CAUSAL FACTORS IN OBESITY 2023

Information and guidelines for applicants

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Information about the call

Grant capital:
DKK 24 million

Award amount:
Up to DKK 3 million (or up to DKK 4 million if the project includes an international co-applicant) for up to 3 years

Application form opens:
5 September 2023

Application deadline:
18 January 2024, 2pm (CET)

Applicant notification:
May 2024

Earliest start date:
1 August 2024

Latest start date:
30 June 2025

Review committee:
Committee on Endocrinology and Metabolism

Contact:
Jamie Batchelor   Mads Fiil Hjorth
Grant Specialist   Senior Scientific Manager
E-mail: jar@novo.dk   E-mail: mfh@novo.dk

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1   CAUSAL FACTORS IN OBESITY 2023

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.

- **Chapter 1** describes the overall frame and conditions of the call, eligibility criteria and evaluation process.
- **Chapter 2** provides technical guidance for how to access and navigate in the application and grant management system NORMA.
- **Chapter 3** gives essential information regarding the requirements to content, structure, and budget for 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 chapter 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

The purpose of the programme is to stimulate and support novel, early stage, high-risk/high-gain research ideas, to identify and validate causal biological, physiological, and psychological factors for obesity development. The project period will support early testing of the idea and its basic concepts, and the generation of initial data that can establish a firm basis for continuing into a more complex and expanded project stage. Therefore, the research should have potential for disruptive science and development of new research areas to enable design of effective non-pharmacological strategies to reduce the obesity epidemic, while strengthening and internationalising Danish research.

1.2   AREAS OF SUPPORT

Obesity is a multifactorial condition that evolves over years and involves the interplay between genes, epigenetics, metabolism, microbiome, and behaviour, and is triggered by environmental factors that are currently not well understood but likely to be deeply rooted in social inequity. Changes in food systems (e.g., energy dense, processed and highly palatable food) contribute, but it is likely the interplay with the person's innate biological and psychological factors that determines the individual's susceptibility to excessive energy intake and obesity. Genes alone cannot explain the excessive growing development in the numbers of people with overweight and obesity or the socio-demographic variations. Thus far, many strategies for prevention and treatment of overweight and obesity have not been successful, and it has not been possible to identify and isolate specific causes of obesity to be able to have a meaningful impact on the obesity epidemic.

A strategy to prevent and treat overweight and obesity should focus on causal factors. Interventions aimed at preventing obesity based on assumptions or weak evidence about causes are likely to fail and further increase stigma on people living with obesity. Identification of tangible factors is crucial for the success of endeavours to reduce the prevalence of overweight and obesity.

Therefore, projects within the 'Causal Factors in Obesity' Programme should go beyond simple calorie counting and recommendations for lifestyle changes and focus on novel, testable hypotheses with a potential physiological effect on the pathogenesis of human obesity which have not yet been sufficiently tested or have been overlooked. This could involve environmental factors such as stress, sleep, pollutants, diet components, exercise regimens, atmospheric CO_2, noise, ambient temperature, microbial environment, viral infections, drugs, and other yet unknown factors with a potential interplay with (epi)genetics, some of which are likely to be deeply rooted in social inequity.

1.3   ELIGIBILITY

In general, all study designs will be eligible for funding (e.g., follow-up studies, observational studies, registry-based research, re-analysis of existing original data and RCT) as long as it is the most appropriate method for the given research question within the allocated time and budget.

It is possible to include one international co-applicant in the project who is associated to a university, hospital, or other non-profit research organisation. If an international co-applicant is included, they must significantly contribute to the scientific advancement of the project and receive part of the funding.

To be eligible for a grant:
- The main applicant must be based at a Danish university, hospital, or other non-profit research organisation. They must have at least a 50% affiliation at this institution.
- **If there is a co-applicant, they must be employed at a university, hospital, or other non-profit research organisation outside of Denmark**. The co-applicant should significantly contribute to the scientific advancement of the project and receive part of the funding.
- Collaboration with industry is possible within this programme, however funding cannot be awarded to industrial partner(s).

