Hersen STICHTING

Grant Program
Towards a Cure

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1 Mission of the Brain Foundation

The Brain Foundation is dedicated to ensuring healthy brains for everyone. For over 30 years, the foundation has linked different types of brain disorders, recognizing that learning about one condition can help with others. To achieve this, we collaborate with scientists, healthcare professionals, experts, patients, and the public. Together, we find solutions to keep brains healthy, treat brain disorders more effectively, and help individuals with brain conditions participate fully in society. These goals are outlined in our impact agenda.

1.1 Impact Agenda

Prevention

Prevention is better than cure. A healthy lifestyle can reduce the risk of brain disorders and delay the effects of aging and brain diseases. The foundation, together with professionals, supports initiatives promoting sustainable brain-healthy behaviors related to sleep and physical activity.

- Sleep: Helping people improve their sleep behavior for better quality sleep.
- Exercise: Encouraging people to be more physically active.

Treatment

Over 4 million people in the Netherlands suffer from brain disorders, and for most diseases, there are no solutions yet. The foundation, in collaboration with professionals, promotes research and innovations that lead to treatments that can cure, halt, or slow brain diseases, or improve the quality of life for those affected.

- Towards a cure: Slowing, stopping, or curing brain diseases.
- Quality of life*:* Substantially improving symptoms that greatly impact daily life.
- More applicable research results*:* Developing humane measurement models and optimizing the use of data.

Participation

We support people in getting the most out of life. We advocate for a society where mental diversity is embraced, and stigmas disappear. Together with professionals, we create initiatives that enable people with brain disorders to participate in work, physical activity, and leisure.

- Work**:** More people with brain disorders find or keep suitable work.
- Exercise*:* More individuals with brain disorders participate in regular sports and physical activities.
- Leisure: More people with brain disorders join the same activities as those without brain conditions.

2 Aim of the Grant Program

This grant program focuses on developing and advancing treatments that can slow, stop, or even cure brain diseases. The needs of the target group and the advancement of results toward application in healthcare are central to this effort.

The (final) treatments may be pharmacological, technological, or psychological in nature, targeting the disease process. This means the (final) treatment alters how the condition develops over time. Unlike symptomatic treatments, which alleviate symptoms of a condition but do not address the underlying cause, these types of treatments do not qualify for a grant under this program.

2.1 Excluded topics for round 4

- The Brain Foundation has partnered with ZonMw in a new grant program focused on therapeutic applications of psychedelics in psychiatry, so no applications related to this topic can be submitted.
- The Brain Foundation is developing a consortium program on mild traumatic brain injury, so no applications related to this topic can be submitted.
- Proposals on treatment-resistant depression cannot be submitted this call. If you have any questions regarding, please contact us.

2.2 Criteria

Grant applications must meet the following criteria, which are divided into relevance and substantive criteria. Section 2.3 provides more detailed explanations of these criteria. In the appendices, you can read some examples of research projects that meet these criteria.

2.2.1 Relevance Criteria

1. Need-driven: The research addresses a need identified by the target group. This need directs the research.
2. Application-oriented: The project facilitates the application of the results closer to practical healthcare.

2.2.2 Substantive Criteria

3. Brain disorders: The research focuses on one or more brain conditions of a neurological or psychiatric nature.
4. Targeting the disease course: The project involves developing or advancing treatments that can slow, stop, or cure brain diseases. This must involve an identified intervention point that can be substantiated.
5. Development stage: The research is preclinical, translational, or clinical.
6. Human-centered: The research preferably involves patients, patient materials, or models, data, or systems derived from them.
7. Diverse and inclusive: Preference is given to research whose findings provide insights into the diversity of society.

2.3 Explanation of the Criteria

1. Need-driven
   The grant application must be based on the needs of the target group. Involve the target group both in developing the project idea and later in the project application. The target group includes experts, such as (former) patients and/or their relatives.

