Program for Advanced Clinical Cancer Studies

Call for Project Proposals

With reference to Haukeland University Hospital's recent investment in dedicated facilities for clinical studies – The Clinical Trial Unit - and its ambitions towards obtaining accreditation as a Comprehensive Cancer Centre (**CCC**), Trond Mohn Research Foundation (**TMF**) has invited Haukeland University Hospital (**HUH**) to nominate proposals for TMF funding as outlined below.

Program aims:

By offering competitive funding for advanced clinical cancer studies within the framework of the HUH Clinical Trial Unit, the foundation wishes to:

- Encourage high quality research that may support HUH's effort to obtain CCC-accreditation.
- Extend the opportunities for cancer patients in Western Norway to receive high-quality experimental treatment.
- Contribute to the development of high-quality cancer patient healthcare services, where clinical studies are a natural and integral part of the effort towards increased survival and quality of life.

Program scope:

Proposals under this funding scheme must, in addition to the general criteria as laid out in Appendices A to C, meet both requirements number 1 and 2 below:

Requirement 1: Proposed projects must include plans for clinical trials in advanced cancer treatment with high potential for clinical impact. Project proposals under this call may target one or a combination of the following themes:

A. Investigation of biomarkers in the diagnosis, treatment, or rehabilitation of cancer patients thus supporting personalized therapy to improve survival and reduce treatment-related late effects.
B. Comparative studies on conformal radiotherapy using photons or protons, and trials combining radiotherapy with drugs to improve treatment outcomes (e.g. optimizing effects and reducing treatment-related toxicity).
C. Multidisciplinary approaches to diagnosis, treatment, and rehabilitation of patients experiencing late effects after cancer therapy in order to improve quality of life.

Requirement 2: Proposed projects should exploit the research opportunities posed by the Clinical Trial Unit at Haukeland University Hospital and /or be clearly beneficial to the ongoing process towards CCC-accreditation for HUH.

In addition to meeting the technical requirements outlined in this invitation, proposals must adhere to the following criteria:

1. Each project must be led by one dedicated principal investigator (PI) of high academic standing and with proven project leadership experience.
2. At the time of submission, the PI must have a permanent main position at Helse Bergen or MED UiB.
3. The PI must be prepared to contribute to the scientific development of the Clinical Trial Unit and contribute towards the HUH aim of CCC accreditation.

Please note:

- Each project may normally be granted a maximum of NOK 6 million from TMF during a maximum three years (on average 2 million pr. year). Well justified exceptions may be agreed for multicentre studies
- The minimum grant for any project is 3 million NOK.
- Any TMF funding must be matched by resources at about the same level from the participating institution(s). Please note that the inclusion of relevant national and international partner institutions is encouraged and expected.

For further information: Please consult Appendices A to C

Appendix A – How to apply for funding under this program.

HUH may nominate a minimum of 5 and a maximum of 7 proposals under this funding scheme. To ensure that TMF funding will contribute towards the aims of the Clinical Trial Unit and the CCC accreditation of HUH, the HUH Department of Research and Innovation will coordinate the nomination process in collaboration with the relevant hospital departments and faculties.

The nomination process leading up to the submission of applications to TMF should focus on the scientific qualities of the project ideas with reference to this invitation, the criteria and requirements as detailed in this document. In addition, the mix of collaborations and competencies represented should be taken into consideration.

There will be a two-step application process as follows:

Step 1: Pre-qualification

Step 1 will be organised by the HUH Department of Research and Innovation and implemented jointly by Helse Bergen and MED UiB. Eligible proposals will be evaluated by an international expert panel appointed by Helse Bergen and MED UiB.
The evaluation criteria listed in Appendix C will be the basis for evaluation of proposals. In addition, project proposals which will clearly give synergies with areas of strategic interest to HUH, may be given priority.

In Step 1, based on the outcome of the expert panel, a minimum of five and a maximum of seven proposals will be selected to be entered into Step 2.

Step 1 Proposals must be written in English and contain the following:

- The research plan
- The budget sheet
- A commitment letter from the host institution describing the nature and level of its contribution to the project. The letter must be signed at the appropriate institutional level.
- In cases where institutions other than the host institution are expected to contribute with resources to the project, a letter signed at the appropriate level of the contributing institution should be included. The letter should describe the nature of the resources to be committed and confirm institutional support of the proposal and its budget.
- An outline of the clinical protocol (to be) submitted to the EU application portal Clinical Trials Information System (CTIS). Be aware that clinical trials that fall outside the geographical scope of CTR are to be submitted to the REK portal.

How to submit Step 1 proposals:

One copy of the proposal and the required attachments, compiled into one (1) PDF file, is to be submitted to the same e-mail address. Receipt of submitted applications will be confirmed by email. *Application deadline for Step 1 proposals is **15.08.2024** at 12:00 (noon).*

Proposals that are submitted after the deadline and/or that do not meet the formal requirements will not be evaluated.

Questions about Step 1 and the requested commitment letter can be directed to Department of Research and Innovation at HUH (kliniske_studier@helse-bergen.no).

Following the Step 1 evaluation, PIs of successful Step 1 proposals will receive an invitation from TMF with information on how to proceed with the Step 2 applications.

Step 2 Final

Step 2 – final - will be organised and implemented by TMF. Eligible proposals will be evaluated by an international expert panel appointed by TMF. The evaluation criteria listed in Appendix C will be the sole basis for evaluation of proposals.

