

Open subsidy call for preclinical research  
into Frontotemporal Dementia

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*Geef om je hersenen*

Hersenstichting



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# I Introduction

## I.1 Mission and goals of the Netherlands Brain Foundation

There are hundreds of different brain disorders, but you have just one brain. Every day the chance grows that your life will be physically, mentally or socially affected by a brain disorder. We must not let that happen.

The Netherlands Brain Foundation is dedicated to doing everything for healthy brains, to save and restore as many lives as possible. We aim to accomplish this through lowering the mortality and disease burden due to brain disorders, and we feel it is important that people with a brain disorder are recognized and acknowledged.

Our ambitions can be realised thanks to the gifts, donations and bequests from the Dutch public. The current call for proposal for translational preclinical research into frontotemporal dementia (FTD) derives from a private earmarked gift from a private fund.

## I.2 Background and starting point

Every once in a while, private donors knock on our door with a major donation that they want to devote to research into a specific brain disorder. They want their money to contribute to a solution for that particular brain disorder, often one they have been personally exposed to it in their circle of family and friends.

With these earmarked gifts, the Netherlands Brain Foundation works closely together with the donors and researchers to realise an effective result for the intended purpose. Supplementary conditions are attached to these subsidies. For example, shorter intervals between reports, reports written in laymen's language, and site visits by the donors. The Netherlands Brain Foundation considers it important in this case that project leaders keep the origin of the designated-use donation subsidy in mind when conducting the project and help increase the donor's involvement and perhaps that of the general public as well. It is also important to keep the target in mind: the treatment in clinical practice and the patients' needs. That is why we ask applicants to actively contribute ideas about where they are positioned in the chain from 'bench' (laboratory) to 'bedside' (the patient) and what is required for the next step. Involving lay experts and other end users is an essential aspect of this. The Netherlands Brain Foundation will facilitate this process wherever possible.

In our experience, all parties consider that this adds value and is worthwhile.

## I.3 Aim of this call

The aim of this call is financing a research project that targets preclinical research into the disease mechanisms of frontotemporal dementia. This research must contribute towards the ultimate goal: finding new solutions and starting points for the treatment of frontotemporal dementia.

## 2 Guidelines for applicants

### 2.1 What the subsidy should be used for

Projects to be subsidised by the earmarked gift concern scientific research with a maximum duration of 4 years. The call for proposals for this subsidy is limited in 2 points: 1) type and phase of research; 2) content restriction. The project application will be judged by these aspects, and fulfilling each one is a precondition for being awarded a subsidy.

#### 1. Type and phase of research

- The project concerns preclinical research that targets investigation of the disease mechanisms with the intention to study starting points for a future intervention. There is a perspective of translation to the clinic.
- In the case of animal studies, the researcher must be able to justify why 1) the study cannot be done with a model that does not involve an animal; and 2) the chosen animal model is suitable for developing a new intervention for this condition in humans.
- Starting in the application phase and during the course of the project, consideration must be given to potential follow-up steps that could be taken in the development of the treatment for patients. The researcher can spell out the next steps to be taken and the relevant stakeholders required and involve them at an early stage if need be. This will be elaborated during the course of the project in an 'Implementation plan' and will also be decisive for the composition of the users' committee (see page 8).
- The researcher has involved lay experts (patients and/ or their family members) and relevant stakeholders (researchers of other disciplines, health care professionals or health insurers/ regulators) in writing the application and has asked their opinion of how well the proposed research and intended solution would meet the needs of these end users and patients with FTD.

#### 2. Content restriction

- Only research that focuses on investigating studying possible solutions for frontotemporal dementia is eligible. It is the specific wish and commission of the donors that this research into the disease mechanisms will work towards solutions for patients: new or improved treatments and ultimately stopping or delaying FTD.
- The project has a research plan to answer the scientific question and hypothesis. The project thus has a clearly delineated 'head and tail' with concrete deliverables. The plan in the application guides the conduct of the study.
- The researcher can clarify how her research contributes to the solution for the treatment of the brain disorder.

## 2.2 Who can apply

This form of subsidy targets a concrete objective: developing new disease-modifying treatments. It is not tied to one person, and several applicants can apply together as part of a multidisciplinary collaboration<sup>[1]</sup>. It is also possible to employ personnel using this subsidy. They can be supportive personnel like technicians/ support staff, or doctoral students, or postdocs/fellows.

To promote the feasibility and workability of the projects, conditions applicable to the applicants have been formulated:

### Conditions for the applicant(s) and the study team:

- The researcher(s) have a doctorate degree and are working at a Dutch knowledge or care institution (polytechnic, university/ UMC) or research institute (RIVM, TNO, KNAW, NWO institute).
- Each main applicant may only be involved in one application. Each person may be involved in at most two applications, and is the main applicant in only one of them. One exception to this rule involves project members with a supportive role such as, for example, statisticians, ethicists, heads of GMP facilities and comparable roles.
- The applicants must be able to prove that they have the relevant experience with the topic and the type of research.
- The project group may be expanded and preferably is interdisciplinary (e.g. collaboration between clinical and non-clinical researchers). All disciplines that are relevant for the study are included; clinical and non-clinical researchers work together.
- Participating corporations are not eligible for funding.
- Earlier applications rejected by the Netherlands Brain Foundation may not be re-submitted without revision. Proposals being resubmitted must have undergone substantial changes based on the feedback from the earlier rejection.

