer and senior research officer ensure that the rules and procedure established for the process are complied with.

Secretary General

The Secretary General has overall responsibility for the review process and for questions of scientific nature. The Secretary General is also the person who deals with any complaints following the grant decision.

1 Call and preparations



Creating an account in Prisma

Create an account in Prisma if you do not already have one. Log into Prisma and ensure that the account and personal data is correct. You should also decide whether or not you want to receive remuneration for your review work. Follow the instructions in Prisma's User Manual.

Allocation of applications to review panels

Once the call has closed, the applications are allocated to the review panels. Usually, each application is allocated to the group the applicant has listed as the first choice. However, if the chair considers that an application should be reviewed by another panel, it might be moved.

Reporting any conflict of interest

Once the applications have become available in Prisma, you must report any conflict of interest concerning the project leader and participating researchers. The chair will then allocate applications to individual members. Let the chair and the Swedish Research Council personnel know if any doubts arise, or on issues of conflict of interest or competency to review. Report immediately to the chair and the research officer responsible if you discover a conflict of interest later on in the process.

Allocation of applications to reviewers

Each application is allocated to at least three reviewers, of which one is given the role of rapporteur. The rapporteur is the reviewer who is responsible for presenting the application for discussion at the review panel meeting, and for summarising the review panel’s final statement following the meeting.

Preparation for digital meetings in Zoom

The review panel meeting is held over the digital platform Zoom. Download the Zoom Desktop client to your computer (https://zoom.us/download) before the meeting.

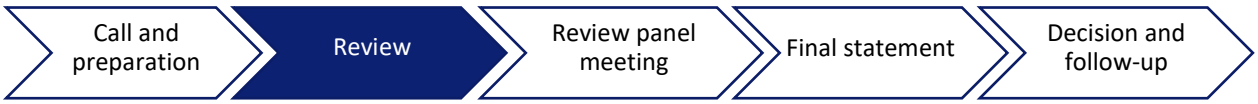
Make sure you have access to a stable network connection, a computer camera, built-in or external, and a microphone. We strongly recommend that you use a headset with a microphone, as this provides the best sound both for yourself and

for other participants. If you do not have access to a headset, you may buy one at our expense, at a maximum cost of 50 EUR. We also recommend that you use a large screen in addition to your laptop, if possible.

Call and preparations: Summary of tasks

Task	**Completed**
☐ State account information in Prisma.	At the latest
☐ Download Zoom and check technical equipment.	Before the first digital meeting
☐ Report any conflict of interest in Prisma.	Before deadline

2 Review



During the review period, you should

- read the applications allocated to you,
- write assessments and preliminary statements,
- grade the applications reviewed by you.

At the same time Prisma closes for editing, the system opens for reading other panel members assessments. Prepare for the discussions at the review panel meeting by reading the assessments by the other reviewers. During this stage, a first sifting of the applications is also carried out.

Individual review

Each application is reviewed and graded by at least three members of the review panel; one rapporteur and two reviewers. For the applications where you are the rapporteur, you should write a *preliminary statement.* The preliminary statement consists of a numerical grade and detailed written comments on all evaluation criteria where strengths and weaknesses of the project are pointed out.

In the role as reviewer, you should write an *assessment.* The assessment, consists of a numerical grade and written comments, but the comments can be less detailed. The assessment you provide will support the discussion during the review panel meeting. It will also support the rapporteur in writing the joint final statement after the meeting. It is therefore a good practice to point out the strengths and weaknesses your assessment is based on.

Irrelevant information

Base your assessment on the content of the application. Information that is not relevant to the assessment should not be used. An example of irrelevant information is matters you think you know even though it is not written in the application. Other examples are various types of rumours about for example lack of research ethics or assumptions that someone else wrote the application.

Consulting a colleague

Information about the applicant should not be shared outside of the review panel during the review process. Sometimes questions arise as to whether it is acceptable to consult with a colleague during the review work. As long as you do not share the application you may consult colleagues on limited specific topics in parts of the content of a research plan. This must only be practiced exceptionally.

