SPEAKING WEB

THE CALL OPENED 14:00 23 JANUARY 2019

THE CALL CLOSED 14:00 26 FEBRUARY 2019

Research environment grant within clinical therapy research

(OUTLINE APPLICATION) 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. Therapy studies refers to both intervention and observation studies. Areas such as prevention, diagnostics, follow-up, implementation, care and rehabilitation are also included. The grant aims to enable a constellation of researchers within county councils/regions and academia to work towards a common research goal. The Swedish Research Council rewards research of the highest scientific quality in national competition.

Support form
Research environment and collaboration support

Area
Clinical Therapy Research

Focus
Clinical therapy research

Applicant
Individual researcher

Participating researchers
No participating researchers may be invited to join the project outline.

Grant period
3 years

Grant amount
The maximum amount is 20 million SEK for 3 years. The minimum amount you may apply for is 400 000 SEK per year.

Budget framework

A total of 240 million SEK over a 3-year period has been set aside for this call.

Call deadline
Outline application: The outline application closes 26 February (14:00)

Full application: The full application opens 12 June (14:00) and closes 27 August (14:00)

Publication of grant award
No later than the beginning of December 2019

Start of grant period
January 2020

Please note:

- Please read and follow the instructions: In addition to this specific call text, you also need to read our Guide for applicants
- Please do not state anybody's full personal identity number in the application.
- A new feature is that under this call, you must describe whether sex and gender perspectives are relevant in your research, and if so, how you will use such perspectives, or why you are choosing not to use them. How sex and gender perspectives are managed in the research project will form part of the assessment of scientific quality. Read more under the heading "Research description".
- As from spring 2019, you will need to have a data management plan (DMP) for data generated within the research we award funds for. You must not submit or send it to us with the application for a grant, but according to our general grant terms and conditions, your administrating organisation must confirm that a data management plan will be in place when you start your project or corresponding, and also that the plan will be maintained.
- Read more about grants awarded in previous years

Call text in full

Application procedure

Applications for research environment grants within clinical therapy research are submitted in a two-step process. First, you as applicant must submit a project outline for evaluation. Applicants whose project outlines are approved shall then submit a full application.

Project outline

In the project outline, the emphasis shall be on the research question and the expected patient benefit and societal benefit. The study design, method and materials shall be described sufficiently clearly to allow the feasibility of the project idea to be evaluated. Please note that there must not be any major discrepancies between the project outline and full application in terms of the research plan or budget.

The Swedish Research Council will make a decision on the project outlines in May 2019. If your project outline is accepted, you will also receive notice via email, including instructions for how to submit a full application. Relevant information from the project outline will automatically be transferred to your draft for the full application.

Full application:

The call for full applications will be open from 12 June to 27 August 2019.

In relation to the project outline, the full application must include information such as

- a more comprehensive research plan, including specific interim goals to be reported back and evaluated on an ongoing basis
- more detailed descriptions of "Call-specific information" (see below)
- a full budget description
- a full list of publications
- participating researchers (mandatory minimum is one), plus their CV details and publications.

Contrary to what applies to the project outline, the full application must also be signed by an authorised representative of the administrating organisation.

Eligibility criteria for applicants

The following requirements must be fulfilled in order for you to be eligible to apply for the grant. We carry out checks to ensure unqualified applications are rejected from further processing.

Focus

The research shall be clinical-based and assumes access to healthcare structures and resources. Projects of relevance for this call are clinical therapy studies, aimed at producing reliable and implementable results that may be of benefit to patients and society within a relatively short period of time (within 2–10

years after completion of the project). National collaboration is a requirement, and the main part of the research in the application shall be conducted in Sweden. Of the funds set aside for this year's call, one portion shall be allocated to projects answering to identified and prioritised needs for evidence, which is done in consultation with the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU).

Link to SBU's interpretation and evaluation of an evidence gap.

Applicant

The research environment grant within clinical therapy research is open to individual researchers. You are the project leader and have scientific responsibility for the project. You must set aside adequate time for the project throughout the grant period, with a scope (activity level) that corresponds to at least 20 per cent of a full-time equivalent.