Phase 1: Project Idea:

- Check if there is a relevant knowledge agenda, developed by a patient and/or relatives' association, containing research priorities and needs that were methodically collected from their constituency. Base your project idea on this.
- If no relevant knowledge agenda exists, consult at least three lay experts for advice on needs and relevance to form the basis of the project idea.

Phase 2: Project Application (if invited):

- Ask lay experts for advice on feasibility, workload, inclusion criteria, and ethical issues regarding the study's feasibility for participants.

2. Application-oriented
   Ensure that project results are directed towards application in healthcare by involving relevant stakeholders.
   - Multidisciplinary collaboration: Involve clinical researchers for preclinical research and vice versa.
   - Other stakeholders: Involve healthcare professionals, business developers, clinicians, insurers, or other experts for advice during the development phase.

3. Brain Disorders
   - The Brain Foundation's scope includes the brain, the part of the central nervous system located within the skull. The meninges, pituitary gland, and pineal gland are also considered part of the brain. The spinal cord and eyes, as well as the skull itself, are excluded.
   - The project should focus on a brain disorder with a primary cause in the brain. Conditions with (primarily) a primary cause in the spinal cord, peripheral nervous system, or muscle diseases fall outside the scope of the Brain Foundation.
   - We recommend contacting us early if you are unsure whether the condition for which you wish to submit a project idea falls within the Brain Foundation's scope.

4. Targeting the Disease Course

- The treatments developed or advanced target the cause or progression of the disease, rather than its symptoms. This means slowing, stopping, or curing brain diseases. Treating symptoms without addressing the underlying condition and without changing the course of the disease does not qualify.
- The underlying biological, psychological, or physiological intervention point that the final treatment will target must be identified. This means there must be a plausible scientific rationale, which can be clearly explained and demonstrated.

5. Development Stage
    - The grant application should involve research that is in the preclinical, translational, or clinical phase.
    - It must be substantiated why this type of research is still necessary for realizing the treatment.
    - Fundamental research falls outside the scope of this grant program. The main difference between fundamental research and preclinical research is that fundamental research aims to generate new knowledge and understanding of a phenomenon, whereas preclinical research focuses on developing and testing potential treatments before they are tested in humans.

6. Human measurement models
    - The research should preferably focus on patients, patient materials, or models, data, or systems derived from them.
    - If animal experiments are part of the grant application, it must be thoroughly substantiated how this aligns with the human situation and contributes to the objectives of this grant program. This type of research will only be funded if it is a necessary step toward developing a treatment.

7. Diverse and Inclusive
    - Preference is given to research that provides insights into societal diversity. Consider factors like gender, age, ethnicity, or socio-economic status. By including different demographic and biological factors in the research, the results can be translated into treatments and interventions that are effective for diverse groups, maximizing the impact of the research and ensuring that everyone can benefit.

3 Guidelines for Applicants

3.1 Who Can Apply?

Grants are awarded to knowledge institutions, not to individuals. Applications can be submitted jointly by multiple parties, provided the following conditions are met:

- **Lead Applicant:** Must have a permanent position at a knowledge institution, such as a Dutch university, academic hospital, or university of applied sciences.
- **Co-applicants:** Can be employed at knowledge institutions, healthcare institutions, companies, or act as experts.
- **Number of Applications:** One application can be submitted as a lead applicant, and up to two applications as a co-applicant.
- **Companies:** Can only receive grants for material costs.
- **Previously Rejected Applications:** Cannot be resubmitted. However, project ideas that were rejected may be resubmitted, provided substantial improvements are made.

3.2 Budget

A maximum of €400,000 can be requested per project. The requested budget must be proportionate to the project plans. If there are more fundable project applications than available financial resources, the Brain Foundation may consider working with applicants to organize fundraising efforts to raise the necessary funds. However, no guarantees are provided.