Good research practice

Contact the Swedish Research Council immediately if you suspect any deviation from ethical guidelines or good research practice. Continue with the review task without the impact of this as long as we do not notify otherwise. The Swedish Research Council will ensure that the matter is further investigated.

Ethical guidelines

The applicant should explain what applies to the proposed research, whether it is subject to requirements such as ethical permits or similar, and how to obtain these. If parts of the research will take place elsewhere than in Sweden, the applicant should be able to describe how it affects any requirements for permits and approvals.

The applicant should also reflect and give an account of ethical issues and/or problems that the research may raise. You can find exemplary questions to help the applicant in the call text.

Relevance concerning sex and gender perspectives

It is part of the assessment of the scientific quality to assess how sex and gender perspectives are handled in research, when relevant. The applicant must state whether a sex and gender perspective is relevant in the research or not. The applicant should also describe in what way it will be applied, or justify why he or she chooses not to include it. Sex and gender perspectives in research can concern anything from including and analysing both women and men in the study (sex perspectives) to problematising and reflecting on how gender affiliations are created and understood (gender perspective).

Evaluation criteria and grading scales

The assessment of the scientific quality of the applications is made based on four basic criteria:

- Scientific quality of the proposed research
- Novelty and originality
- Merits of the applicant
- Feasibility

In addition to the basic criteria, the applications are also assessed using an additional criterion Patient value and benefit for the society. The criterion is evaluated against a seven-point grading scale.

The purpose of using several criteria is to achieve a multi-faceted assessment.

For each criterion, there are guiding questions to support your assessment of the application.

A seven-grade scale is used to evaluate the criteria the scientific quality of the project, patient value and benefit for the society, novelty and originality and the merits of the applicant:

Grade	Definition
7	**Outstanding** Exceptionally strong application with negligible weaknesses
6	**Excellent** Very strong application with negligible weaknesses
5	**Very good to excellent** Very strong application with minor weaknesses
4	**Very good** Strong application with minor weaknesses
3	**Good** Some strengths, but also moderate weaknesses
2	**Weak** A few strengths, but also at least one major weakness or several minor weaknesses
1	**Poor** Very few strengths, and numerous major weaknesses

Please note that the grading scale is an ordinal scale, where it is not possible to specify distances between the different values.

Feasibility grade

The criterion is evaluated on a three-grade scale:

Grade	Definition
3	**Feasible**
2	**Partly feasible**
1	**Not feasible**

For all criteria, you can mark "Insufficient", if you consider that the application lacks sufficient information to allow a reasonable evaluation to be made of the criterion.

Overall grade

The above subsidiary criteria are weighed together into an overall grade, which reflects the review panel's joint evaluation of the application's scientific quality.

Guiding questions

Scientific quality of the proposed research (1–7)

An assessment of the quality of the project's research question and methodology, including its potential for future research.

- Are the ethical considerations for the proposed project properly described and addressed? Does the applicant adequately consider risk/value/suffering for humans, animals, nature and/or society?
- Is the main research question motivated and specified?
- Are the purpose and the plan for how the proposal will lead to a future application for a research environment grant within clinical therapy research clarified and well justified
- Are the planned activities clearly specified and fit for purpose, for example, how to
  - work on regulatory issues topical for the project, such as approval from the Swedish Ethical Review Authority, permits from the Swedish Medical Products Agency, etc.
  - optimize the study design and develop a statistical analysis plan
  - make an inventory of the patient material – total number of eligible patients in the catchment area and number of those patients possible to include in the study
  - obtain medicine approval for the research project
  - start the procurement of study drug(s) to be used in the research project
  - obtain a quote for placebo, if relevant
  - meet the requirement on national collaboration
  - gather necessary expertise and actors to create a network that can lead to a future application for research environment grant within clinical therapy research
  - perform a systematic review of the research field if systematic reviews are lacking for the research area
- Is there a well worked-out plan for how both junior and senior researchers will participate in the network?
- Have the applicants described if and how sex and gender are relevant to the research question?
  - If sex and gender is described as relevant to the research question, have the applicants considered sex and gender in their description of the proposed work, including choice of study population, design, analyses, and implementation?
  - If sex and gender is not considered in the description of the proposed work, including choice of study population, design, analyses, and implementation, have the applicants justified why this is the case?