You must hold a Swedish doctoral degree or a corresponding foreign degree, awarded no later than the deadline for this call. The degree award date we use is the date you fulfilled all the requirements for a doctoral degree, such as mandatory courses, oral defence and an approved doctoral thesis. For applicants with Swedish doctoral degrees, the award date listed in Ladok applies.

At the time of application and throughout the grant period, you must hold a clinical position in Sweden, such as employment as a physician, nurse, dentist or physiotherapist. The scope of this employment must correspond to a minimum of 20 per cent of a full-time equivalent. You must describe your clinical position in your application (see instructions under "Clinical position" below).

Grants from the Swedish Research Council shall be administered by a Swedish higher education institution or another Swedish public organisation that fulfils our criteria for administrating organisations. Your organisation must therefore be approved as an administrating organisation for you to apply.

If you are awarded a grant, you must be employed by the administrating organisation at the start of and throughout the grant period and any additional availability period, unless the Swedish Research Council approves an exception. The employment must equal at least 20 per cent of a full-time equivalent. You do not have to be employed by the administrating organisation at the time of applying.

Number of applications and previous grants

What grants may I apply for simultaneously from the Swedish Research Council?

Research environment grant and research project grant

You may apply for this grant at the same time as you apply for a project grant, but if your application for the project grant forms part of this grant application, this fact will be considered during the overall weighted assessment of the resource requirement.

Number of applications for a research environment grant

You may only submit as the applicant, one application for a research environment grant under this call. There is no limitation on being included as a participating researcher in several applications under the call.

You may not apply for a research environment grant under any other of the Swedish Research Council's calls, but you may be included as a participating researcher in such applications. Other restrictions on the grants you may apply for during the same year are shown in the table below.

Table: Grants you may apply for simultaneously

What requirements apply if I already have a grant from the Swedish Research Council?

There are certain restrictions if you are the project leader of a previously awarded grant that is ongoing, that is to say where the grant period (payment period from the Swedish Research Council) overlaps the grant period of the grant this application covers. Please note that the availability period, that is to say the

time during which you can draw down the grant awarded, is normally longer than the grant period. Information about the criteria for your previous grant can be found in the “Approval of Conditions” you received from the Swedish Research Council.

If you have already been awarded a research project or career grant

You may apply for a research environment grant if you are the project leader for an ongoing research project grant (however not if this is within the area of clinical therapy research) or career grant. A prerequisite for the application to be granted is that the grant awarded is not part of the application for a research environment grant, but on the other hand, the grant awarded may complement the application.

If you have already been awarded a research environment grant

You may not apply for this grant if you are the project leader for an ongoing research environment grant.

If you have already been awarded a grant within the distinguished professor programme, or are a researcher recruited within the Swedish Research Council’s call for international recruitment

If you have a distinguished professor grant with a grant period that overlaps the grant period for this call, or are a researcher recruited through the Swedish Research Council’s international recruitment call, you may not apply for a research environment grant. On the other hand, you may participate in an application for a research environment grant.

Please see the table below for further information and any restrictions relating to grants you may apply for if you have an ongoing grant.

Table: Grants you may apply for if you have an ongoing grant

Note: If you have been the project leader for previous grants from the Swedish Research Council that have ended, final financial reports for all of these must have been submitted within the permitted time frame in order for you to apply for a new grant. Please contact your administrating organisation if you are unsure whether all your final reports have been submitted.

What applies for applications to or grants from other funding bodies?

If your application to the Swedish Research Council relates to the same project idea as a grant you have already been awarded by, or are applying for to another funding body, please describe this.

Participating researchers

No participating researchers may be invited in this project outline. Please describe your collaborating partners and their roles under the heading “National collaboration” (see instructions under “Call-specific information” below).

Costs and grant amounts

The grant may be used to fund all types of project-related costs, such as

- salaries (including your own salary, however no more than corresponding to your activity level in the project)
- premises
- running costs (such as consumables, travel including stays at research facilities, publication costs and minor equipment)
- depreciation costs.