General rules for applications:
- Being the recipient of another Novo Nordisk Foundation research grant does not preclude receiving a Causal Factors in Obesity Programme grant.
- An applicant may submit only one application per call as "main-applicant".
- NNF does not allow double funding of project-specific expenses. If an applicant has applied for, or has received, funding for the project or parts of the project from others, this must be detailed in the budget of the application. If the applicant receives funding for the project or parts of the project from other sources following submission of the NNF application, NNF must be contacted immediately.
- For further information that apply when applying for/receiving a grant from the NNF, please refer to our general terms and conditions https://novonordiskfonden.dk/en/conditions-for-grants.

1.4   FUNDING

The total budget for this call is DKK 24 million.

Grants can be up to DKK 3 million (or up to DKK 4 million if the project includes an international co-applicant) and with a duration of up to three years.

If relevant, the grant period can be extended to 4 years to cover 4-year PhD stipends, without changing the granted amount.

If there is a co-applicant, it is expected that the main applicant receives at least half of the project funding but no more than DKK 3 million.

The grant cannot be used to cover the main applicant's or the co-applicant's own salary.

Applicants may apply for funding for the following types of expenses (see chapter 3.4 for details):
-    Salary for scientific, technical, and administrative staff
-    Tuition fee for PhD students
-    Direct operational project costs
-    Equipment
-    Scientific publications costs
-    Collaborative activities
-    Conference participation
-    Bench fee
-    Direct administrative expenses (up to 5% of the total budget applied for).

NNF will not award funding for:
-    main applicant's or the co-applicant's own salary
-    commercial activities
-    overhead

1.5   LANGUAGE

The application and any additional uploads must be written in English.
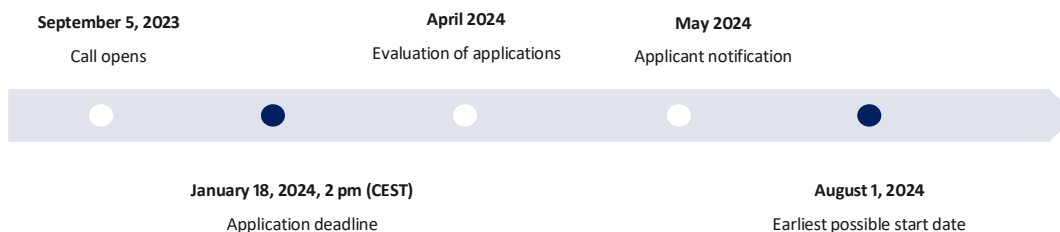
1.6   APPLICATION PROCESS

The application process consists of a one phase submission that must include the following elements (see chapter 3 for details):
-    An extensive detailed project description
-    Applicant and co-applicant details (CV, research summary, publication list)
-    Letter of commitment from the Danish host institution
-    A detailed budget including all participating groups
-    Bench Fee policy for all institutions who apply for bench fee

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

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

| September 5, 2023 | | April 2024 | | May 2024 | |
| Call opens | | Evaluation of applications | | Applicant notification | |

| | January 18, 2024, 2 pm (CEST) | | | August 1, 2024 | |
| | Application deadline | | | Earliest possible start date | |

The Novo Nordisk Foundation's Committee on Endocrinology and Metabolism evaluate the applications and applicants will be notified in May 2024 about whether they have been awarded a grant. The notification e-mail will be sent from norma-noreply@novo.dk to the e-mail address entered on initial registration.

> ⚠️ NNF does not provide feedback in case an application is not selected for funding.

1.7   ASSESSMENT CRITERIA

Applications will not be evaluated on absolute feasibility, as high-risk/high-gain research is encouraged. In the evaluation of the applications, the committee will primarily focus on the following aspects:
- Scientific quality of the project.
- Idea, creativity, and novelty.
- How the data expected to be acquired during the project period supports the novel idea and may extend the research into larger-scale projects.
  Managerial and scientific qualifications of the programme leader/main applicant and, if relevant, the co-applicant.