Patient value - benefit for the society

- Is there a well worked-out plan for how to include users (that is to say patients, patient organisations and patient relatives) in the planning of a future study and the choice of endpoints?
- May the results of the planned clinical therapy study contribute to a better use of the resources in the healthcare sector? Factors such as prevalence, the severity of the disease, the current burden on the health care system, and social costs should be weighed in the assessment of clinical relevance.

Novelty and originality (1–7)

An assessment of how well new theories, concepts, methods and questions are implemented and developed.

- Have similar studies been conducted before? If so, why is the proposed one needed?
- Does the planned study have the potential to deliver implementable results beneficial to patients and society?

Merits of the applicant (1–7)

An assessment of the merits and competences in relation to the proposed project. In the assessment of the applicant's merits, only the "research active" years should be considered when assessing the scope of the scientific production. Time for parental leave, leave due to illness, or other similar circumstances should therefore be deducted.

- Does the team have a track record in carrying out research within the subject area?
- Does the main applicant have documented experience of leading major collaboration projects? If not, is there a clear description for how senior members in the project group will provide this competence to the governance of the project?
- Has any team member been involved in critical assessments or guideline establishment?
- If an intervention study is planned: Is there any involvement of a clinical trials unit or any experienced trial staff?
- Does the application contain a plan for statistical competence?

Feasibility (1–3)

An assessment of the feasibility of the proposed project. An application must have a grade 2 or 3 in Feasibility in order to be funded.

- Does the applicant adequately consider relevant legal and formal requirements for the proposed research, such as ethical permits and guidelines?
- Has the proposed project potential to result in an application for a research environment grant within clinical therapy research within 1-2 years?
- Is the planned preliminary work, including the time-frame, realistic for the proposed project?
- Are the study design, statistical methods and patient cohorts adequate and well adapted to the research question?
- Does the application contain a plan for feasibility?
- Are the costs reasonable and well justified?

Overall assessment (1–7)

The above subsidiary criteria are weighed together into an overall grade, which reflects the review panel’s joint evaluation of the application’s scientific quality.

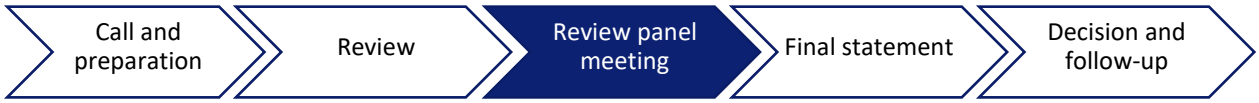
External reviewers

The review panel chair should identify applications that require external review, and propose which external reviewers to be used in consultation with the review panel members. External review may come into question if the scientific character of an application means that the joint competency of the review panel is not sufficient for a thorough review. Another reason is if the conflict of interest situation within the group makes an application difficult to evaluate.

Review: Summary of tasks

Task	Completed
☐ Grade and write detailed comments (preliminary statement) on all applications for which you are the rapporteur.	Before deadline
☐ Grade and write comments (assessment) on all applications for which you are a reviewer.	Before deadline
☐ Prepare for the meeting by reading the other panel members' comments, including any external assessments.	Before the meeting
☐ Prepare a short presentation of the strengths and weaknesses of the applications where you are the rapporteur.	
☐ Contact the Swedish Research Council personnel and the chair if you discover a conflict of interest with any of the applications you are to review, or if you discover any problem with an application.	As soon as possible
☐ Contact the Scientific Research Council immediately if you suspect that there may be deviations from ethical guidelines or good research practice, or if you suspect scientific misconduct.	

