HELSE MIDT-NORGE

# Current regulations for regional research funding from the Central Norway Regional Health Authority (RHA)

- valid for funding calls announced through *Samarbeidsorganet* and *Felles forskningsutvalg (the Joint Research Committee) between St. Olavs hospital and the Faculty of Medicine and Health Sciences, NTNU (FFU)*

## A. Formal requirements for applications

**Participation from a health trust.** All projects must have active participation from at least one person employed in a health trust in the region. Active participation means that the health trust employee must have participated in the planning and writing of the project description and play a central role in the project. The individual's contribution should be described under "Participants" in eSøknad. For applications where host institution is not a health trust, e.g. NTNU or a university college, a description of the collaboration between the host institution and the health trust must be included in the project description (section 4.2). In these cases, the description of the collaboration will be assessed particularly. If the collaboration does not appear in the application, or the involvement of the clinic is found to be weak, this may be of importance for award, despite a good evaluation of quality and benefit. However, the employment rate for the applicant or partner from health trust does not affect eligibility. It is assumed that the projects result in publications where health trust(s) are credited through the author's affiliation.

**Confirmed collaboration.** All collaborating partners should confirm their participation through the *eSøknad* submission service. The confirmation is provided easily either by e-mail or SMS by opening a link to the application sent from the system due to submission (see guidance in eSøknad). It is the applicant's responsibility to ensure that partners confirm their participation in *eSøknad.* This can be done until 1 September.

**Management commitment**
*Commitment in the health trust:* all applications must be supported by the appropriate head of clinic (*klinikksjef*) at the applicant institution (søkerinstitusjon). It is expected that the head of clinic is informed about the application prior to submission and approves the participation and contribution from the participant(s) employed in the clinic. The head of clinic must provide a short written statement about the application in *eSøknad*, which explicitly states that the application is supported. It is the applicant's responsibility to ensure that management commitment is given within deadline, and we recommend good internal communication in the research group to comply with this requirement. *Deadline for confirmation of commitment from the head of clinic is 3 July.*

*Commitment in the health trust for projects involving more than one clinic:* Applications for projects involving collaboration with several clinics, e.g. infrastructure, can be committed at a higher administration level in the health trust. In such cases, the commitment must be clarified with the relevant clinics as well as the health trust management prior to submission. Applications submitted without clarification with management in advance or applications not considered relevant for commitment at this level will not be considered. For questions about management commitment for such applications, contact the secretariat (samarbeidsorganet@mh.ntnu.no)

*Commitment in universities/university colleges/private sector:* projects from academic institutions or private actors (i.e., where the *host institution* is not a health trust), must ensure management commitment from the host institution as well**.** For this purpose, a separate commitment form should be attached to the application. There are separate management commitment forms for Samarbeidsorganet and Felles Forskningsutvalg, and the form can be downloaded from the website for each of the calls. The management commitment form must be signed by the head of

department/unit and uploaded with the attachments to the application within the application deadline 13 June. *Submission of the signed commitment form after the deadline will not be accepted. Applications lacking management commitment will not be assessed. For more information on the procedure for management commitment, see webpages of Helse Midt-Norge RHF.*

**User involvement.** In line with policies from the Ministry of Health and Care Services, applications for regional funding must describe who the users of the project's results will be and explain the extent of user involvement during the planning and/or realization of the project. In this context, users are regarded as patients and their dependants. How users are involved will depend on the nature of the project. If user involvement is not regarded as relevant to the project in question, the reasons for this must be provided in the project description. Further information about user involvement in research, incl. regional guidelines, can be found on Helse Midt-Norge's webpages.

**Impact.** All applications must describe expected benefits for patients and the health service, in line with policies from the Ministry of Health and Care Services. Expected benefits should be described both in *eSøknad* and as part of the project description. During the evaluation of the application, scientific quality and potential impact/benefit will be considered on an equal footing (see section B).

**Applicant institution and host institution.** When creating the application in *eSøknad* you will be asked to select an *applicant institution* (*søkerinstitusjon*) which is a clinic at the participating health trust. If the project will be managed financially by an institution other than the health trust (e.g., university or university college), this should be stated as the *host institution* (under the section "Classification") in the application form.

## B. Evaluation of applications

**Scientific committees.** Applications that meet the formal requirements will be distributed to scientific committees, which conduct a peer review in accordance with the determined evaluation criteria. The scientific committees are broad-based and consist of professionals invited from the other health regions. Samarbeidsorganet coordinates four committees, while a separate committee will be appointed for Felles forskningsutvalg.

**Evaluation criteria.** The applications will be assessed and ranked based on the current evaluation criteria for scientific quality and benefit, which have been decided by Samarbeidsorganet. The ten different criteria will be scored on a scale of 0 – 5, 5 being best.

**Recommendation for funding**
*Samarbeidsorganet:* Following the scientific committees' evaluation, the applications will be ranked by application category by a chief committee, consisting of the leaders of each sub-committee. *The working committee for Samarbeidsorganet (AU SO)* will then prepare a recommendation for funding for approval in the *Regional Collaboration Committee for Research and Innovation (SUFI)*, before the final decision on allocation of funding is made by Samarbeidsorganet. In the recommendation for funding, the review from the scientific committees will be considered, along with user involvement, collaboration with health trust (where host institution is not a health trust), relevant strategic objectives and regional priorities.

