Forskningsrådet

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Information for applicants for a Centre for Clinical Treatment Research (FKB)

Contents

1 Purpose of this document

This document, together with the call for proposals and the document *Societal and Industry-oriented Research Centre – Requirements and Guidelines,* is intended to provide applicants with important details about the FKB scheme and the requirements applicants must meet connected to the call issued for the submission deadline of 12 May 2021.

Applicants are encouraged to familiarise themselves with all the documents.

Applications that do not meet the requirements and guidelines for an FKB will be rejected.

2 Background

The Centre for Clinical Treatment Research (FKB) scheme is a competition-based, national initiative in which the Research Council awards funding and status as an FKB. The initiative is the result of the Research Council's report following up the HealthCare21 strategy from 2014.

The first call for proposals for an FKB was issued in 2018 and was then limited to the thematic area of serious diseases affecting the central nervous system, in particular amyotrophic lateral

sclerosis (ALS), multiple sclerosis (MS), and Alzheimer's (dementia). One centre was awarded status as an FKB and started up in autumn 2019.

3 Objectives and main features of the FKB scheme

3.1 Objectives of the FKB scheme

The overall objective of the FKB centre scheme is to establish clinical research groups that carry out top-calibre research to help to improve treatment for Norwegian patients.

FKB centres are to:

- perform high-quality clinical studies with potential to bring about changes in clinical practice;
- promote innovation in treatment;
- promote evidence-based treatment;
- promote increased national and international collaboration;
- help to translate basic discoveries into clinical applications;
- encourage new scientific ideas and discoveries;
- promote robust and mutually beneficial collaboration between the business sector and hospitals;
- promote investment in Norwegian industry based on clinical trials;
- train skilled clinicians and clinical researchers.

The general aim of establishing centres of this type is to provide Norwegian research groups with the framework conditions they need to pursue ambitious research ideas and become competitive, attractive partners in an international context. The longer-term perspective and more generous funding make it possible to establish groups with a certain critical mass and the requisite scientific breadth. The centres will in this way generate added value in the form of knowledge development, competence-building and researcher recruitment for both the host institutions and the partners.

The FKB scheme has a higher level of ambition, a longer perspective and greater concentration of resources than the Research Council's other thematically-oriented clinical research programmes.

The primary research tasks for an FKB centre will be to perform clinical studies. Research activities at the centre may encompass a wide variety of interventions, including pharmaceutical trials, studies on medical equipment, surgical procedures, e-health and other interventions and treatment modalities. Activities will primarily focus on applied research and should fall within the scope of clinical treatment research.[1] Other research tasks (including translational studies, registry-based studies and health economics studies) should be incorporated as part of the centre's research plan. It is also important to incorporate humanities and social science perspectives into the centre's research activities.

[1] The national programme for clinical therapy research in the specialist health services (KLINBEFORSK: http://kliniskforskning.rhf-forsk.org/forside/) defines clinical treatment research as research aimed at inclusion of patients to improve existing treatment practices, including the use of pharmaceuticals and medical technology and/or the development and evaluation of new ones. It may also include comparative efficacy studies, such as evaluation of diagnostic methods and/or established drugs, as well as streamlining of treatment processes and procedures. The definition does not include screening.

Research activities at an FKB centre are to lay the foundation for Norwegian business development and broad collaboration with national and international business stakeholders.

The centres are to provide open access to research results. It must nonetheless be possible to protect results that can be commercially exploited, for example through patenting prior to publication. Rights will in such case be set out in a consortium agreement drawn up between the partners.

3.2 Relationship to the Research Council's other instruments

The FKB scheme shares several features with the Research Council's other centre schemes, i.e. the *Centre for Environment-friendly Energy Research (FME), Centre for Research-based Innovation (SFI)*, and *Centre of Excellence (SFF)* schemes. Unlike the SFF and SFI schemes, the FME scheme and the FKB scheme target specific thematic areas.[2]

The Research Council's health research programme area seeks to offer a broad palette of instruments that cover the needs of skilled clinical research groups by generating new research projects and/or opportunities to commercialise research results.

Research groups that wish to establish an FKB centre should be able to refer to good results from previous and ongoing clinical research, but also describe a significant development potential.

4 About the call for proposals with the deadline 12 May 2021

4.1 Thematic and structural guidelines

The call is open to applications for all thematic areas. In terms of structure, the Research Council will place weight on developments in clinical research and patient treatment. Research and treatment are becoming more and more integrated and treatment is more commonly expected to be adapted to each patient's specific needs.

