Peer review handbook

Clinical Therapy Research (KBF) 2024
Grant for Research Environment

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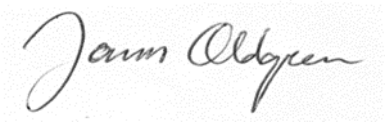
Foreword

Welcome as an expert reviewer for the Swedish Research Council's peer review process in Clinical Therapy Research for 2024 and our call for Grant for clinical study within 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 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 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 intervention and observation 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 2024

Additional information regarding the applicant's competence and merits

A new contextualising part has been introduced in the application, which should be seen as a complement to the other parts of the application that deal with the applicant's competence. In this part, the applicant must describe how the merits that has been indicated in the CV and under "Publications and other research output" show the competence to carry out the proposed research.

Publications and other research outputs

The list of publications in the application is now called "Publications and other research outputs." It consists of two parts where the applicant must separate between publications and research outputs that are peer-reviewed and not peer-reviewed.

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 co-applicant must not be reviewed by your review panel.
- Any application where a close relative of yours is the applicant (does not apply to co-applicants) 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. The review panel shall calculate the approval rate in the call and refer to, and possibly comment on, how this impact the 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.

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 prioritise the applications (step 1, spring evaluation) and read and grade the applications (step 2, fall evaluation) ahead of the review panel meeting. As rapporteur, you are responsible for starting the discussion of the

application at the meeting, and for writing a 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 user participation, 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 for clinical therapy research and the secretary general responsible after the review.

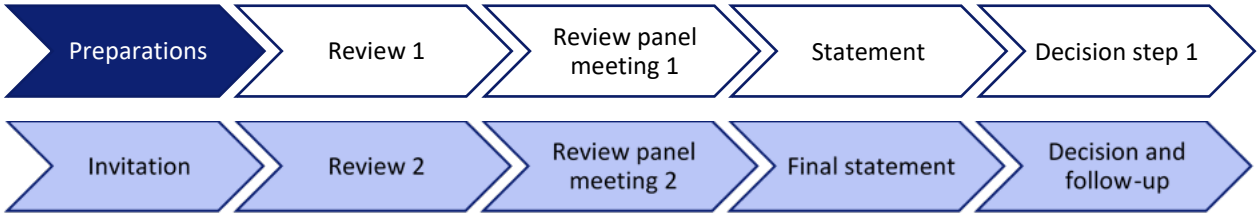
Swedish Research Council personnel

The research officer and senior research officer responsible administer the review and support the chair and panel members in the process.

Secretary general for clinical therapy research

The secretary general has 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. 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.

If you have any technical questions and cannot find the answer in Prisma's user manual, please contact the research officer responsible.

How we allocate 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 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 a 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 administrator responsible.

Reviewers and rapporteurs

When all the re-allocations between review panels have been completed and all review panel members have reported any 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 summarising 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

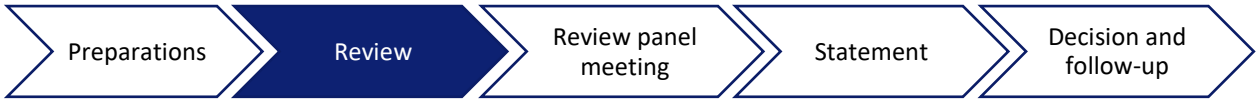
The review panel meeting will be held via the digital platform Zoom. Download Zoom Desktop client to your computer before the meeting.

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 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 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
☐ Reporting any conflict of interest.	Before the deadline in Prisma

Review



Individual review

Each application is reviewed and graded by all members of the review panel: where one is appointed as rapporteur.

During the individual review period, you should

- read the applications,
- prioritise (step 1) and grade (step 2) the applications.
-

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

In step 1, in the role as reviewer, you read and submit priority in Prisma for all applications allocated to your review panel. 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

In step 2, you as reviewer, 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 assessment consists of a numerical grade and written comments of the strengths and weaknesses.

When 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.

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 user 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.

Ask for advice from others only in exceptional cases

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

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 impacts any requirement 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 project.

Sex and gender perspectives

The assessment of scientific quality includes scrutinising how sex and gender perspectives are included in the applications. The applicant shall justify their

answer, irrespective of whether it is relevant or not. Read the instructions for applicants.

