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# Information about the call

Grant capital:

Total DKK 40 million.

Award amount

Up to DKK 10 million per grant

Application form opens:

October 26, 2023

Application deadline:

January 10, 2024, 2pm (CET)

Applicant notification:

Beginning of April 2024

Interviews:

March 8, 2024 (for selected and invited applicants only)

Earliest start date:

May 1, 2024

Latest start date:

February 1, 2025

Review committee:

<u>Committee on Clinical and Translational Medicine</u>

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# 1 CLINICAL EMERGING INVESTIGATOR 2024

These guidelines are intended to assist you in the application process when applying for a grant from the Novo Nordisk Foundation (NNF). It is important that you carefully read these guidelines before initiating the application process, as the guidelines contain the complete call text as well as instructions regarding the completion of the application.

NNF will treat all applicant and application information confidentially. Read more about how NNF processes personal data under 'privacy & security' in the online application system, NORMA. See how to access NORMA in section 2 of these guidelines.

Furthermore, please read 'General Terms and Conditions' for grants from NNF that all Grant Recipients must comply with:

http://www.novonordiskfonden.dk/en/content/conditions-grants

#### 1.1 PURPOSE

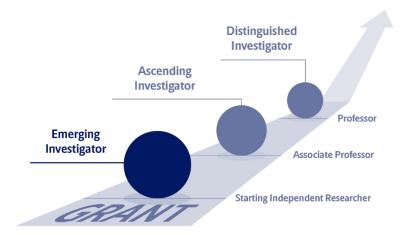
To support and strengthen the development of young and promising clinical research leaders and promote Danish clinical and translational research at a high international level, the Novo Nordisk Foundation seeks to support the starting clinical research leaders with ambitions of combining their clinical work with clinically relevant research.

# 1.2 AREAS OF SUPPORT

The overall goal is to support medical research with relevance to patients and human health. The research fields could be within, but are not limited to: Patients and disease related research, translational and clinical research, research in: disease mechanisms; treatment methods; disease trajectories, epidemiology; diagnostic methods; public health and family medicine, intervention studies, register-based research, proof-of concept studies, pilot projects, initial clinical trials and clinical testing, biomedicine etc.

# 1.3 THE RESEARCH LEADER PROGRAMME

To support the best and the most talented research leaders at all steps of their careers from start-up to established principle investigators, the foundation offers three specific grants within the 'Research Leader Programme' (schematized below) to stimulate excellence and the possibility to pursue ambitious and original projects. The 'Clinical Research Leader Programme' is targeted the best clinical researchers, who combines, or wishes to combine, clinically relevant research with clinical work and responsibilities. The continued clinical responsibility throughout the project and grant period is essential, as it is considered key to facilitate deep roots of both the research and the researcher in the clinic. The calls 'Emerging', 'Ascending' and 'Distinguished' target principle investigators at specific career-stages and applicants are encouraged to familiarise themselves with the requirements in each call, to ensure they are eligible to apply.



# 1.4 'CLINICAL EMERGING INVESTIGATOR PROFILE'

The 'Clinical Emerging Investigator' grant is intended for clinicians who are fully qualified to start or under their medical specialist training, who already has research experience, and who wants to combine his/her clinical work with research.

Applicants must commit to dedicate part of their time to research, while extending their medical specialist training, and <u>must apply for part-time substitute replacement salary from parts of the applicant's clinical obligations for five years.</u>

The grants are designed to support clinical doctors who are building their own research/research group and hence not for clinical researchers who are well established and has a permanent employment.

Clinical activities in departments must be continued, and therefore the salary for a substitute must be a part of the budget allowing the young PI to leave for research.

Salary for substitute must be applied from NNF every budget year!

# 1.5 ELIGIBILITY

The project must be a 5-year project and it must be anchored at a Danish university, hospital or other non-profit research institution.

