

GUIDELINES AND OPERATIONAL RULES FOR SCIENTIFIC PROJECTS

I. Introduction

The nutritionDay (nDay) Scientific Board (SB) welcomes all types of research projects linked to data collected on nutritionDay or requiring targeted additional data. The focus should be primarily the use of the already available data.

II. Submission of a research project

1. General principles

All submissions and communication with the SB has to occur in English. The submissions will be evaluated in order of the date of submission.

In case of duplicate or simultaneous submissions the nDay SB will give a first opinion/advice, which will be communicated to both investigators. Cooperation between the two submitting investigators is a possible option. The final decision will be taken by the nDay Scientific Board.

2. Who can submit

Researchers who are formally involved and actively participate in the nDay audit may submit research projects. This includes all individual unit participants, regional and national coordinators, supporting national and international organizations and members of the nDay advisory board.

Any project which is submitted by a non nDay researcher has to be endorsed by a nDay researcher who will supervise the project scientifically and will have the financial responsibility (responsible investigator).

3. Deadline and addresses

All proposals need to be submitted electronically to **office@nutritionday.org**, from where they are automatically forwarded to the SB.

4. Types of Proposals

In order to simplify the procedure of application for research projects, the Scientific Board supports the following two steps in research proposals:

- Letter of Intent (1-3 pages)
- Full Proposal

At each step, the SB will get back to the investigators in order to avoid unnecessary efforts if a project is not felt to be worth pursuing or if coordination with other projects is necessary.

4.1. Letter of Intent

The purpose of a letter of intent is to inform the SB about a plan for a Scientific project. A preliminary discussion of such a proposal will help the investigators to finalize their project within a major scope of the scientific agenda of the SB. The SB will also make suggestions for additional study aims or research groups to be included in the final project.

The letter of intent will include a short general description of the research question, the rationale and the resources likely to be needed. Minimum requirements include:

- A short introduction with 1 - 5 key references
- The study objectives
- The study design
- A preliminary budget
- The timeframe
- The dissemination strategy

For a project which needs only standard datasets and no financial support, the decision can be taken on the basis of a letter of intent. For funding, a full proposal has to be elaborated.

4.2. Full Proposal

The detailed description of the study should concisely present all the information necessary to permit a complete assessment of the proposal. In general, it should consist of 10 pages or less. The following information is required.

4.2.1. Administrative information

The name of all investigators of each center involved in the project should be mentioned. It is understood that they have all agreed to participate actively in the submitted proposal. The chief of the unit/organization has to approve the proposal.

For each project, a responsible investigator has to be identified (see point 2)

4.2.2. Summary

Please provide 1-page summary (maximum) in English. The author should provide a running title (or the complete title) for announcement on the nDay website in case of acceptance

4.2.3. Background

- Present state of knowledge in the area of the proposed research with key references
- Objectives of the project in relation to state of knowledge

4.2.4. Own research in the field

- Including relevant experience and a list of publications
- Relevant background information on the other investigators

4.2.5. Study aims and objectives

- The hypothesis which this project proposes to test
- The scientific and practical significance of the proposed research

4.2.6. Study design and research plan

- Investigations and tests to be performed in patients
- Laboratory methods
- Follow-up evaluation; patient management issues
- Bio-statistical methods
- Time-frame for the project (the research tasks to be performed within the credit and the duration of the projects should be explicitly mentioned)



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4.2.7. Statistical analysis

- The statistical partner involved is part of the researcher proposal
- Statistical analysis could be done at the Section of Medical Statistics of the Medical University in Vienna. The costs related to statistical analysis services shall be discussed in advance with the nDay Team and if additional man power has to be hired for a particular project has to be decided in a case by case model.
- Partner of the researcher may also do the analysis if specified in the researcher protocol.

