Peer review handbook

Clinical Therapy Research (KBF) 2025
Grant for research environment

Contents

Foreword

Dear esteemed reviewer,

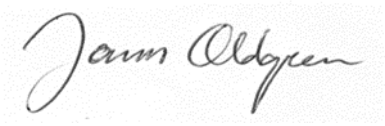
Welcome to the Swedish Research Council's peer review process for our calls in clinical therapy research 2025. We are delighted to have you join us as an expert reviewer. The evaluation of research applications is the cornerstone of the Swedish Research Council's work, and your role as a member of our review panels is a significant position of trust. Your contributions are invaluable, and we, along with all the scientists applying for funding this year, deeply appreciate your efforts.

This handbook is designed to assist you in your upcoming work. It outlines the review process step by step, making it easy to find the information relevant to your tasks. Inside, you will find essential practical instructions on assessing applications and drafting final statements for applicants. Additionally, it includes information on the Swedish Research Council’s general guidelines, conflict of interest policy, and gender equality strategy.

Please take the time to read both the instructions and the provided links carefully to ensure you are well-prepared for your review work.

Thank you once again for your dedication and welcome as a reviewer for the Swedish Research Council.

Best regards,



Introduction

The grant type Grant for clinical study within therapy research are submitted in a two-step process. In step one applicants submit an outline application for evaluation and upon approval receives an invitation to submit a full application in step two. The purpose of the grant is to provide support for clinical therapy studies that are justified by the needs of health and medical care in Sweden and are expected to lead to patient and societal benefit within a relatively short period of time. A clinical study in therapy research includes both interventional and observational studies, and areas such as prevention, diagnostics, follow-up, implementation, care and rehabilitation are also included. The grant aims to enable a constellation of researchers within regions and academia to collaborate with a common research goal.

This handbook is designed to reflect the review process step by step. We want to make it easy for you as a panel member to find the information you need for the tasks to be carried out in each step.

New features in the review process 2025

A new feature for 2025 is that the requirement for national collaboration entails collaboration between a minimum of 5 regions (previously 4), unless there are special reasons. This requirement is fulfilled by both active patient recruitment and participating researchers.

The scientific quality, patient value and benefit for the society, and from 2025 also feasibility, should be given equally weight in the overall assessment, followed by novelty and originality and merits of the applicant.

In step 2, the application must include a more comprehensive study plan and intermediary objectives/milestones per calendar year to be reported back and evaluated during the grant period. This is important both in the review of the application allowing better assessment of feasibility of the clinical study and, if granted, for follow-up of the project.

Important starting points and principles

Peer review

The Swedish Research Council regards peer review as a guarantor that our support goes to research of the highest scientific quality in all scientific fields. The Board of the Swedish Research Council has formulated guidelines for peer review based on eight principles. Read the guidelines for peer review.

Conflict of interest

To avoid any conflict of interest situation, we have established strict guidelines. Read the Swedish Research Council's conflict of interest policy and guidelines for managing conflicts of interest.

If you have a conflict of interest, you must not take part in the handling or assessment of that application during any part of the process. The following applies for panel members:

- Any application where you are the applicant or participating researcher must not be reviewed by your review panel.
- Any application where a close relative of yours is the applicant (does not apply to participating researchers) must not be reviewed by your review panel.

You are obliged to notify any conflict of interest for all applications handled by your review panel.

Gender equality

The Swedish Research Council aims to ensure that women and men have the same success rates and receive the same average grant amounts, taking into account the nature of the research and the form of support. Before the review panel agrees on the priority list, the approval rate shall be calculated for women and men respectively. Any differences must be commented on by the review panel. Read our policy and our guidelines concerning gender equality.

Confidentiality and integrity

Handle the applications and the review of them in a confidential manner:

- Do not disseminate documents that you get access to.
- Delete documents that relate to the review work after completing the task.
- Do not speak to outsiders about what was discussed during the review.
- Do not use information in the application for personal gain.
- Let the Swedish Research Council personnel manage all communications with applicants.

AI in the assessment of applications

Generative AI tools (ChatGPT or similar) must not be used in the scientific assessment of the applications. There is however no prohibition against using digital AI tools for tasks such as improving the language in written statements on applications, as long as this does not entail factual contents or the applicant's personal data being disseminated.