3.3 Budgeting

The budget must provide a clear overview and explanation of all project income and expenditures. Costs can be divided into:

- **Personnel:** The grant can be used for scientific and support staff.
- **Bench fee:** A maximum of €5,000 for PhD students and senior researchers for promotion costs and conference attendance.
- **Materials and consumables:** Only direct material costs will be reimbursed.
- **Implementation costs:** Reserve up to 5% of the budget for METC/CCD approval, implementation of results, involvement of experts, and other required consultations. For certain projects, a positive opinion from the METC or a CCD permit is required. You can budget up to €2,500 for an application.

What is not covered?

- Salary/costs of applicants with a permanent position at a knowledge institution.
- Overhead costs.
- Infrastructure costs.
- Purchase of new equipment.
- Travel and accommodation costs for conferences.
- Training costs.

Personnel

It is possible to use the grant to hire both scientific and non-scientific staff. This may include support staff, such as technical or support personnel, and healthcare personnel directly involved in executing the study.

For personnel costs, the agreement allows reimbursement for the duration of the research to hire researchers and/or support staff. Salary costs for scientific personnel will be calculated based on the 2008 agreement 'Funding of Scientific Research' with the Universities of the Netherlands (UvN), with the ZonMw addendum for UMCs. There is a distinction between UvN institutions (e.g., universities) and NFU institutions (e.g., UMCs).

For UvN institutions, the following functions apply: PhD student, Senior scientific staff, Non-scientific staff (MBO), Non-scientific staff (HBO), and Non-scientific staff (Academic).

- Salary table for Dutch Universities 2024

For NFU institutions, the following functions apply: PhD student, Postdoc, (Medical) researcher, Non-scientific staff (MBO), Non-scientific staff (HBO), and Non-scientific staff (Academic).

- Salary table for Dutch UMCs 2024

(If newer salary tables are available, they may be applied.)

For the reimbursement of other functions, the actual salary component will be used, provided the necessity for the role in the project is well justified in the project application and supported by referees. Such personnel costs include:

- Actual salary costs per year of the personnel directly involved in the project; specify the salary scale, the level of placement, and the working hours factor, and calculate twelve times the gross monthly salary.
- A 40% surcharge on salary costs to cover additional personnel costs. This includes social security contributions, year-end bonuses, a 13th-month salary, vacation pay, unemployment benefits, sickness risk, advertising and recruitment costs, commuting expenses, parental leave and allowances, other leave costs, training costs, HR support, bonuses, domestic business travel, death benefits, social activities, relocation and installation costs, health insurance allowances, and project termination costs.
- If the placement level of the involved personnel is not yet known, the salary costs will be calculated at the midpoint of the scale. If the level is known, the actual placement will be used.
- In project budgets, an annual salary increase of no more than one step and an inflation adjustment of 2% per year should be assumed. Final accounting will consider actual costs incurred, within the maximum grant amount. Significant deviations due to unpredictable inflation may lead to further consultation.

Personal Bench Fee

PhD students (based on a four-year appointment) and senior scientific staff (based on a two-year appointment) will receive a personal bench fee of €5,000 for the entire project duration. For shorter appointments, the bench fee will be proportionally allocated.
The bench fee is intended for promotion costs and (international) conference attendance. The bench fee is allocated to the project executor but made available through the project leader. The

executor is entitled to the bench fee. The use of the bench fee must be agreed upon between the project leader and the executor. For PhD students, this includes the printing costs for the dissertation, so they are not eligible for separate printing cost reimbursement. The bench fee can be used as deemed necessary by the project leader and executor.

Materials, Equipment, and Consumables (specified)
Material costs are reimbursed according to the amounts awarded in the grant. Only direct material costs, as requested and approved, are reimbursed. Infrastructure costs (housing, office automation) and overhead are not covered. Applications for new equipment purchases are not granted, but usage costs for equipment may be included.

Implementation Costs (specified)
You must reserve part of the budget for the additional requirements we set for project execution (the guideline is a maximum of 5%). These costs must be proportionate and may include:

- METC/CCD (see positive opinion METC/CDD section).
- Implementation/embedding of results.
- Involvement of experts, including compensation for their expenses.
- Meetings of one (or more) user committees.
- Consultations with regulators.