If you have an active grant from NNF, this may be taken into consideration in the evaluation of your application for a new grant. In general, it is recommended that the Grant Recipient has delivered results on the active 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

Chapter 2 and 3 provide guidance on completing and submitting an application through NNF's online application and grant management system, NORMA. Chapter 2 contains general technical

information, while chapter 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 username 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 e-mail. 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 Standards for Good Research Practice 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.

3 APPLICATION CONTENT

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

3.1 APPLICANT(S)

The APPLICANT-tab contains information about the main applicant and up to one co-applicant

MAIN APPLICANT
The main applicant is the responsible party for the application and should 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 only possible to be main applicant on one application per application round. If a main applicant submits more than one application for this specific call, the first application submitted will be evaluated, while the subsequent applications will receive an administrative rejection.

CO-APPLICANT
For this call, **one co-applicant from a research institution abroad is allowed** for the application. Co-applicants must be invited through NORMA and subsequently enter their details through the APPLICANT DETAILS-task with the type 'co-Applicant' in the system. Please follow the instructions in NORMA on how to invite co-applicants to your application.

Co-applicants participate actively in organising and implementing the project and receive a share of the grant. The project description should clearly describe the role of the co-applicant, and the budget should clearly indicate the co-applicants' share of the total budget.

The co-applicant must be invited through NORMA and subsequently enter their details in the system. When the co-applicant accepts his or her invitation and has registered as a user in

NORMA, they will gain access to the application. In addition, they will be assigned an APPLICANT DETAILS-task, available under MY TASKS from the APPLICANT PORTAL in NORMA. Co-applicants will only be able to edit their own APPLICANT DETAILS-task, as well as make changes to the main application. The main applicant, on the other hand, can review and edit all Applicant Details-tasks for the application including those for co-applicants.

> ⚠️ Note that inviting co-applicants can be time-consuming. Please start the invitation process as soon as possible and well in advance of the submission deadline

MANDATORY INFORMATION

The following information about each applicant is mandatory and is collected through individual tasks in the APPLICANT DETAILS-section:

- **CV**: can be a maximum of 4,000 characters. Please include in your CV a short bibliographic overview summarizing total number of peer-reviewed publications, number of first authorships, number of corresponding authorships, number of citations, h-index, etc. Applicants are strongly encouraged to provide a link to an updated profile with a full publication list on, e.g., ORCID, Google Scholar, Web of Science, or Scopus.
- **Publications list**: Can be a maximum of 5,000 characters. Please only include the 10 most relevant publications for evaluating your merits. Include a complete specification of all authors for each publication with your own name highlighted.
- **Summary of own research and support of application**: Can be a maximum of 2,000 characters. Please provide a short summary of your research, your support for this application, and explain how the past years of research fit into the current proposal and collaboration.
- **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 and what results has been delivered.

> ⚠️ 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) 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).

BRIEF PROJECT DESCRIPTION

Please provide a brief stand-alone summary of the project describing its purpose, target group and activities (maximum 2000 characters, including spaces).

PROJECT DESCRIPTION

Please provide a comprehensive project description (maximum 30,000 characters, including spaces). The project description should be well-written, clear, concrete, and avoid unnecessary repetitions from the brief project description (which supposedly contains descriptions of purpose and target group).

Consider the following:
- Describe your research project in detail – including purpose, state-of-the-art, background, methods, novelty, feasibility, and the significance of the project.
- Describe the novel high-risk/high-gain idea, its timeliness, and how the data expected from the project will support the overall idea and potentially a transition into a larger-scale project.
- Clearly formulated hypotheses and details on work packages and methodologies (existing or developing).
- A description of identified risks in the project, i.e. describe which part(s) of the proposal contains high risk elements. *Note: As the programme focuses on high-risk/high-gain and exploratory ideas, a mitigation plan is not expected.*
- If the project involves collaboration, the nature of collaboration and the role of the co-applicant and/or collaborator should be described in the project description.
- Up to four illustrations (figures, tables, diagrams etc.) can be uploaded. Please only include illustrations relevant for the assessment of your application. Inclusion of a Gantt Chart and preliminary data as figures are welcomed.