Roles in the review process

Chair and vice chair

The role of the chair is to lead and coordinate the work of the panel. The vice chair's task is to stand in for the chair of the review panel in situations where

they cannot or should not take part, such as when the chair has a conflict of interest.

Panel member

As a panel member, you may be a reviewer or a rapporteur. In both roles, you shall read and grade (only step 2) the applications ahead of the review panel meeting. The rapporteur is responsible for presenting the application for discussion at the meeting. As rapporteur, you are also responsible for summarising the review panel's final statement on the application after the meeting.

Statisticians

A significant part of any clinical study in therapy research is the study design and how the statistical analysis is handled in the study and these parts should be well described in the applications that are considered for funding. To ensure a proper review of both the scientific topic and the underlying statistics, each peer review panel is reinforced with a statistician.

Patient representative

To ensure a proper review of both the scientific subject and patient and public involvement, each review group is strengthened with a representative from a patient organization.

Observer

An observer from the committee for clinical therapy research will monitor and safeguard the quality of the review panel's work. The observer reports back to the committee and the secretary general responsible after the review.

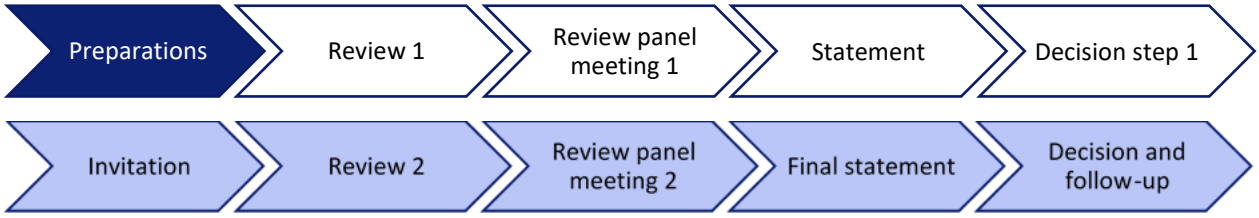
Swedish Research Council personnel

The research officer and senior research officer ensure that the rules and procedure established for the process are complied with. They also support the chair and panel members in the review process.

Secretary general for clinical therapy research

The secretary general has the overall responsibility for the review process and for questions of a scientific nature. The secretary general also handles any complaints following the grant decision.

Preparations



Prisma

As a reviewer, you work in the web-based system Prisma throughout the review process. The first thing to do is to create an account in Prisma, if you do not already have one. Make sure all your account information and personal data are correct. You must 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

Once the call has closed, the applications are allocated to the review panels. Each application is allocated to the group the applicant has listed as their first choice. However, if the chair considers that an application should be reviewed by another panel, it might be moved. An application may also be moved due to conflict of interest.

Reporting any conflict of interest

Once you have been notified that the applications are accessible in Prisma, you must report any conflict of interest. You should therefore check who the project leader and participating researchers are for all applications allocated to the review panel. Please contact the Swedish Research Council personnel and/or the review panel chair if you have any questions about conflict of interest. If you discover later on in the process that you have a conflict of interest, this must be reported as soon as possible to the chair and the research officer.

Reviewers and rapporteurs

When all the re-allocations between review panels have been completed and all review panel members have reported conflict of interest, the chair will allocate the applications to members of the review panel. Each application shall be read by all reviewers, one of which is given the role of rapporteur. The rapporteur is responsible for presenting the application for discussion at the meeting. As rapporteur, you are also responsible for summarizing the review panel's statement on the application after the meeting.

Additional appraisals

All applications are also allocated to the statistician and the patient representative.

Technical preparations

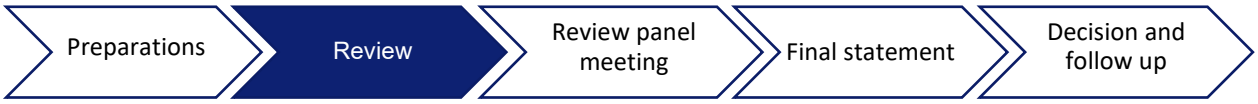
The review panel meeting will be held via the digital platform Zoom. Download Zoom Desktop client to your computer before the meeting.

Make sure you have access to a stable network connection. Your computer also needs to have a built-in or external camera and microphone. We 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 one, you may buy one at the Swedish Research Council's expense, at a maximum cost of 50 EUR or equivalent. We also recommend that you use a large screen next to your laptop computer, if possible.