Step 2 applications must be written in English and contain the following:

- The research plan (template to be provided by TMF)
- The budget sheet (template to be provided by TMF)
- A commitment letter from the host institution describing the nature and level of its contribution to the project. The letter must be signed at the appropriate institutional level.
- In cases where institutions other than the host institution are expected to contribute with resources to the project, a letter signed at the appropriate level of the contributing institution should be included. The letter should describe the nature of the resources to be committed and confirm institutional support of the proposal and its budget.
- The draft clinical protocol (to be) submitted to the EU application portal Clinical Trials Information System (CTIS) for drug trials, or to REK for studies on other medical interventions.

For eligible Step 2 proposals, TMF will appoint a panel of internationally recognized experts to evaluate the proposals and make recommendations for funding to the foundation. In addition to the proposals, the expert panel will have access to this invitation text including the evaluation criteria as detailed in the below table. Please note that only documents especially requested in this Invitation will be made available to the expert panel.

Each proposal will be assessed on its own merit. The assessment shall focus on the scientific quality including plans for generation and pursuit of novel scientific ideas. In addition, priority will be given to proposals that clearly will contribute to the overall aims of the program.

How to submit Step 2 proposals:

One copy of each proposal and the required attachments, compiled in one (1) PDF file, should be submitted to *grants[at]mohnfoundation.no*

Receipt of submitted applications will be confirmed by email.

*Application deadline for Step 2 proposals (by invitation only) is **10.01.2025 at 12:00** (noon).*

For questions about step 2 proposal preparation, please contact:

Oddveig Åsheim: phone +47 416 63 164, oa@mohnfoundation.no

Anja Hegen: Phone +4704640690416, ah@mohnfoundation.no

Appendix B – Project funding and project grant agreements.

Depending on the experts' quality assessments and recommendations, TMF may grant a maximum of 18 MNOK under this program. Each project may normally receive a maximum of NOK 6 million from TMF during a maximum three years (on average 2 million pr. year). This will allow for three-year projects. It is expected that three projects may be selected for funding, depending on quality assessments and project design.

It is a prerequisite for funding that any TMF contribution is matched by resources from the participating institutions at about the same level. The overall budget of each project should allow for the establishment of a research team and for collaborative and/or cross- disciplinary research to take place.

Matching resources from the participating institutions may include salaries, consumables, equipment, and overhead related to positions funded by TMF and "leiestedskostnader" (e.g. the use of labs / equipment / sampling). Funding from the foundation may not be put towards overhead and/or other expenses not directly related to the project. For this call, TMF funding may normally not cover the salary of the project leader or "frikjøp."

For funded projects, a project grant agreement will be entered into by TMF and the host institution, in which their respective responsibilities will be detailed in full.

In conjunction with the grant agreement, consortium agreements between the collaborating institutions/departments must be put in place as well as an agreement ensuring the project's affiliation to the Programme and access to the relevant research infrastructure.

Please note: The reply to this invitation involves the recording and processing of personal data (such as name, address, and CV). Such data will be processed pursuant to Norwegian law. The questions and any personal data requested are required to evaluate the application in accordance with the specifications of the call for proposal and will be processed solely for that purpose by TMF. The review process requires that personal information given in the proposal must be made available to external reviewers. All such experts are required to sign and adhere to a declaration of confidentiality in this regard.

Appendix C – Evaluation criteria (both step 1 and 2)

CRITERIA	Description
SCIENTIFIC QUALITY	• Originality relative to the state-of-the-art in the field • Is the overall aim and underlying research questions, hypotheses and objectives clearly and adequately specified? • The degree to which the project may challenge current practices (clinical and research)?
SIGNIFICANCE	Please assess the project's potential towards one or more of the following: • To improve methods, the utilization of equipment/data and /or clinical practice? • To meet clearly identified needs of specific patient group(s), carers, or other identified users. • To have long-term positive impact on clinical practice
FEASIBILITY	The extent to which the conceptual framework, design, methods, and analyses are appropriate for the aims of the proposed research. How well are the following addressed: • Risk identification and management. Are there appropriate contingency plans? • Plans for data collection and availability of preliminary data Is the proposed budget sufficient for conducting the planned activities.
ENVIRONMENT	The extent to which the available resources, the institutional commitments, and any other unique features, will contribute towards the success of the proposed research. • Access to infrastructure, equipment, and resources • Relevant collaborators creating a research environment of capacity. • Cross-disciplinarity where relevant
INVESTIGATORS including the PI	The extent to which the Investigators' experience, track record, training, preliminary data/past progress will contribute towards the success of the project.
IMPACT / POTENTIAL LONG-TERM EFFECTS	With reference to the plans as outlined in the project proposal, what is the potential for the project to have a long-term positive impact on • The improvement of health services and clinical practices • The knowledge base / filling knowledge gaps, academic impact
INNOVATION AND TRANSLATION:	The suitability of the described approach towards translation and innovation. -
INTERNATIONAL COOPERATION	The extent and quality of the international cooperation activities set out for the project. • International networks. • International mobility
NATIONAL COOPERATION	The extent to which the project will make use of national research expertise and help to promote national network building.
DISSEMINATION AND COMMUNICATION OF RESULTS	Plans for scholarly publication, dissemination, and other communication activities. Plans for dissemination and communication activities vis-à-vis the public as well as end-users.
PLAN FOR USER INVOLVEMENT	Are relevant user groups identified? Is there a relevant plan for user involvement?