Please do not use abbreviations and limit the use of acronyms – the applications will be assessed by a committee with members that are not necessarily experts within all disciplines covered by the call. An abbreviation might mean something in one discipline, and something

different in another discipline. In the same line, please use a language directed towards persons that are not subject matter experts but have a high academic level.

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 8000 characters, including spaces).

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 1000 characters, including spaces).

> ⚠️ 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.

The Novo Nordisk Foundation does not allow double funded projects. If co-funding is obtained for the research project described in the application, or parts of it, from other sources the applicant must inform the Novo Nordisk Foundation as soon as possible.

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.

ELIGIBLE BUDGET COSTS

Applicants may apply for funding for the following types of expenses when directly related to the project:

- **Salary for scientific and technical employees**, e.g., PhD students, postdoctoral researchers, assistant/associate professors, researchers/senior researchers, laboratory administrators. Salary will not be covered for applicants, co-applicants, or scientific faculty with time-unlimited contracts.
- **PhD Tuition fee** up to DKK 80,000 per year per student (include separately in the budget).
- **Equipment**, provided that it is essential for the proposed project, and its use after completion of the project can be clearly justified.
- **Operating expenses**, e.g., materials, consumables, data management and services.
- **Collaborative activities**, e.g., workshops, meetings, exchange, seminars, travel, and other efforts directed at ensuring fruitful collaboration and synergy between the partners of the programme.
- **Conference participation**, e.g., travel, accommodation, and registration for scientific conferences.
- **Publication costs** related to scientific publications originating from the project.
- **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 full-time equivalents (FTE,) working on the project, and the budget must specify the expenses covered by the bench fee, which may include:
  o Common or shared laboratory expenses and consumables
  o Laboratory utilities (electricity, gas, water)
  o Maintenance of essential equipment
  o Service contracts
  o 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/or the hosting institutions of the co-applicants, and it must apply for all employees independently of funding source.
  Bench fee policy documentation: Official Documentation stating that the administering institution or the co-applicant's hosting institution has a general bench fee policy must be included. 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:
  o can cover expenses such as for accounting, payment of salaries, purchasing, hiring, as well as auditing and financial reporting on the project
  o cannot cover administrative expenses that are not directly related to the project
  o can via the host institution be shared between the institutions of the main- and co-applicant(s), as detailed in the application budget

o   is not automatically included in the grant, and must be stated/applied for in the application budget, but should not be specified in detail

Please make sure it is clear which of the applicants each expense is dedicated to and include a high-level overview of the budget in the SUPPLEMENTARY INFORMATION field, explaining the distribution of funds among the collaborators and activities.

FULL-TIME EQUIVALENTS (FTE)
For salary items, the number of full-time equivalents in years must be stated in the field FTE.

For salary items, the number of full-time equivalents in years must be stated in the field FTE. One full-time employee for one year equals 1.0 FTE. Most institutions have defined a standard annual number of working hours which equals 1.0 FTE. NNF does not require the institutions to use a particular number of annual working hours.

EXAMPLE: To find the FTE for e.g. 74 hours, the calculation is: 74 (hours) / 1554 (standard annual hours (example)) = 0.05, which is what should be stated in the FTE field.

Budget item (illustrative purposes only)	**FTE**	**Description** (illustrative purposes only)
Salary – PhD	1	PhD (1 person-year full time)
Salary – project employees	0,08	Project staff (2 x 60 hours)
Salary – TAP	0,21	Technical staff 2.5 person months full time

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

3.5   APPENDICES
- **A signed hosting letter from the Danish host institution**, taking responsibility to hosting the project as well as administrating the grant
- **Bench fee policy documentation (if applied for):** Official Documentation stating that the administrating- and co-applicant institutions has a general bench fee policy

Please do NOT attach other appendices such as recommendations, support letter from collaborators, offers on equipment, etc.

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.

September 2023

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.