Preparations: summary

What you need to do	When
☐ Provide account information in Prisma.	Before the first digital meeting
☐ Download Zoom and check your technical equipment.	Before the first digital meeting
☐ Report any conflict of interest.	Before the deadline in Prisma

Review



Individual review

The reviews of applications for grants for a clinical study in therapy research are made using a two-step procedure. In step 1 applicants submit an outline application for evaluation and upon approval receives an invitation to submit a full application in step 2.

You will either be appointed as a reviewer or a rapporteur.

Individual review step 1

In step 1, in the role as reviewer, you read all applications allocated to your review panel. We recommend taking brief notes on the strengths and weaknesses of the applications. Notes will not be included in Prisma but will serve as a valuable support during the discussions at the Step 1 review panel meeting.

In step 1, if you are the rapporteur, you shall write a preliminary statement in a word-file. This shall consist of a detailed written comments on all evaluation criteria. The comments shall highlight strengths and weaknesses in the project.

Individual review step 2

The applications in step 2 (full applications) include:

- a more comprehensive study plan and intermediary objectives/milestones to be reported back and evaluated during the grant period
- a full budget description
- participating researchers' CV details and publications
- letters of support from all participating regions
- description of implementation
- a more detailed information on the clinical benefit and patient and public involvement.

In step 2, in the role as reviewer, you read and write an assessment in Prisma for the applications allocated to you. The assessment consists of a numerical grade and written comments of the strengths and weaknesses, but the comments can be less detailed. The assessment will support the discussion during the review panel meeting and the rapporteur in writing the joint final statement. You should therefore get used to ending your review of each application by listing the strengths and weaknesses that your assessment is based on. **In step 2, in the role as rapporteur**, you shall write a preliminary statement in Prisma. The preliminary statement consists of a numerical grade and written comments of the strengths and weaknesses.

In step 2, when Prisma closes for editing, the system opens for reading other panel members assessments. Prepare for the discussions at the review panel meeting step 2 by reading the assessments by the other reviewers.

Additional individual appraisal

Each application is also reviewed by the **statistician**. The task of the statistician is to do an appraisal of the study design and statistical part of the application.

- In step 1, you as statistician, review and take notes on each assigned application in the evaluation word template provided by the research officer.
- In step 2, you as statistician, review and take notes on each assigned application in Prisma.

The applications are also reviewed by the **patient representative**. The task of the patient representative is to do an appraisal of the patient and public involvement and patient value and benefit for the society.

- In step 1, you as a patient representative, review the applications. You give a verbal comment during the panel meeting.
- In step 2, you as a patient representative, review and take notes on each assigned application in Prisma.

Deviations in the application

If you suspect that the content of an application does not follow good research practice, please inform the Swedish Research Council personnel as soon as possible. Continue with the review unless we notify otherwise. The Swedish Research Council is responsible for further investigation in cases of deviations in the application.

Irrelevant information

Base your assessment only on the contents of the application itself. Irrelevant information must not impact on the assessment. Disregard facts that you believe you know despite them not being included in the application.

Do not disseminate information about the application

You must not disseminate information about the applications or applicants outside of the review panel. Only in exceptional cases, and on condition that you do not show the application itself, it may be justified to ask a colleague about for example the use of specific methods or new research findings.

Ethical aspects

The applicant shall state whether there are any requirements for permits and approvals for the research planned. If there are such requirements, the applicant shall also describe how the permits and approvals will be obtained. If parts of the research will be conducted abroad, the applicant must be able to describe how this may affect any requirements for permits or approvals. Necessary permits

and approvals must be in place when the research begins. The assessment of legal and formal requirements is a part of the **feasibility criterion**.

The assessment of ethical aspects also includes examining how applicants reflect on ethical considerations. The evaluation of ethical considerations is part of the criterion for the **scientific quality of the proposed research**.

Sex and gender dimensions

The assessment of scientific quality includes scrutinising how the sex and gender dimensions are included in the applications. The applicant shall justify their answer, irrespective of whether it is relevant or not. Read the instructions for how applicants shall consider sex and gender dimensions in research.