3 Review panel meeting



Discussion on applications

The chair leads the discussion of an application. The rapporteur starts by presenting the strengths and weaknesses of the application, followed by the other reviewers of that application giving their assessments. The chair is responsible for including any assessments from external reviewers in the discussion. For each application discussed at the meeting, the panel should agree on subsidiary grades and an overall grade. The rapporteur for each application makes notes ahead of the task of formulating the panel's joint final statement.

The review panel has equal responsibility for each application reviewed by the panel, and each one should be evaluated based on its own merits. Irrelevant information should not be discussed. At the same time, the panel's applications should compete with each other on equal terms. No application may therefore be given a higher or lower grade because it belongs within a certain subject area. Nor should the panel carry out any quota-based allocation between the scientific disciplines included in the panel.

It is also important that an application/applicant receives a new assessment each time of applying, and that all applications are assessed in the same way. For this reason, the review panel will not have access to any previous applications or assessments.

Be aware that the meeting time is limited, and that many applications have to be discussed within that time. It is therefore important to try to find a balance in the time allocated to each application. The chair and the Swedish Research Council personnel keep track of the time.

If you discover any possible conflict of interest (your own or another's) during the meeting, please bring this up with the chair and the Research Council in private, and not in front of the entire panel.

Prioritising

Once all applications have been discussed, and the panel has agreed on an overall grade for each application, the panel should carry out a prioritisation of the applications with the highest scientific quality that could be considered for funding. This prioritisation should conclude with the review panel's proposal for applications to be awarded grants.

In conjunction with the overall prioritisation, the review panel should consider the success rate of women and men, and as necessary prioritise applications from applicants of the under-represented gender when applications are deemed to be of equivalent quality.

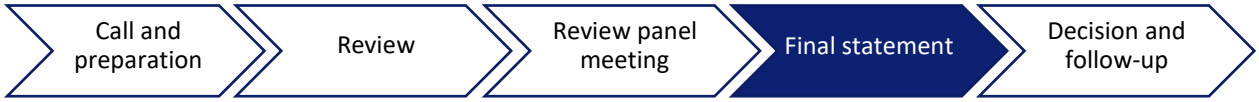
Feedback

In conjunction with the review panel meeting, the panel members are encouraged to provide feedback on the review work carried out. We will ask for comments on various aspects of the process.

Review panel meeting: Summary of tasks

Task	Completed
☐ Decide on subsidiary grades and an overall grade for sifted applications.	During the review panel meeting
☐ Agree on subsidiary grades and an overall grade for each application discussed.	During the review panel meeting
☐ Agree on a proposal for the applications to be awarded funding within the review panel's budgetary framework.	During the review panel meeting
☐ Agree on a priority list with reserves.	During the review panel meeting
☐ Contribute with feedback on the review process.	During the review panel meeting

4 Final statement



The rapporteur writes a final statement

The discussion at the review panel meeting forms the basis for the review panel's final statement. It is the end product of the review process. The Swedish Research Council bases its funding decision on the review panel's final statement in the matter. The final statement is also sent to the applicant when the grant decision is published.

You are responsible for writing final statements on the applications for which you are the rapporteur. The preliminary statement you have entered into Prisma ahead of the review panel meeting should form the basis for the final statement. You should, however, modify the preliminary statement to reflect the review panel's joint overall evaluation of the application. Check your notes of what was discussed at the meeting, so that the final statement includes the main strengths and weaknesses of the application. You usually have one week in which to submit your final statements following the end of the review panel meeting.

The chair reviews all final statements

Once the final statements have been entered into Prisma, the chair and the senior research officer read through them. The chair is responsible for ensuring the final statements on the applications discussed at the review panel meeting reflect the panel's discussion, and that the written justifications correspond to the grades. The chair does not carry out comprehensive editing of the final statement. You may therefore be asked to supplement or adjust it.

General advice and recommendations on final statements

The final statement should reflect the review panel's joint overall evaluation, including any external assessments.