Grants may not be used for scholarships. If a doctoral student participates, project funds may not be paid out as salary for the period when the doctoral student is teaching. Only additional costs in conjunction with clinical studies are covered by the grant, not other medical care costs.

The minimum amount you may apply for is 400 000 SEK per year, including indirect costs. The maximum amount you may apply for is 20 million SEK over a three-year period, including indirect costs.

The Swedish Research Council assumes that the administrating organisation will cover any costs in excess of the amount received.

Grant period

The grant period is three years, starting in January 2020. The first payment will be made no earlier than December 2019.

National collaboration

National collaboration between a higher education institution and a number of county councils/regions (usually at least four county councils/regions) is a requirement when applying for this grant. This is to ensure the studies and their results have good impact. The requirement for national collaboration may be fulfilled either through active patient recruitment in several regions, or through collaborators in several regions (for example if patient recruitment is not done actively). The collaboration shall be based on an actual need for interaction. The need may, for example, consist of ensuring sufficiently large patient numbers. Other needs for collaboration may related to access to high-quality data sources, equipment or specialist competency within several disciplines. Collaboration with companies in the medical sector that are active in Sweden should also be taken into account.

Within certain areas, such as national highly specialised care, or diseases that are relevant to very few county councils/regions, it may be difficult to achieve up to four collaborating county councils/regions. In these cases, the applicant shall justify why it is not possible to achieve four county councils/regions.

What must the application contain?

Please refer to the application form in Prisma in parallel with reading the instructions below, which describe the call-specific content of the application. More information on what to do in practical terms is available in our Guide for applicants.

Language

Foreign peer reviewers are involved in the scientific assessment of the applications. To ensure fair and equitable assessment and efficient processing, please therefore complete your application in **English**.

Sections of the application

The application form includes the following tabs:

- Descriptive information
- Research description
- Call-specific information
- Budget and research resources
- Publications
- Administrating organisation
- Review panels
- Participants (only administrators in this call)
- CV

Descriptions of the information requested under each tab follow below.

Descriptive information

Abstract

The abstract shall include a brief description of the following:

- what is to be done: purpose and aim
- how the research problem will be studied in an overall project design, including patient selection, variable selection, data collection and analysis methods, and time plan. For intervention studies: please use PICO (population/intervention/control/outcome)
- what the direct patient benefit is from the planned research.

The abstract shall provide a brief outline of the purpose and implementation of the research. Please use wording to ensure persons with another scientific background can understand the information.

The description may cover a maximum of 1 500 characters including blank spaces (approximately one third of an A4 page in Arial, font size 11, single line spacing).

Popular science description

Describe the project in such a way that a person who is not familiar with the subject can understand it. Describe what is to be done and why, and explain in what way the new knowledge may be important.

The popular science description is an important tool when we inform about the research funded by the Swedish Research Council. If we grant your application, we reserve the right to use the description for information purposes.

Note: The popular science description must be written in Swedish, unlike the rest of the application.

The description may cover a maximum of 4 500 characters including blank spaces (approximately one A4 page in Arial, font size 11, single line spacing).

Research description

Ethical considerations

Describe the ethical issues raised by your project or corresponding. You must also describe how you plan to address ethical dilemmas that may arise. Please justify why the research should be carried out against the background of the ethical issues you have identified. How do your research questions and expected results measure up in relation to the ethical issues? Please also state whether the research involves any handling of personal data, or experiments on animals or human subjects. If no ethical issues are raised, please justify this.

Sex and gender perspectives

Please state whether sex and gender perspectives are applicable in your planned research, and justify your decision. Please note that we are not asking for information about the composition of the research team (men/women). Read more about sex and gender perspectives in research content.

The following applies:

- If you answer “Yes”: Justify your answer, and describe also how you take account of sex and gender perspectives in the research plan (see further instructions under “Research plan”). If you have stated that sex and gender perspectives are applicable, but still choose not to include them in your research plan, you will need to justify this here.
- If you answer “No”: Please justify your answer.