Assessment criteria

You shall assess the scientific quality of the application based on five basic criteria:

- Scientific quality of the proposed research
- Patient value and benefit for the society
- Feasibility
- Novelty and originality
- Merits of the applicants

The purpose of using several basic criteria is to achieve a multi-faceted assessment. The criteria are evaluated on a seven-degree or a three-degree scale.

Please use the guiding questions we have produced for each criterion to support the assessment of the application.

Guiding questions

Scientific quality of the proposed research (1–7)

Assess the quality of the research question and method, and also its potential for future research.

- Is the main research question(s) motivated and specified?
- Is the study design adequate and described in accordance with the instructions? Would an alternative study design have increased efficiency?
- Is the patient selection (age, sex, gender and/or other relevant factors) convincingly described and adequate for the research question and the study design? If sex and gender is described as relevant, has the applicant considered this as part of preliminary data, patient selection or data analyses?
- Are the primary and secondary outcomes well defined and the most appropriate?
- Are the power calculations, sample size, variables and measurements/assessments convincingly described and adequate for the research question and the study design?

- Are the ethical considerations for the proposed study properly described and addressed? Does the applicant adequately consider risk/value/suffering for humans, nature and/or society?

Patient value and benefit for the society (1–7)

Assess how well the applicant describes the patient group involvement and patient value.

- May the results of the study be directly implementable into clinical practice within a relatively near future (within 5 years after the end of the study)?
- Are patients and public involved in the planning, design and choice of primary and secondary outcome variables? Are patients and public involved in the conduct, evaluation and implementation of the study?
- May the study results contribute to a significantly increased clinical benefits and/or less harms? Assessed clinical value can be influenced by prevalence, severity of the disease or social costs.
- May the results of the study contribute to a better use of healthcare resources?

Feasibility (1–3)

Assess the feasibility of the proposed project. Generally, applications must have a feasibility grade of 3 to be funded.

- Are the time plan (4+1 years) and relevant milestones adequately described and realistic for the proposed study? For instance, is recruitment of planned number of patients feasible?
- Does the applicant adequately consider relevant legal and formal requirements for the proposed research, such as ethical permits and guidelines?
- Is the national collaboration, team composition and its environment suitable for carrying out the proposed research?
- Is there involvement of a clinical trials unit and/or skilled trial staff (if applicable)?
- Are the availability and accessibility of relevant personnel, including statistician, legal support, equipment, facilities/infrastructures and other necessary resources described?
- Are data sources, data collection, and data management clearly described?
- If applicable, is the intervention (e.g. study drug, placebo, or medtech device) readily available? If not, is production and availability planned and secured?
- Are study related risks and challenges identified and adequately described, including plans to mitigate them?

Novelty and originality (1–7)

Assess how well the applicant develops and implements new theories, concepts, methods, and questions.

- Will the results of the study have the potential to change clinical practice?

- Is there a gap in knowledge and need of more research in this area in accordance to existing systematic reviews, national and international guidelines?
- Have similar studies been conducted before? If so, does the applicant describe why the proposed study is relevant?

Merits of the applicants (1–7)

The assessment of the applicants' merits shall be done based on their relevance for the specific research project and in relation to the applicant's career age. Time off for parental leave, sick leave, or similar circumstances should be deducted.

- Do the applicant and the participating researchers have sufficient clinical research experience, expertise, and scientific network for performing the proposed study?
- Based on previous research output and other scientific achievements, do the applicant and the participating researchers show a track record of high quality and ability to successfully disseminate research findings? Focus should be given to the most relevant and important publications and reports with emphasis on quality rather than quantity.
- Do the applicant, and the participating researchers, have the experience, and/or access to clinical resources to facilitate and conduct a clinical study?

Overall assessment (1–7)

Weigh together the above subsidiary criteria into an overall grade that reflects your assessment of the application. The scientific quality, patient value and benefit for the society, and feasibility, should be given equal weight in the overall assessment, followed by novelty and originality and merits of the applicant.

Grading scales

The assessment of the scientific quality of the application, novelty and originality, and merits of the applicant is done on a seven-degree scale.

Grade	Explanation
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

Grade	Explanation
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

The assessment of feasibility is done on a three-degree scale.

Grade	Explanation
3	Feasible
2	Partly feasible
1	Not feasible

For all criteria, you can also mark “Insufficient (0)”, if you consider that the application lacks sufficient information to allow you to make a reasonable assessment of the criterion. Please note that any such mark may only be used in the individual review before the review panel meeting, and not in the final grade.