When completing your final statements, you should consider the following:

Do's

- **Do focus on describing both the main strengths and weaknesses of the application.** Try to emphasise relevant conceptual, structural and/or methodological issues as discussed at the review panel meeting.
- **Do make sure that the written comments correspond to the grades**. Use the definitions of the grading scale in the justifications. For example, if a

grade of 4, “Very good”, is given, the justification should contain both strengths and minor weaknesses in line with the definition of this grade.
- **Do consider the guiding questions** for the different criteria when you formulate the final statement.
- **Do write concisely but do not be too brief**. The final statement should help the applicant understand the grounds for the assessment.
- Do comment on whether divergence from the general instructions for the application has been weighed into the assessment of the application.
- Do use a language that is constructive and objective.

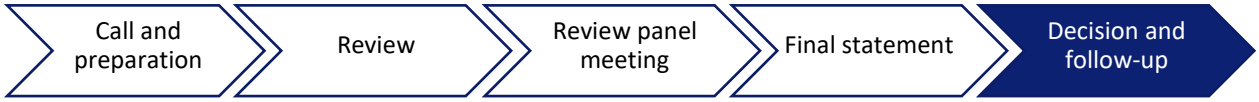
Don’ts

- Do not include a long summary about the applicant or the research described in the application. The focus should be the assessment of the application, not a description of the project.
- Do not state any individual comments such as “I think” or “In my view”. The final statement is from the review panel collectively.
- Do not include quantifiable data, such as the exact number of publications, or bibliometric data.
- Do not include personal details, such as gender or age.
- Do not include any recommendation on whether to refuse or grant an application.
- Do not state that an application does not belong to or is unsuitable for the review panel, or for the Swedish Research Council. The review panel is obliged to review all applications in the panel.

Final statement: Summary of tasks

Task	Completed
☐ Write and submit the review panel’s final statement on the applications for which you have been the rapporteur.	One week after the review panel meeting
☐ As necessary, supplement final statements following review by the chair.	
☐ Submit receipts for any expenses to the panel’s research officer responsible.	

5 Decision and follow-up



Decision

The Committee for Clinical Therapy Research is based on the priority lists arrived at by the review panels, any justifications for the lists from the chairs and the review panels' final statements. The decision is then published shortly thereafter on vr.se and in Prisma, and the applicants are also informed of the outcome.

Follow-up

Following each review period, an internal follow-up is carried out of the process and the outcome. An important starting point for this follow-up is the feedback you provide as a panel member. In addition to opinions from the review panel, statistics of various kinds are produced.

Complaints and questions

If you receive any question about the evaluation of an individual application, you must refer this to the Swedish Research Council's personnel. All complaints or wishes about clarification should be registered and then handled by the Secretary General responsible in consultation with the chair and senior research officer of the review panel. You might be contacted by the chair in the event of any questions.

Summary of your tasks

Task	Completed
☐ Refer any questions about the evaluation of individual applications to the Swedish Research Council's personnel.	
☐ Be prepared to assist the chair and the Secretary General responsible in the event of any questions.	

6 Checklist

Below is a summary of the various tasks you have during the different stages of the process.

Step in the process	Tasks
Call and preparation	☐ State account information in Prisma. ☐ Assess your conditions to participate in a digital panel meeting. ☐ Report any conflict of interest.
Final statement	☐ Write the review panel's final statement on the applications for which you have been the rapporteur. The final statement should be entered into Prisma no later than one week after the review panel meeting (see Prisma for the exact date). ☐ As necessary, supplement final statements following review by the chair. ☐ Submit receipts for any expenses to the panel's research officer responsible. ☐ Contact the Swedish Research Council immediately if you suspect any deviation from ethical guidelines or good research practice, or if you suspect scientific misconduct.
Decision and follow-up	☐ Refer any questions about the evaluation of individual applications to the Swedish Research Council's personnel. ☐ Be prepared to assist the chair and the Secretary General responsible in the event of any questions.