- Applicants must have an MD and should have a Ph.D., a dr. med. or similar qualifications.
- Applicants must either be ready to start or be under their medical specialist training. I.e. KBU and the introductory position must be completed if applicants are not yet under medical specialist training. Applicants may not have ended their medical specialist training at the time of application deadline.
- Applicants must commit to minimum 20% (1 workday) and maximum 60% (3 workdays) research time, leaving from 80% (4 workdays) to 40% (2 workdays) to clinical work at a Danish hospital. The amount of time dedicated to research and clinical work can vary over the five

- project years, as it best fits the project and applicant. It must be specified how much time will be spent on research under the tab 'Applicant Information/' supplementary information'.
- Applicants must have institutional support from the heads of both the clinical department and the department where the research is to be performed (hosting and support letters **must be uploaded** to the application, please see section 3.5 for further information).
- Upon granting, it is the applicant's responsibility to establish an agreement with the regional council on postgraduate medical training for their individual case.
- 'Clinical Emerging Investigator' grants are individual grants at the disposal of the applicant. If
  the applied project involves collaboration, the collaboration and the nature of the collaboration
  should be described in the project description, but the applicant must be the clear driver of the
  project (it is not possible to have or register co-applicants for this specific call).

An applicant may **only submit one application to the NNF 'Research Leader Programme'** in 2024 within all NNFs funding areas. If you submit more than one, the first application submitted will be evaluated, while subsequent applications will be administratively rejected.

Applications from Master students, Ph.D. students and postdocs will not be taken into consideration.

# 1.6 FUNDING

Each grant must run over five years and can be up to 10 million in total over the five years depending on the time spend / level of commitment from the applicant to the research project.

In the case of many applications of exceptionally high quality within one career stage of the Research Leader Programme, the committee may decide to transfer up to DKK 10 million from one career stage to another.

Applicants must commit to minimum 20% (1 workday) and maximum 60% (3 workdays) research time, leaving from 80% (4 workdays) to 40% (2 workdays) to clinical work at a Danish hospital. The amount of time dedicated to research and clinical work can vary over the five project years, as it best fits the project and applicant. Hence, the time, which the applicant commits to the research project, can vary from project year to project year, going from an average of 1 weekly day to 3 weekly days, depending on how it fits with the continued medical specialist training.

Applicants may apply for funding for the following types of expenses:

- Salary for the substitute who will take over PI's clinical responsibilities <u>must be applied for</u> from the Novo Nordisk Foundation every budget year!
- **Salary for research and technical assistance** required for the project, e.g. postdoctoral researchers, PhD students (incl. tuition fee up to DKK 80,000 per budget year, which must be specified/applied for in the budget), technicians and research-year students, etc.
- **Operating expenses**, e.g. lab consumables, chemicals and reagents, research animals, sequencing/proteomics and other analysis services directly related to the project.
- **Equipment** required for the project, however not exceeding 20% of the total budget.
- **Travel expenses** in relation to the project, i.e. conference and workshop participation and presentation of research results, up to DKK 50,000 per budget year.

- **Other travel expenses** directly related to the project, i.e. experiments carried out in other labs for a limited period.
- **Publication of results** emanating from the research project, up to DKK 25,000 per budget year.
- **Administrative support**, up to 5% of, and included in, the funding applied for.
- **Bench fee** can be included in the budget for support of individual researchers to cover expenses needed to conduct the proposed research.

Bench fee is calculated per academic employee actively working on the project and may only be used for expenses that are related to the research project and which cannot be included within another individual budget category. Bench fee may account for maximum DKK 8,000 per month per FTE working on the project, and the budget must specify the expenses covered by the bench fee, which may include: Common or shared laboratory expenses and consumables, laboratory utilities (electricity, gas, water), maintenance of essential equipment, service contracts and technical and IT support.

Note, that bench fee cannot cover rent, administrative support, representation, social contributions etc. To include a bench fee in the budget, the fee must be a part of the general expense policy of the administrating institution, and it must apply for all employees independently of funding source.

Documentation that the administrating institution has a general bench fee policy should be included in an 'hosting Letter' from the [administrating institution enclosed as link or appendix. An unspecified bench fee without documentation will not be accepted.

**Administrative support** may account for a maximum of 5% of the total budget and must be included therein. The administrative support:

- can cover expenses such as for accounting, payment of salaries, purchasing, hiring, as well as auditing and financial reporting on the project
- cannot cover administrative expenses that are not directly related to the project
- can via the host institution be shared between the institutions of the main- and coapplicant(s), as detailed in the application budget
- is not automatically included in the grant, and must be stated/applied for in the application budget, but should not be specified in detail

Applicants may not apply for funding for the following types of expenses:

- Own salary for principal investigator (it is essential, that applicant's own salary must be covered throughout the entire 5-year project period)
- Commercial activities



The grant may not be used to cover 'overhead' (i.e. rent, electricity, water, maintenance etc.)

# 1.7 LANGUAGE

The application and any additional uploads must be written in English (including layman description).