External reviewers

External review may be used if the joint competency of the review panel is not sufficient for a thorough review or in a conflict of interest situation. In normal cases, the chair determines the need for external reviewers and the research officer will contact the suggested reviewers.

Review: summary of tasks step 1

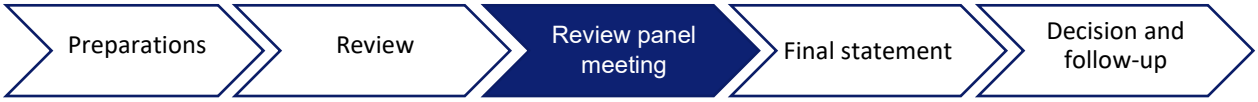
Task	Completed
Read all applications allocated to your review panel.	Before deadline
Write detailed comments (preliminary statement) on all applications for which you are the rapporteur.	Before deadline
Prepare for the meeting by reading the statement by the statistician and any external assessments.	Before the meeting in April
Prepare a short oral presentation of the strengths and weaknesses of the applications for which you are the rapporteur.	Before the meeting in April

Task	Completed
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.	As soon as possible

Review: summary of tasks step 2

What you need to do	When
☐ Grade and write detailed comments (preliminary statement) on all applications for which you are the rapporteur.	Before the deadline
☐ Grade and write comments (assessment) on all applications for which you are a reviewer.	Before the deadline
☐ Prepare for the meeting by reading other panel members' comments and any external assessments.	Before the meeting
☐ Prepare a brief presentation of strengths and weaknesses in the applications for which you are the rapporteur.	Before the meeting
☐ Contact the Swedish Research Council personnel and the chair if you discover during the review that you do, after all, have a conflict of interest with any of the applications, or if you discover any problem with an application	As soon as possible
☐ Contact the Swedish Research Council personnel if you suspect any deviation from ethical guidelines or good research practice.	As soon as possible

Review panel meetings



Discussion of applications

The purpose of the review panel meeting in step 1 is to agree on a part of the outline applications that will be invited for step 2 (full application). In step 2, the purpose of the review panel meeting is to agree on subsidiary grades, an overall grade and a proposal for applications to be awarded grants. During both review panel meetings, the rapporteur shall take notes to support the wording of the panel's statement.

The chair leads the discussion of the applications. As a rule, the rapporteur begins by presenting an application's strengths and weaknesses. The statistician then provides their comments, followed by the patient representative. Afterward, the other reviewers can share their assessments. The chair is responsible for ensuring that any external assessments are included in the discussion.

The statistician should take part in the evaluation discussion so that the statistical parts are included and evaluated.

The patient representative should participate in the discussion so that patient value and benefit for the society and patient and public involvement is included and evaluated in the review.

All applications shall be treated equally

The review panel is responsible for ensuring each application is assessed on its own merits.

- Irrelevant information shall not be discussed.
- The applications shall compete with each other on equal terms.
- No application shall be given a higher or lower grade because it belongs within a certain subject area.
- The panel shall not carry out any quota-based allocation between scientific disciplines.
- An application is guaranteed a new assessment under each call – even if similar applications have been submitted in conjunction with previous calls.
- There must be a balance in the time the review panel allocates to each application.

Conflict of interest during the review meeting

Persons who have a conflict of interest in relation to an application should not take part in the discussion of that particular application. They should leave the

room or the digital meeting while the application is discussed. If you discover any possible conflict of interest (your own or another's) during the meeting, you should bring this up with the chair and the Swedish Research Council personnel in private.

Prioritisation

In step 1, once all applications have been discussed, the panel agrees on a recommendation of the applications with the highest scientific quality, patient value and benefit for the society and feasibility.

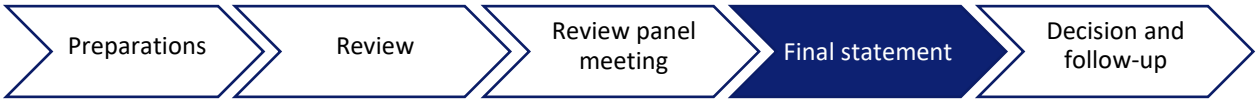
In step 2, once all applications have been discussed, and the panel has agreed on a joint grading for each application, a prioritisation shall be carried out of the applications with the highest scientific quality, patient value and benefit for the society, and deemed feasible to conduct. This prioritisation shall conclude with the review panel's proposal for applications to be awarded grants. After the panel meeting the panel chairs forms a panel and decide upon a joint prioritisation list to be presented for the Committee for funding decisions. This joint prioritisation list will also include reserves.