*Felles forskningsutvalg: The working committee for Felles forskningsutvalg (AU FFU)* will prepare a recommendation for funding based on the ranking of applications by the scientific committee. User involvement, collaboration between department (NTNU) and clinic (St. Olavs hospital)[1] and relevant strategic goals will be considered as well. The final decision on allocation of funding will be made by Samarbeidsorganet upon recommendation from FFU.

[1] For applications to Felles Forskningsutvalg, collaboration between Faculty of medicine and health sciences (NTNU) and St. Olavs Hospital is required, regardless of host institution.

**Projects that have been favourably evaluated elsewhere**. Applicants are encouraged to apply for funding from external sources (for example the Research Council of Norway, the EU and non-profit organizations). If the project has been assessed favourably by an external funding source, this will be taken into account during the evaluation. In such cases, the evaluation from the external funding source must be attached. Projects with external funding that have already received additional funding from Helse Midt-Norge will not be given priority.

**Transparency of evaluation and right to appeal.** All applicants will receive written feedback from the scientific committee by 31 December. Unless the applicant opposes this upon submission, the closest manager in the host institution (head of clinic/department/other) will also gain access to written assessment on request, to be able to work strategically towards future calls.

Decisions about the allocation or refusal of funding are based on both expert judgement and strategic evaluation. Due to the Public Administration Act (*Forvaltningsloven*), such evaluation cannot be appealed, but it is possible to appeal on the grounds of procedural errors. The deadline for appeals is three weeks after the evaluation of the application has been received. Appeals must be made in writing and the reasons for the appeal must be stated. If the appeal is not accepted in these bodies, the appeal may be sent to an external committee for secondary review on request.

## C. Terms and conditions of grants

**Publications and requirements for affiliation.** Where the research funding leads to scientific publications, the grant recipient must credit these to the appropriate health trust by affiliating the clinic. The relevant clinical division must be indicated together with the health trust. Example: *"Clinic of Surgery, St. Olavs Hospital, Trondheim University Hospital, Trondheim, Norway"*. Affiliation to the clinic should be additional to any affiliation to academic institutions/private actors. Note that receivers of grants who are not themselves employed in a clinic, still should affiliate the clinic with which they collaborate, even in cases where co-authors affiliate the same clinic. Reviews of author affiliation in publications based on funding from Helse Midt-Norge are conducted every year.
*Lack of affiliation to clinic may lead to withdrawal of the funding, or the recipient may lose the access to coming calls.*

**Reporting**. There are reporting requirements for all projects funded by Helse Midt-Norge. An e-mail with a request to report will be sent out to recipients of research funding around January every year. The reports submitted form the basis for further reporting to the Ministry of Health and Care Services, as well as the annual "National report from the Specialist Health Service" (Norwegian only). All the reports will be published at eRapport.
*If there are shortcomings in reporting, the funding may be withdrawn before the end of the project period, or the recipient may lose the access to coming calls.*

**Dissemination and regional collaboration.** Everyone who is granted research funding from Helse Midt-Norge is encouraged to participate in the health authority's regional research conference to present research results and contribute to research collaboration in the region. It is also expected that research results will be communicated in the researchers' own and collaborating institutions, and in national as well as international forums.

**Changes in funds granted.** If the need arises for any changes in the use of funds granted, including changes in positions and leave of absence, an application for the change must be submitted to the secretariat through an online form. More information can be found on Helse Midt-Norge's webpages (in Norwegian).

# D. General requirements for medical and health research projects

There are a number of laws and regulations that regulate medical and health research. The responsibility for ensuring compliance with laws and regulations lies with the researcher and the institution or business responsible for the project.

**Ethical guidelines**
Projects financed by Helse Midt-Norge must maintain high ethical standards and follow basic principles for research ethics. Applications to Samarbeidsorganet and Felles forskningsutvalg shall explain relevant ethical issues in the project description. The main responsibility for good research ethics lies with the researcher and the institution that is responsible for the project. Funding from Central Norway does not mean that the project is "approved" based on current laws and regulations.

**REC approval**
All medical and health research projects will be approved by the regional committee for medical and health research ethics (REC) before they are initiated. When applying for research funding from Central Norway Health Authority, the status of application to REC shall be stated in eSøknad. Read more about the procedure for applying for approval on REC website.

**Privacy regulations**
All processing of personal data shall be in accordance with the General Data Protection Regulation (GDPR). It is the duty of the researcher or institution responsible for the research project to ensure and document that the processing of personal data takes place in accordance with the law. The researcher responsible for the project must assess whether the requirements of GDPR are fulfilled. If the processing of personal data will entail a high risk for the rights and freedoms of persons, a data protection impact assesment (DPIA) shall be carried out. Contact your institution's data protection officer if you have any questions regarding data protection impact assesments.

**Data Management Plan**
For all projects that receive funding from the Central Norway Health Authority, the project manager must assess the need for a data management plan (DMP). A DMP is a tool for managing research data and describes how data should be handled during the project period and after the project is completed. The purpose is to assess various aspects of the handling of research data, from collection, processing, analysis, documentation, to storage and future sharing of data. A DMP should help to ensure that research data can be handled legally, structured and securely, stored and reused in the future. Read more on NSD website.

This overview is not complete. There may be other requirements for approvals in your research project that are not listed here. See the health authorities' quality system (EQS) for guidance and routines for the planning and implementation of medical and health research projects. NTNU also has a website with guidance for health research projects.