Research plan

The research plan shall consist of a brief but complete description of the study. The focus shall be forward-looking, and it shall cover a maximum of 4 page-numbered A4 pages in Arial, font size 11, single line spacing, including references and any images.

The research plan shall include the following headings and information, listed in the following order:

- **Purpose and aims:** Describe the research problem and the main purpose together with a short scientific background that justifies the project. Specify the main research question(s) and the primary endpoint(s), which must be clinically relevant. If you have stated that sex and gender perspectives are applicable, please describe how these perspectives relate to the purpose, goal and questions of the research project.
- **State-of-the-art:** Summarise briefly the current clinical practice and evidence-based clinical knowledge about the research field. List any systematic reviews, national and international guidelines and identify evidence gaps that justify more research being needed (maximum one half of an A4 page). Please exclude any review of pre-clinical and technical data and of the burden of disease. Describe briefly how sex and gender perspectives have been handled previously within the field/area the project relates to.
- **Study design:** Describe how the research problem will be studied in an overall study design, according to the description below. When applicable, describe how sex and gender perspectives relate to the choice of design, questions, method and materials, population/study participants and also data processing and analysis, for example statistics and presentation of results divided up by sex.

  The study design must include the following information under separate headings, listed in the following order:

- ***Research questions:*** Structure the purpose into research questions. What is to be studied, and in whom? Specify the primary outcome variable of each research question and the secondary outcome variables involved as well. In therapy effect studies, the effect variable (such as difference or percentage change) shall also be specified. Justify any use of a surrogate endpoint.
- ***Variables and measures:*** Describe how each variable (primary, secondary, background or explanatory) will be measured and recorded (for example binary, categorical, ordered categorical, continuous or transformed). Uni- and multi-dimensional variables, such as pain, ability, severity, quality of life are commonly assessed on rating scales in various questionnaires. In such cases, specify the dimensions/sub-variables of the questionnaires used, as well as the type of scale-categories (for example numeric, verbal or VAS), and also how the data will be used in the study. Please include appropriate references to the questionnaires/rating scales.
- ***Material: Patient selection – Population, sample:*** Describe briefly the inclusion and exclusion criteria for a representative sampling of patients. Describe also how the participating clinics contribute to the patient selection, and how any differences between clinics that could affect the study will be handled. In registry-based studies, the register used shall be stated, and the potential risk of systematic under- or over-registration of patients must be considered when defining inclusion- and exclusion criteria. For randomising: Describe the randomisation approach, and specify who is responsible for the randomisation. Also indicate for whom (patient, physician, examiner) the randomisation is blinded, and justify any exceptions.
- ***Estimated sample size and power:*** Explain and justify the smallest difference in treatment effect/primary outcome variable between control and treatment (or equivalent) to be clinically important to detect and estimate the sample size of the study/sub-studies. Calculate the power of the study for the planned sample size, taking account of estimated drop-outs, if possible based on previous own experiences, by reference to other studies or registers, and where appropriate planned interim analysis. The distribution of patients across the participating clinics are also issues to consider in the sample size estimation. Describe also, where applicable, how the patient compliance with the treatment will be monitored.
- ***Statistical methods:*** Each research question should be linked to specified statistical methods that are based on the specified variable selection, the method for data collection and planned management of data for statistical description. The choice of statistical analysis (hypothesis testing) and/or modelling, quality assurance or similar shall be clearly stated. It is not enough to use general concepts such as descriptive statistics, parametric and non-parametric methods or standard methods for analysis. The criteria for any interim analyses shall be stated. Please note that the normal distribution could be a possible probability distribution for symmetric quantitative data, but never for skewed data or for data from assessments on rating scales. How will dependent data be handled, for example within the group and/or between groups? Which statistical methods are planned for complex data from multi-dimensional questionnaires and other subjective assessments, which generate superior category data? How will longitudinal data, and missing data/drop-outs be handled? Specify who is responsible for the statistical analysis plan!
- ***Time plan:*** Describe briefly the time plan for the study during the grant period.
- ***References:*** Include references, but limit them to maximum half an A4 page.
- ***Project organisation:*** Describe the project organisation, including county councils/regions, and clarify your own and the participating researchers' roles. Describe the added value of including the participating researchers and how their participation will strengthen the project.