The review panel shall take into account the approval rate for women and for men during the summarising prioritisation. The goal is to have the same success rates for women and men within an area. When applications of equivalent quality are compared during the prioritisation of applications within a review panel, the application that results in a more even outcome of the success rate shall therefore be prioritised.

Review panel meeting: summary

What you need to do	When
☐ In step 1 agree on a proposal for the applications to be recommended to step 2.	At the review panel meeting step 1
☐ In step 2, agree on subsidiary grades and an overall grade for each application discussed.	At the review panel meeting step 2
☐ In step 2, agree on a proposal for the applications to be awarded funding.	At the review panel meeting step
☐ In step 2, agree on a prioritisation list.	At the review panel meeting

Final statement



The rapporteur writes a final statement

The discussion at the review panel meeting forms the basis for the review panel's joint final statement. The final statement is the end product of the review process to which each application is submitted. It forms the Swedish Research Council's basis for decision-making in the matter, and is also sent to the applicant in conjunction with the grant decision being published.

You are responsible for writing final statements on the applications for which you have been the rapporteur. After the meeting, you should write *final statements* (in step 1 in a word-file and in step 2 in Prisma) that reflects the review panel's joint assessment of the applications. You usually have one week in which to write final statements following the end of the review panel meeting.

All applications in step 1 and step 2 receive a final statement.

Additional appraisal to the final statement

As a statistician, you assist the rapporteur in writing the statistical part of the final statement.

Patient representatives view on patient and public involvement is shared with the panel.

The chair reviews all final statements

Once the final statements are completed, they are checked by the chair and by the Swedish Research Council personnel. 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. In conjunction with the chair's review, you may be asked to supplement or adjust a final statement.

General advice and recommendations on final statements

The final statement shall reflect the review panel's joint and overall assessment, including any external assessments.

Completing the final statements, you must

- focus on describing the main strengths and weaknesses of the application.
- ensure the written justifications correspond to the grading – feel free to use the definitions in the grading scale in your written comments.
- consider the guiding questions for the different assessment criteria.
- write concisely, but not too briefly – the content is more important than the length of the text.
- comment on whether the review panel has weighed in deviations from the Swedish Research Council's general instructions in the assessment of the application.
- be constructive and factual in your comments.

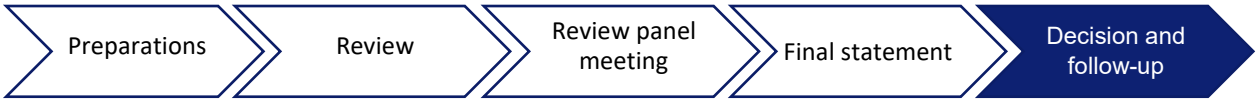
Completing the final statements, you must not

- summarise the content of the application or the merits of the applicant.
- introduce personal comments – the final statement shall constitute the review panel's joint assessment.
- state quantifiable data.
- state any personal information about the applicant.
- write any recommendation whether to refuse or approve an application in the final statement.
- comment on whether an application belongs in the review panel, as all the applications allocated to the panel shall be assessed.

Final statement: summary

What you need to do	When
☐ Write the review panel's final statement in a word-file (step 1) or in Prisma or (step 2) for the applications for which you are the rapporteur.	One week after the review panel meeting
☐ Supplement final statements following review by the chair if you have been asked to do so.	After the review panel meeting

Decision and follow-up



Decision

The Committee for Clinical Therapy Research decides on grants for study within clinical therapy research.

In step 1, the decision is based on the recommendation lists provided by the review panels, any justifications for the lists from the chairs and the review panels' final statements. The decision of who is recommended or not recommended to submit their full version of the application in step 2 is notified in Prisma.

In step 2, the decision is based on the prioritisation lists provided 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, internal follow-up is also 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 conjunction with the review panel meeting. We also produce statistics of various kinds.

Complaints and questions

If you as a review panel member receive any question about the assessment of an individual application, you must refer this to us. The Swedish Research Council personnel make sure that all complaints or requests for clarification are handled.