Positive Opinion METC/CCD
For certain projects, a positive opinion from a recognized medical ethics committee (METC) or a project permit from the Central Committee for Animal Experiments (CCD) is required. You can find relevant questions in the project application form. It is advisable to check whether a positive opinion is required for your project. According to our grant conditions, a project requiring such approval cannot begin participant or animal inclusion without providing a copy of the approval. For the application of the METC statement or a CCD permit, you can budget up to €2,500, substantiated by applicable rates. Reassessment costs cannot be charged and are at your own expense.

You can find more information about the METC at the Central Committee on Research Involving Human Subjects (CCMO). Information about animal testing permits can be found on the CCD website.

3.4 Co-financing

Expenses that are not covered by the Brain Foundation's requested budget but are still necessary for the project are listed as ‘Other Financing’ in the budget. For contributions from co-financiers (in-kind/in cash), you are required to provide written confirmation from the co-financier for the relevant budget item. Co-financing is not mandatory unless the budget requires it.

A condition for co-financing is that the Brain Foundation is the main financier and approves the co-financing. Financiers whose goals conflict with those of the Brain Foundation or who damage the foundation’s reputation are excluded.

If a grant or other financial contribution for the same activities is requested from other parties, the lead applicant must report this in the project application, including the current status of the assessment of that application(s).

If other financial sources are found for the project application at a later stage, the Brain Foundation must be informed as soon as possible, and a revised budget will be discussed.

Note: Substantially changing the originally submitted plan and budget or failing to inform the Brain Foundation on time may result in reconsideration of a (provisional) grant award.

4 Procedure

4.1 Project Idea

For this grant call, a pre-selection is made using a project idea form for submitting project ideas. In addition to this form, one or both of the following documents must be submitted:

- Knowledge agenda form (as described in paragraph 2.3 under criteria 1, need-driven) with an explanation of how your project idea aligns with it.
- Need-driven advice form (as described in paragraph 2.3 under criteria 1, need-driven).

These project ideas with attachments are submitted to the review committee, consisting of members of the Advisory Council on Science & Innovation (AWI) and members of the Advisory Council of Experts (AvE).
The goal of the project idea step is to select the most relevant, suitable, and promising ideas. Submitted project ideas must meet the established criteria and conditions.
Members of the AWI and AvE from the Brain Foundation assess the project ideas on relevance and whether they meet the established conditions for project applications. The applicants with the most promising project ideas will be invited to submit a project application via our digital application system.

4.2 Project Application

Project applications are evaluated by at least two external (international) experts for quality, feasibility, and relevance, and by experts on relevance, feasibility, and usability for the target group. For the experts, an expert form is filled out in generally understandable Dutch. Based on the comments of the referees and the experts, the applicant may formulate a rebuttal. All comments and the rebuttal will be submitted to the AWI and AvE for advice.
During this writing period, the Brain Foundation offers the EATRIS mentor program.

EATRIS Mentor Program

EATRIS is a European non-profit organization that focuses on improving and optimizing the preclinical and early clinical development of medicines, vaccines, and diagnostics, and overcoming barriers to health innovation.
During the project application writing phase, EATRIS organizes digital sessions where grant applicants receive personal advice from experts on which activities should be undertaken in the project to increase the chances that patients will ultimately benefit from the results. This may include legal regulations or intellectual property (IP) strategies.
Participation in the mentor program is mandatory. This advice is provided by the Brain Foundation to research groups to increase the chances that results find their way to patients. This mentor program is not part of the evaluation process.

4.3 Allocation

Based on the evaluation by external referees, experts, and the rebuttal, the AWI and AvE will issue a final recommendation to the board of the Brain Foundation. The board will then make a decision.

No objections can be raised against the outcome of this procedure.

4.4 Timeline

Project ideas can be submitted throughout the year via aanvraag@hersenstichting.nl. Once a year, a selection process takes place, and selected applicants are invited to submit a detailed project application. The dates for the rounds can be found on the Brain Foundation's website.