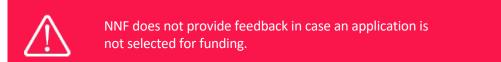
# 1.8 APPLICATION PROCESS

The application must be completed and submitted using NNF's online application and grant management system, NORMA, which can be accessed from: <a href="https://norma.novonordiskfonden.dk">https://norma.novonordiskfonden.dk</a>

Further information on how to access and navigate in NORMA can be found in chapter 2.



When all applications have been assessed, applicants will be notified about whether or not they have been awarded a grant. The notification e-mail will be sent from <a href="mailto:norma-noreply@novo.dk">norma-noreply@novo.dk</a> to the e-mail address entered on initial registration.



# 1.9 ASSESSMENT CRITERIA

NNF's <u>Committee on Clinical and Translational Medicine</u> will primarily assess the applications based on the following criteria:

- Quality of the research question and scientific impact
- Scientific approach
- Societal impact
- Past performance
- Research leadership and/or potential
- Collaboration and research environment

NNF does not allow double funding of projects and to ensure sufficient time commitment, considerations regarding existing funding at the time of application is taken into consideration. In general, it is recommended that the Grant Recipient has delivered results on the active NNF grant(s) before submission of a new application to NNF. If you apply, while having an active grant from NNF, you must describe how the project you propose in this application is different from

and/or coherent with the project(s) already funded and briefly describe the progress of the already funded project(s).

# 2 THE APPLICATION AND GRANT MANAGEMENT SYSTEM – NORMA

Sections 2 and 3 provide guidance on completing and submitting an application through NNF's online application and grant management system NORMA. Section 2 contains general technical information, while section 3 contains information specific to the individual call. All the fields of the application form must be completed in accordance with these guidelines and the instructions in NORMA.

# 2.1 USER REGISTRATION

NORMA can be accessed through links on NNF's website or directly at: https://norma.novonordiskfonden.dk

Before you begin, please read the instructions on the login page.

If you do not have a user profile in NORMA, you can register by clicking REGISTER from the login-page. Here you can also retrieve forgotten passwords by clicking the FORGOT PASSWORD-link. The main applicant should only have one user profile. Please use your work e-mail address for registration. After registration, you will receive an e-mail with your user name and a temporary password, which you can then use to log in to NORMA. After logging in for the first time you will be asked to provide a password of your own choosing.

A registered user who submits an application is legally responsible for the truthfulness of the content of the application.

If you experience technical problems, please contact NORMA Support: norma-support@novo.dk.



An applicant cannot change the e-mail address provided at registration. Please contact NORMA Support if you need to change your e-mail address.

#### 2.2 CREATING AN APPLICATION

Initiate an application by finding the call you wish to apply for in the OPEN CALLS-section on the Applicant Portal in NORMA. Use the search filters at the top of the section to filter by e.g., overall funding area, and initiate an application by clicking APPLY NOW next to the relevant call.

Applications can be edited up until the deadline. A draft application can be saved by clicking SAVE DRAFT and may be cancelled at any time up until the deadline by clicking CANCEL APPLICATION. An

application is not submitted to NNF until an applicant has clicked SUBMIT and has received confirmation that the application has been successfully submitted.

You can review the application at any time by reopening from within NORMA. Opening the application will also allow you to download the application in its entirety as a PDF. Make sure the PDF is readable and formatted appropriately before submitting your application.

# 2.3 TEXT AND ILLUSTRATIONS

For all applications, the individual fields must be completed in accordance with these guidelines and the instructions supplied in NORMA.



To prevent loss of data, it is essential to press SAVE DRAFT before you leave NORMA or navigate in the system.

#### **TEXT FIELDS**

Text from Microsoft Word or comparable word processors can be copied and pasted into most text fields of the application. It is, however, important to check that formatting, special characters, and symbols have not been converted or lost in the text fields after copying and pasting. If the formatting looks wrong in NORMA or in the PDF, try changing all text to *Normal* using the FORMAT dropdown. It is the responsibility of the applicant to ensure that the pdf looks correct before submitting.

The available options for formatting text are at the top of the text fields. Some shorter text fields do not have the option to use rich text formatting.



For readability purposes, standard fonts, font size 11-12, and line spacing between 1.0 and 1.5 must be used.