Scientific report on previously awarded grants

If you are or have been the project leader for a research environment grant within the area of clinical therapy research, you must submit a preliminary scientific report on the scientific activities, including a financial report. The report shall state how the project has proceeded to date. Please note that this preliminary scientific report does not replace the mandatory final report to the Swedish Research Council.

Please state the project name, case number, grant amount and grant period (that is the payment period from the Swedish Research Council; the remaining availability period shall not be included) for the previous project.

Please describe the following:

- the scientific results achieved to date within the previously awarded project
- the relationship between the previously awarded project and the planned project
- the total research resources available for the implementation of the project during the reported grant period, and how much of the research resources have not yet been used. State the grant type, funding body, holder and amounts involved (including the previously awarded grant from the Swedish Research Council).

The description may cover a maximum of 8 000 characters including blank spaces (approximately 2 A4 pages in Arial, font size 11, single line spacing).]

Call-specific information

Clinical significance and health economic considerations

Describe how the project findings – in terms of direct patient benefit – are expected to come into practical clinical use within a relatively short period of time (within 2–10 years after the end of the project). Specify and explain in which way the results are being requested by patients and other stakeholders. Factors such as prevalence, the severity of the disease and the cost to society shall be weighed into the description of clinical relevance.

Describe how the project findings may contribute to better use of resources within health and medical care, and any potential gain for society as a whole. Discuss the possible health economics considerations that the project results may lead to.

The description may cover a maximum of 1 500 characters including blank spaces (approximately one third of an A4 page in Arial, font size 11, single line spacing).

User involvement

User involvement is necessary to ensure that user viewpoints, and also expressed wishes and needs, are taken into account when selecting the primary outcome variables for the study. Describe the way in which user involvement has been included in the planning of the study and in the choice of primary outcome variables. In addition to patient groups, the concept of user involvement shall include patient organisations, relatives and others who may benefit from the results of the research. If you or anyone else has prioritised among existing evidence gaps within the area with the help of user involvement, please describe this.

The description may cover a maximum of 1 500 characters including blank spaces (approximately one third of an A4 page in Arial, font size 11, single line spacing).

Implementation

Describe how the result of the proposed research can be utilised through being implemented in health and medical care. Include a clear level structure and a time plan for implementation. State also the clinical effect goals that shall be used to measure implementation.

The description may cover a maximum of 1 500 characters including blank spaces (approximately one third of an A4 page in Arial, font size 11, single line spacing).

National collaboration

State which Swedish county councils/regions, other researchers and companies will collaborate in the project. Describe also any collaboration with foreign equivalents. Describe the positive effects the collaboration may lead to. These may relate to factors such as ensuring a sufficiently large patient sample, access to high-quality data sources, equipment or specialist competency within several disciplines. For further information, please see the heading “National collaboration” above, under the section “Application requirements”.

The description may cover a maximum of 1 500 characters including blank spaces (approximately one third of an A4 page in Arial, font size 11, single line spacing).

Please state the number and names of the Swedish county councils/regions that are contributing to patient recruitment in the separate text fields. Please make sure the number of county councils/regions corresponds to the number of names selected for participating county councils/regions.

Specification of clinical position

To apply for the research environment grant within clinical therapy research, you must hold a clinical position in Sweden, such as employment as a physician, nurse, dentist or physiotherapist. The scope of this employment must correspond to a minimum of 20 per cent of a full-time equivalent. Describe how you fulfil this requirement.

The description may cover a maximum of 750 characters including blank spaces in Arial, font size 11.

Budget and research resources

The maximum amount you may apply for is 20 million SEK. The grant amount includes cover of indirect costs. Please contact your HEI for information on what constitutes indirect and direct costs.