4.2.8. Study budget

- Indicate infrastructure and manpower already available for the study
- Indicate what funds you expect to obtain from other sources (Industry, etc...)
- The budget should include appropriate details as well as external funded expenses.
- For personnel, the requested position(s) and duration should be justified by a description of the tasks
- The budget of the study should take into account only costs not already covered by the core research project ND
- Source of funding (public, grant, other sponsor)

Note the 4 phases of a project: preparation, operation, data analysis, manuscript writing. Specify the following costs: personnel, special tasks requested from the Data Center, diverse.

- The budget may be modified by the Scientific Board. If the authors do not agree with the modified budget, they should immediately notify the nutritionDay project manager, particularly if they think that the whole project cannot be fully carried out with the proposed funds. In principle, supplement funding at a later stage will not be possible.

4.2.9. Other information

- Interim analysis (if applicable)
- How you imagine to disseminate your results (publication in scientific journal, thesis, internal report, conference, etc.)
- A proposal for authorship should be part of each submitted project.

4.2.10. References

4.2.11. Attachments

Please attach whatever information you feel would help support the submission. Such information includes:

- A covering letter
- The curriculum vitae of the principal investigator (if not already sent before)
- Approval of the university's ethical review board

5 Confidentiality agreement and third parties:

A data sharing agreement between the principal investigator, the Medical university of Vienna and ESPEN, needs to be signed before data transfer or start of the analysis. Any results communications to third parties need mutual agreement.

Data should remain under the responsibility and control of the principal investigator or the statistical partners and should not be delivered to any third party that was not part of the research agreement.

6. Evaluation and decision process:

- The SB has to evaluate all submitted projects. It will appoint one or two members as "expert" for each submitted project.
- The experts review the project and send a written structured comment to the SB. They must verify that there is no overlap with an ongoing project. Should this be the case, the expert must inform the SB which will contact the investigator.
- A project is accepted with the approval of 2/3 of the SB members.
- The responsible investigator will be informed about the decision within three weeks following the proposal submission.
- Authors, who do not agree with the rejection of a project can appeal to the SB within one month. The SB will then take a final decision.

Submission of a modified project:

A project for which modifications have been required by the SB may be resubmitted:

- A point by point reply to all comments of the SB is requested from the investigators (like for publications)
- The modified protocol, with relevant changes highlighted in yellow, and the point by point reply (filled into the specific text box of the full proposal template) have to be sent to nDay address (office@nutritionday.org)
- The modified protocol is sent to the experts who have initially reviewed the project
- The project is discussed within the SB

Urgent decision needed:

- Rapid decisions may be taken by email but they are limited to very special circumstances: Temporal delay would jeopardize the timely publication of the work (e.g. late breaker abstract, important publication in a very competitive situation)
- Submissions have to be done as usual through email with request for rapid evaluation (office@nutritionday.org)
- The Scientific Board will decide whether special circumstances are met and the investigator will be informed about the decision.
- The proposal is first discussed by email by all SB members using the SB address (office@nutritionday.org) during 7-10 days. The deadline is given by the SB.
- After the discussion period, the SB members will be asked to **vote** by direct mail to (office@nutritionday.org): 14 days turnaround time. The decision is final if all voting members accept the proposal. If this is not the case, the project will automatically be put on the agenda of the next Advisory Board meeting

7. Progress report

6 to 8 months after having initiated the project, the responsible investigator has to send a short progress report to the Coordination Center. It should contain:

- Quantitative figures if appropriate (% of objectives reached)

- Delay in the initial time schedule should be explained and a revised time schedule has to be presented (termination, manuscript, publication).

8. Publications

8.1. Authorship

The nutritionDay team will nominate 1- 3 co-authors depending on the involvement of the Vienna Team in the research project

The word nutritionDay has to appear in the research article title

8.2. Footnote

All the nDay national coordinators, national nutrition societies and participants should be acknowledged in the research paper.

8.3. Source of funding

The source of funding should be stated as following:

“nutritionDay is yearly financed by ESPEN (the European society for Clinical Nutrition and Metabolism) and by the Medical University of Vienna”

8.3. Reporting of Observational data

Please refer to the recommendations made by [STROBE](#)

8.4. Any submitted or published manuscript

with mention of the project number, should be sent by email to: office@nutritionday.org