# **ILLUSTRATIONS**

Illustrations such as figures, charts, tables, images, etc. related to the project description can be uploaded under PROPOSAL. A Maximum of four illustrations are allowed. The illustrations will be placed on a separate page in the application PDF but can be referenced throughout the project proposal as needed. For readability, please name the files numerically by the order in which they are referenced.

The following file formats for illustrations are accepted in the system: JPG, JPEG, PNG and BMP. The maximum accepted size for each illustration is 1050\*1650 pixels.

# 2.4 SUBMITTING THE APPLICATION

The application in its entirety must be submitted electronically via the application system by clicking SUBMIT. It is not possible to submit an application or any part of it by standard mail or email. Any material submitted outside the application system will not be included in the evaluation and will not be returned.



Please remember to check that the PDF version of the application is legible and contains all data and uploads before submitting.

All applicants must read and accept NNF's <u>Standards for Good Research Practice</u> before submitting the application. Further, the applicant must declare that the information provided in the application is true and accurate.

An application cannot be submitted unless all the required fields have been completed. Applications can be cancelled at any time before submission. If you need to withdraw an application after the deadline, please get in touch with NNF via e-mail, using the contact information on page 3.



A list of any incorrect or incomplete entries will be generated at the top of the screen when you click SUBMIT. Clicking one of these error messages will take you to the relevant field. Amending incorrect or incomplete entries can be time-consuming, so we recommend submitting applications well before the deadline.

# 3 APPLICATION CONTENT

This section provides guidelines on the content required in the sections of the online application form for this call.

#### 3.1 APPLICANT

The APPLICANT-tab contains information about all those involved with an application, meaning the main applicant or the contact person applying on behalf of an organization/institution as well as any co-applicants. Information about each applicant is collected through individual tasks in the APPLICANT DETAILS-section, detailing experience, publication history, application history with NNF, etc.

#### **MAIN APPLICANT**

The main responsible party for the application can enter their details through the Applicant Details-task with the type 'Applicant'. After filling in all mandatory fields, the applicant should complete the task to save the details.

It is essential, that <u>applicant's own salary must be covered throughout the entire 5-year project</u> period.

Clinical activities in departments must be continued, and therefore the salary for a substitute <u>must</u> be a part of the budget allowing the young PI to leave for research.

Salary for a substitute must be applied from NNF every budget year!

#### PREVIOUS AND CURRENT GRANTS FROM NNF

If you have previously submitted other applications in the same calendar year, summarize how these applications are related to the current application.

If you have received any grants from NNF as an applicant or a co-applicant within the past five years, you must provide the application number, project title, grant period (in years), grant amount and the percentage share of the grant (100% if there is no co-applicant). Briefly summarize how any of the grants are related to the current application.

## CO-APPLICANT(S)

It is not possible to have or register co-applicants for this specific call.



Please note that co-applicants can read, edit, and upload information in the entire application but cannot submit the application.

# 3.2 INSTITUTION

Please provide information about the institution where the grant will be administrated. This institution is where you will be employed during the grant period and the institution which will be responsible for budgeting, accounting, and staff supported by the grant.



Registering a new administrating institution in NORMA can take up two working days. The application can be edited but cannot be submitted before this information is registered. We therefore recommend that you register an administrating institution in good time.

# 3.3 PROPOSAL

Describe the project using the fields on the PROPOSAL tab. Each field (Project title, Brief project description, Project description, Illustration uploads, Lay project description, and Research

methods) will have a short instruction text describing the expected input and maximum characters available.

#### **PROJECT TITLE**

Please provide a short title for the project (maximum 150 characters, including spaces and special characters).

#### **BRIEF PROJECT DESCRIPTION**

Please provide a brief stand-alone summary of the project describing its purpose, target group and activities. (maximum 2,000 characters, including spaces and special characters).

#### **PROJECT DESCRIPTION**

Can be a maximum of 30,000 characters (including spaces, line breaks and special characters). Please describe your proposed research project in detail – including purpose, background, methods, collaborations and the significance of the project. Up to four illustrations can be uploaded to the project description.

Abbreviations should be defined at the first use, and preferably a list of abbreviations should be included in the project description.

#### **ILLUSTRATION UPLOADS**

A maximum of four illustrations of 50 mb each can be uploaded here. Accepted formats are .jpg, .png, .gif, .bmp.

#### LITERATURE REFERENCES

Please provide the reference information for the literature cited in the project description (maximum 8,000 characters, including spaces and special characters).