Amount applied for

Please state the amount per year applied for. The amount applied for will be shown under “Operating costs” in the table summarising the overall cost of the project.

Justification of the budget applied for

Justify briefly each cost applied for in the budget stated.

You must clearly show the costs for which you are applying for funding from the Swedish Research Council, and the costs that may be covered via other grants awarded. Only additional costs in conjunction with clinical studies are covered by the grant, not other medical care costs.

If the medicine/therapy to be trialled in the study is patented by a company, please state the reasons why the company is not financing the study.

The description may cover a maximum of 2 000 characters including blank spaces (approximately half an A4 page in Arial, font size 11, single line spacing).

Publications

Please attach your publication list drawn up according to the headings and information below. The list shall cover a maximum of 5 page-numbered A4 pages in Arial, font size 11, single line spacing.

Please sort the publications under each heading in reverse chronological order, so that the latest publication is at the top of the list. Please only include articles or corresponding that are published or accepted for publication at the time of applying. The author order shall be identical to that of the published work. The application cannot be supplemented with publications after the deadline for the call.

1. **Selection of publications:** List the maximum 10 publications of greatest importance to your application. For each publication, please state how you contributed to it, and its relevance to the research project described (maximum four lines per publication). Highlight your name in bold in the author list.
2. **Relevant publications from the last 8 years:** Sort the publications, with your name highlighted in bold in the author list, under each heading (publication type) in the following order:

- **Peer-reviewed original articles**
- **Peer-reviewed conference contributions,** the results of which are not included in other publications.
- **Peer-reviewed edited volumes**
- **Research review articles**
- **Peer-reviewed books and book chapters**
- **Other publications including popular science books/presentations]**

Administrating organisation

Please state the administrating organisation and project site.

Review panels

Please propose the review panel or panels (in priority order) that you wish to carry out the scientific assessment of your application. The final allocation of applications is determined by the Swedish Research Council.

Review panels

Participants

Here you as applicant may invite participating administrators to your application. Please note that participating researchers may not be invited in this outline application.

CV

Under this tab, please upload your relevant CV information from your personal account in Prisma.

The following information, where available, must always be included in your CV, taking into account the stated limitation in numbers:

- **Education:** First, second and third cycle higher education and specialist degrees.
- **Work:** Current employment (including employment form) and longer relevant employment, postdoctoral visits (also included as employment if relevant), research exchanges relevant to the research described and any longer interruptions in the research that have impacted on your opportunity to gain merits as a researcher.
- **Merits and awards:** Docentships/associate professorships, supervisees (postdoctoral and doctoral students; state the overall number of each category and list the 10 most relevant to you), up to 10 of your most relevant grants awarded in competition, up to 10 of your most relevant prizes and awards, and up to 20 other merits relevant to the application.
- **Intellectual property rights:** For example, patents and open access computer programs developed by you; state up to 10 of your most relevant.

How your application is assessed

Scientific quality is the fundamental criterion when the Swedish Research Council allocates grants to research. Your application is evaluated in competition with the other applications on the basis of the following evaluation criteria. The committee for Clinical Therapy Research lends support to clinical studies which are justified by the needs of the healthcare sector, and thereby offer important benefits to patients and society within a relatively short time frame. The applications for grants in clinical therapy research are assessed according to a two-step procedure. First, applicants are required to submit a project outline for evaluation. Applicants, who pass the project outline evaluation will subsequently be asked to submit a complete application.

Evaluation process

The project outlines for grants in clinical therapy research are assessed by review panels consisted of international researchers. The entire review panel then meets at a review panel meeting to discuss and prioritise the project outlines, and finally to make a proposal for a decision to the committee for Clinical Therapy Research. All project outlines will receive an individual final statement that reflects the review panel's discussion of the scientific quality of the application.

Rewiew panels

Evaluation criteria and guiding questions

The evaluation of the scientific quality of your project outline is made based on five criteria (Scientific quality of the proposed research, Patient value – benefit of the research, Novelty and originality, Merits of the applicant, Feasibility). The purpose of using several components is to achieve a multi-faceted

evaluation. Only project outlines that have been assessed to have high scientific quality and patient value will be asked to submit a complete application. Due to the nature of clinical therapy research, the Novelty and originality should be weighted lower than the other criteria.