When selecting a centre, importance will be attached to the potential to strengthen research groups that are at the international forefront of their respective areas and that contribute to structuring clinical treatment research through closer collaboration between research groups, clinical practice, business and industry, and administrative bodies. Collaboration is expected between the best national groups in the specific area of research.

Greater cooperation and competence-building across disciplines, sectors and countries is also expected. A centre's potential to attract international clinical studies and to initiate multi-centre studies with the necessary number of patients will be of major importance. It is assumed that patients from the whole of Norway can be included in the studies. Partnerships with non-university hospitals will also be deemed a positive factor. Utilisation of existing health data in clinical studies is becoming increasingly important, including with regards to digitalisation and use of artificial intelligence, new study designs for precision medicine, real world data (RWD), register-based randomised clinical trials (R-RCT), studies with synthetic control arms etc. Importance will be attached to plans to utilise existing health data in clinical studies.

[2] The Research Council's centre schemes are based on evaluations of research and research policy instruments, both in Norway and other countries, and on experience with existing schemes.

An FKB centre is to develop innovative treatment, facilitate business development, promote utilisation of research results in clinical practice and stimulate greater collaboration and competence-building across disciplines and sectors. Collaboration with the business sector is not an absolute requirement, but will be deemed a positive factor where relevant.

The short and long-term impact must be emphasised. The centre must support patients' health services. Patients must therefore be involved in the centre's planning, activities and utilisation of results. It is the responsibility of the applicant to determine the scientific reach of the centre. The call is open for applications for both a centre with a broad scientific reach that for instance covers whole value chains, or a centre with a narrower scope of research. It is natural for the organisation and size of the centre to reflect this.

The Research Council strives to achieve effective use of research funding, and it is therefore important that new FKBs are coordinated with relevant SFFs and SFIs to avoid overlapping work and ensure synergies. Significant investments have been made in national medical and health sciences research infrastructure, such as NorCRIN, PraksisNett and Biobank Norge, that may be relevant for the centre to collaborate with and utilise.

The groups must refer to significant added value from the centre's establishment and have a robust plan in place for how the centre will help the centre partners to compete for funding from national and international instruments and become more attractive to studies sponsored by the industry.

4.2 Collaboration between the partners

The application must show how the centre will combine the long-term research with a focus on applying the results in practice. It must describe what the centre will do to ensure close collaboration between research partners and between research partners and user partners (companies, public bodies and special interest organisations), and what added value the partners will contribute to the centre as a whole. It must be clearly stated what contributions – over and above financial contributions – are expected from the partners. It is important that user partners are involved at an early stage of the work on the application, so that they are in a position to help shape the centre from the outset.

4.3 International cooperation

International cooperation is vital for improving quality and enhancing capacity in Norwegian research, and it is an objective that the centre is involved and makes its mark in international research arenas, including the EU framework programmes.

The research centre's duration and size must be designed to enhance international research cooperation. The centre must earmark sufficient funds for facilitating international collaboration, including by means of project collaboration and mobility.

The centre's goals and overarching strategies and plans for international collaboration must be described in the application. The application must also describe how the participation of international partners will strengthen the research conducted at the centre and help to achieve its objectives.

4.4 Recruitment and researcher education

A key task of the FKB centre will be to strengthen recruitment to careers in clinical treatment research. This includes master's level and doctoral education, as well as post-doctoral fellowships.

The application must describe how the centre will carry out this task and how the researcher education will be adapted to the knowledge and skills needs that apply to the area of research.

Research stays abroad are an important part of the researcher education and research fellows employed by an FKB should gain experience from abroad. Applicants must describe how this will be addressed.

4.5 Communication, administration and joint activities

Research is the core activity of the FKB centre. However, it is also important that sufficient resources are allocated to administration and joint activities. This is essential for safeguarding the added value created by organising research activities as a centre; i.e. a foundation must be laid for effective collaboration between the various segments of the centre and for centre-building activities and activities that promote effective involvement of the partners.

The FKB centre will have an important role to play in disseminating knowledge to the research community, health services and the public at large. Plans for dissemination work must be presented and resources must be earmarked for this purpose.

The application should outline how the centre will work to profile itself in relation to national and international communities to increase the likelihood of requests to participate in clinical studies.

4.6 Equality

Research institutions should integrate relevant gender equality issues into the planning and preparation of new applications as well as into the proposed centre's recruitment plans. The centres should be able to refer to action plans for good gender balance in the centre.

4.7 Registration of studies and publication of results

The centres must comply with the Research Council's Requirements and guidelines for registration and disclosure of medical and health-related studies involving human participants.