# LAY PROJECT DESCRIPTION

Please provide a brief summary for non-experts in lay language. If the application is awarded a grant, the text may be used for publication (maximum 1,000 characters, including spaces and special characters).



Please note that the application should address all the assessment criteria listed in subsection 1.7.

# 3.4 BUDGET

The budget for the project applied for only comprises the information entered on the BUDGET tab. Additional budget information attached under UPLOADS or added on any other tabs than BUDGET will not be considered.

# **GRANT PERIOD**

Before you can fill in the budget template, start by entering the start and end dates for the grant. This will determine the number of years available from the budget template. The grant period is

the duration of NNF's grant for the project, and the budget counts years following the project start date rather than calendar years.

#### **CREATE BUDGET**

After saving the project start and end dates, the budget template will become available to edit. The budget will open in a new tab, in which you will need to add the subcategories you need for your budget. Please follow the instructions at the top of the screen to complete the budget.

#### Notes:

- The budget continuously saves changes you've made without the need to manually save. You are free to leave the budget at any time and come back at a later point.
- When you are done filling in your budget, please use the SAVE AND CLOSE button. This will
  check that all information has been filled out correctly and in accordance with the
  guidelines, saving the budget to your application.
- You can now return to the BUDGET tab. A summary of the budget will be displayed, review it to ensure that it is correct.
- The full budget details can be viewed or edited at any time before submission of the application by reopening the budget template.

Any comments about the budget can be entered in the SUPPLEMENTARY INFORMATION field.



For salary items, the number of full-time equivalents in years must be stated in the field FTE.

## **FULL-TIME EQUIVALENTS (FTE)**

For salary items, the number of full-time equivalents in years must be stated in the field FTE. There are 1924 gross hours in a year, from where non-working days must be deducted.

**EXAMPLE**: 6 weeks of holidays (222 hours), 10 public holidays (74 hours) 10 educational days (74 hours) deducted from 1924 amounts to 1554 net hours per year. To find the FTE for e.g., 30 hours, the calculation should be: 30 (hours) / 1554 (net hours) = 0.02, which is what should be stated in the FTE field.

Budget item (illustrative purposes only)		<b>Description</b> (illustrative purposes only)
Salary – PhD	1	PhD (1 person-year full time)
Salary – project employees		Project staff (2 x 60 hours)
Salary – TAP		Technical staff 2.5 person months full time



Applicants may only apply for the types of expenses listed in subsection 1.4.

# 3.5 APPENDICES

All uploads must be in PDF format. NORMA automatically places these uploads at the end of the application. Please respect the page limitation and the upload requirements stated in the call. Uploads in excess of these limits may not be considered for evaluation.

Only two attachments must be uploaded to the application before submission:

- 1) A 'SUPPORT LETTER' signed by the head of the clinical department, where the applicant is currently employed (has his/her main employment), accepting that the applicant can be granted part-time release from his/her clinical responsibilities and that the medical specialist training will be extended. The head should also state in this letter that the applicant will remain part-time affiliated with the clinic during the entire project period. In case the applicant has not yet started medical specialist training, a documentation that KBU and the introductory position has been completed must be uploaded instead (as a merged pdf).
- 2) A 'HOSTING LETTER' signed by the head of the department, where the research will take place, accepting the applicants proposed research project to take place at the institute, that the department will provide the required infrastructure such as laboratory and office space, and that the budget applied for will be administrated and used as indicated in the application.

If the main applicant is Head of Department or otherwise part of the management, the hosting letter or letter of support must be signed by someone from the management level above the main applicant.

Please be aware that in the case the research is to be conducted at the place of clinical employment of the applicant, two letters are still required to be uploaded before the application can be submitted, even though they, in this case, will be signed by the same head.

#### Bench fee

If you apply for a bench fee to be covered by the grant, you must provide official documentation that the administrating institution or co-applicant's institution has a general bench fee policy. This should be included in the Hosting letter/letter of support from the administrating institution enclosed as link or appendix. Bench fee may only be used for lab consumables and access to lab space and facilities that cannot be included within 'operating expenses' or another budget category, see section 1.6.

# The Novo Nordisk Foundation

The Novo Nordisk Foundation is an independent Danish Foundation with corporate interests. The objective of the Novo Nordisk Foundation is twofold: To provide a stable basis for the commercial and research activities conducted by the companies within the Novo Group and to support scientific and humanitarian purposes.

The vision of the Novo Nordisk Foundation is to contribute significantly to research and development that improves the lives of people and the sustainability of society.