No grading will however be done for the project outlines. The review panels make an overall scientific assessment based on the five assessment criteria and give the following scores

- *prioritized and asked to file a full application*
- *rejected*

For the assessment of the full application a seven-grade scale is used for four of the assessment criteria: Scientific quality of the proposed research, Patient value – benefit of the research, Novelty and originality and Merit of the applicants. Feasibility is graded using a three-grade scale. The various criteria being used in the assessment will be weighed together to an overall grade (1—7), which reflects the overall assessment of the scientific quality of the application by the evaluation panel. Only applications that have been assessed to have high scientific quality and patient value will be consider for funding.

For each criterion, there are guiding questions to support the panel members' evaluation of your application. These can also function as guidance for you when you write your application.

Scientific quality of the proposed research (1–7)

Guiding questions:

- Is the study design sufficiently described according to the guidelines for the application?
- Is the main research question(s) motivated and specified?
- Is the primary outcome(s) and endpoint(s) well defined and the most appropriate?
- Is the proposed study design the most adequate design to address the objectives? Would an alternative study design have increased efficiency?
- If any, which are the limitations of the study design?
- Are the variables and measurements/assessments, power calculations, sample size and patient selection convincingly described?
- Has the project a clear statistical analysis design that is linked to the research question?
- Is the project national, i.e. it involves collaboration and patient recruitment from a minimum of four Swedish county councils/regions, or does it involve National Specialised Medical Care? Have similar studies been conducted before?
- 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 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 of the research (1–7)

Guiding questions:

- May the results of the study be directly implementable into clinical practice within a relatively near future (2-10 years after the end of the project)?
- Have the target groups (patient groups, patient organizations, family members and others who may benefit from the research findings) been consulted in the planning of the study and the choice of endpoints?
- 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)

Guiding 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?
- Will the results of the project fill an existing knowledge gap in the clinic?
- Does the project have the potential to deliver implementable results beneficial to patients and society?

Merits of the applicant (1–7)

Guiding questions:

- Do the team (applicant and the participating researchers) have sufficient research experience, expertise, and scientific network for performing the proposed project?
- Based on previous publications and other scientific achievements, does the team 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, if applicable, in terms of availability and complementarities of all the relevant expertise, and in how the different roles and responsibilities are distinguished?
- Has the applicant and/or any of the participating researchers been involved in critical evaluation of clinical studies or guideline establishment?

Feasibility (1–3)

Guiding questions:

- Is the recruitment of patients into the study feasible within the time frame of the project – have drop-outs and loss of enrollment in the recruitment due to holidays been taken into account?
- Does the project include the availability and accessibility of relevant personnel, including statistician, skills, equipment, facilities/ infrastructures and other necessary resources?
- Is the team composition and its environment suitable for carrying out the proposed research?
- Is there involvement of a clinical trials unit or any trial staff (if applicable)?
- Is it clear who is responsible for the data management?
- Is the time schedule optimal to carry out the proposed project within the timeframe of three years?

Overall grade (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.

Report for previously awarded research grant

These guiding questions are only to be used for those project outlines where the project leader has earlier received a grant in Clinical Therapy Research. These questions should serve as guidance when assessing the preliminary scientific report for previously awarded research grant.

Guiding questions:

- Is there any relation between the ongoing project and the new proposal?
- If there is overlap, is a new approach presented in the current proposal? Is the new approach novel and justified?
- In what way will the envisaged project deliver reliable and implementable results that can offer large benefits to patients and society that the previously funded project has failed to do?
- Has the funding for the ongoing project been used according to the presented budget?
- Are there research resources not yet spent?

Anh Thu Nguyen Hoang

anhthu.nguyenhoang@vr.se
+46 (0)8 546 44 034

Elisabeth Tehler
elisabeth.tehler@vr.se
+46 (0)8 546 44 229