Assessment criteria

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

- Scientific quality of the project
- Patient value and benefit for the society
- Novelty and originality
- Merits of the applicant
- Feasibility

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 project (1–7)

Assess the quality of the project's research question and method, and also 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, nature and/or society?
- Is the main research question(s) motivated and specified?
- Is the project design adequate and described in accordance with the instructions? Would an alternative study design have increased efficiency?
- Is the primary outcome(s) and endpoint(s) well defined and the most appropriate?
- Are the variables and measurements/assessments, power calculations, sample size and patient selection convincingly described and are they linked to the research question and the study design?
- Is the described national collaboration adequate and relevant in relation to the proposed study and the requirement in the call?
- Have the applicants described if and how sex and gender are relevant to the research question?
  - If relevant, have the applicants considered sex and gender in their description of the proposed work, including choice of study population, design, analyses, and implementation?
  - If not relevant, have the applicants justified why this is the case?

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 project)?
- Have target groups (patient groups, patient organizations, significant others and others who may benefit from the research findings) been consulted in the planning of the study, when designing the primary and secondary outcome variables and the choice of endpoints? Are target groups involved in the continuation planning, evaluation and implementation of the study?
- May the results of the study contribute to a significantly increased clinical benefits and/or less harms for the individual? 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?

Novelty and originality (1–7)

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

- Is there a need of more research in this area in accordance to existing systematic reviews, national and international guidelines and/or identified knowledge gaps?
- Have similar studies been conducted before? If yes, describe why the proposed project is relevant?
- Will the results of the project fill an existing knowledge gap in clinical practice?

Merits of the applicant (1–7)

Merits are assessed in relation to the applicant's career age and to the research task. Only take into account the "active research years" years when assessing the scope of scientific production. Time off for parental leave, sick leave, or similar circumstances should be deducted. The merits of the applicant in the application (publications and other output as well as CV information) must mainly confirm the applicant's merits to carry out the described research.

- Do the applicant and the participating researchers have sufficient clinical research experience, expertise, and scientific network for performing the proposed project?
- Based on previous publications 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)?
- Is there appropriateness of the team of researchers, if applicable, in terms of availability and complementarities of all the relevant expertise, and in how the different roles and responsibilities are distinguished?

- Do the applicant, and the participating researchers, have the experience, know-how and clinical resources to facilitate and conduct a clinical study?
- Has the applicant and/or any of the participating researchers been involved in critical evaluation of clinical studies or guideline establishment?

Feasibility (1–3)

Assess the feasibility of the proposed project. Generally only applications graded 3 for feasability should be funded.

- Does the applicant adequately consider relevant legal and formal requirements for the proposed research, such as ethical permits and guidelines?
- Is the time schedule optimal to carry out the proposed project within the timeframe of four years plus one year of availability period, totally five years?
- Is the team composition and its environment suitable for carrying out the proposed research?
  - Does the project include the availability and accessibility of relevant personnel, including statistician, legal support, equipment, facilities/infrastructures and other necessary resources?
  - Is there involvement of a clinical trials unit and/or skilled trial staff (if applicable)?
  - Are data sources, data collection, and responsibility for data management clearly described?
- Is the recruitment of patients into the study feasible within the time frame of the project – e.g. is the size of the eligible population sufficient, have drop-outs and loss of enrollment in the recruitment due to holidays been taken into account?
- Is the intervention (if applicable, e.g. study drug, placebo, or medtech device) readily available? If not, is development, production, approval and availability planned and secured?
- Does the research plan include adequate identification and handling of project related risks and challenges, and plans to mitigate them?

Overall assessment (1–7)

Weigh together the above subsidiary criteria into an overall grade that reflects the review panel's joint assessment of the application's scientific quality and patient value and benefit for the society.

Grading scales

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

Grade	Explanation
7	Outstanding Exceptionally strong application with negligible weaknesses

Grade	Explanation
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

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”, 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 should only be used in the individual review before the review panel meeting, and not in the final grade.

External reviewers

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, or if the conflict of interest situation within the panel makes an application difficult to evaluate. In normal cases, the administrator responsible at the Swedish Research Council will contact the external reviewers.

Review: summary of tasks step 1

Task	Completed
Prioritise 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 late April
Prepare a short presentation of the strengths and weaknesses of the applications for which you are the rapporteur.	Before the meeting in late April
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 meeting

Discussion of applications

The chair leads the discussion of the applications and suggest the final recommendation (step 1) or grades (step 2). As a rule, the rapporteur begins by presenting an application's strengths and weaknesses. Thereafter, the other members give their assessments. The chair is responsible for ensuring any external assessments are included in the discussion.

For each application discussed at the meeting, the panel should agree on recommendation (step 1) or subsidiary grades and an overall grade (step 2). The rapporteur for each application makes notes ahead of the task of formulating the panel's joint final statement.

Additional 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 user 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 panel's 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 the scientific disciplines included in the panel.
- An application is guaranteed a new assessment under each call – even if it has been submitted in conjunction with previous calls.
- A balance shall be found in the time the panel allocates to each application.

Conflict of interest during the review meeting

Persons who have a conflict of interest in relation to an application shall leave the room or the digital meeting while the application is discussed. A person who

has a conflict of interest in relation to an application shall not take part in the discussion of that particular application. 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 and patient value and benefit for the society.

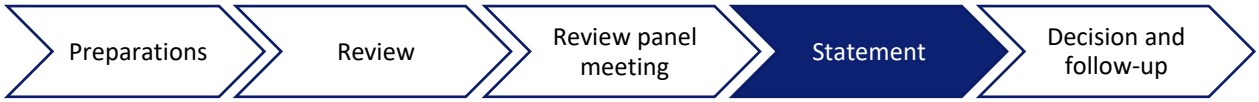
In step 2, once all applications have been discussed, and the panel has agreed on subsidiary grades for all criteria and an overall grade for each application, the panel should carry out a prioritisation of the applications with the highest scientific quality and patient value and benefit for the society and deemed feasible to conduct. This prioritisation shall conclude with the review panel's proposal for applications to be awarded grants within the panel's budgetary framework. 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.

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 a proposal for the prioritised applications	At the review panel meeting step 2
☐ In step 2, agree on a proposal for the applications to be awarded funding within the review panel's budgetary framework.	At the review panel meeting step
☐ In step 2, agree on a prioritisation list with reserves.	At the review panel meeting

Statement



The rapporteur writes a statement

The discussion at the review panel meeting forms the basis for the review panel's joint statement. The 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 statements on the applications for which you have been the rapporteur. After the meeting, you shall modify the *preliminary statement* that you drew up before the meeting (in step 1 in a word-file and in step 2 in Prisma) so that it reflects the review panel's joint assessment of the application. You usually have one week in which to write 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 user involvement, patient value and benefit for the society is shared with the panel and the Committee for Clinical Therapy Research.

The chair reviews all statements

Once the statements are completed, they are checked by the chair and by the Swedish Research Council personnel. The chair is responsible for ensuring the 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 statement.

General advice and recommendations on statements

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

Completing the 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.

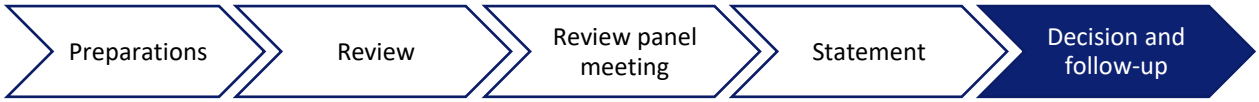
Completing the statements, you must not

- make a long summary of the contents of the application or the merits of the applicant.
- introduce personal comments – the 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 statement.
- comment on whether an application belongs in the review panel, as all the applications allocated to the panel shall be assessed.

Statement: summary

What you need to do	When
☐ Write the review panel's statement in Prisma on the applications for which you are the rapporteur.	One week after the review panel meeting
☐ Supplement 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 registered and handled by the secretary general responsible in consultation with the chair of the review panel. The chair will contact you as necessary.

Decision and follow-up: summary

What you need to do	When
☐ Refer any questions about the assessment of individual applications to the Swedish Research Council personnel.	As they arise

What you need to do	When
☐ Be prepared to assist the chair and the secretary general responsible in the event of any questions.	As they arise