## 2.3 Budget

The available budget for this earmarked gift project is **€ 200,000**.

The subsidy covers in principle the researchers' salary and the cost of the research. You should reserve a small portion (max. 5%) of the budget for the activities listed on p. 8 under point 5.3 (implementation plan and users' committee). An additional bench fee of €5000 may be reserved for dissemination purposes. Requests to purchase equipment will not be honoured. Nor will requests for training expenses, travel expenses for conferences, etc.

### Budget

The budget provides insight into all of the project's income and expenditure. It is accompanied by an explanation of each item.

- The calculation of the amount of a salary (including overhead expenses) is based on the Scientific Research Funding Agreement 2008 arranged with the VSNU and the addendum of ZonMw for UMCs:
- Salary table ZonMw- NFU 2017:  
[https://www.zonmw.nl/fileadmin/documenten/Corporate/Berekening\\_G\\_posten\\_met\\_sal\\_pei\\_1\\_01-08-2017\\_tbv\\_NFU.pdf](https://www.zonmw.nl/fileadmin/documenten/Corporate/Berekening_G_posten_met_sal_pei_1_01-08-2017_tbv_NFU.pdf)
- Salary table ZonMw- VSNU 2018:

[https://www.zonmw.nl/fileadmin/zonmw/documenten/Corporate/Subsidies/Berekening\\_G\\_posten\\_m et\\_sal\\_peil\\_01-07-2018\\_def.pdf](https://www.zonmw.nl/fileadmin/zonmw/documenten/Corporate/Subsidies/Berekening_G_posten_m et_sal_peil_01-07-2018_def.pdf)

### **Co-financing**

Items that do not fall within the budget requested from the Netherlands Brain Foundation, but are required for the project, are listed as 'co-financing' in the budget. We ask you to add to the relevant budget item a written confirmation from the co-financier for cash sums they supplied.

Co-financing may be desirable for large projects. Co-financing can come from the applicant's own organisation, collaboration partners in academia, government, research organisations or corporate funding. Co-financing can be arranged by partnering with other funds or, for example, ZonMw. There is the condition that the Netherlands Brain Foundation is the main financier and that this is acknowledged, while including the result of other subsidy applications.

If a subsidy or other financial contribution is requested for the same activities from third parties, the main applicant must state this in the application, along with the status of the evaluation of the other application(s).

If other financial sources for the project application are found at a later time, the Netherlands Brain Foundation must be informed of this as soon as possible, and a potential budget adjustment will be discussed.

NB: a substantial amendment of the originally submitted plan and budget or not informing the Netherlands Brain Foundation promptly can lead to the award/preliminary award being re-evaluated.

## **3 Procedure**

### **3.1 Selection project applications**

#### **Project applications**

The project proposal must be written in clear and comprehensible English (the content of the application intended for reviewers) and Dutch (the summary for lay experts/patients). See appendix 4.1 for tips. Project proposals must be submitted into the online subsidy system of the Netherlands Brain Foundation.

The proposals are evaluated by at least two specialist external (international) reviewers for their quality, feasibility and relevance, and a panel of end users checks the usefulness of the result for lay experts/ patients. Based on the reviewers' comments, the applicant can prepare a rebuttal. This will be submitted for advice to the Science and Innovation Advisory Board (Adviesraad voor Wetenschap en Innovatie, AWI). Given its own final opinion and the evaluation by the reviewers and end users, the AWI will present recommendations for a subsidy award to the MT of the Netherlands Brain Foundation.

#### **Subsidy award**

The director of the Netherlands Brain Foundation takes a decision based on the AWI's recommendations. No appeal is permitted against the decision. In the case of an even ranking of projects, those projects with more communicative and fundraising strengths are preferred for the subsidy award.

## Timeline

This round for a designated-use donation is separate from our regular open calls and therefore follows a customised pattern.

Deadlines are:

- Deadline for submitting application: 12:00 on Monday, 1 April 2019
- Awarding decision: July 2019

## 3.2 Evaluation criteria project applications

### Criteria for reviewers

#### **Quality** *Quality of the research and the researchers*

- The project proposal is of good, very good or excellent quality.
- The applicant(s) has/have the right qualifications to complete the project properly.
- The research builds on a sound foundation/ rationale from the literature and experiments.
- If it involves an animal study, there is sound support for the use of it and the suitability of the animal model for researching this condition and the development of a new intervention for this condition in humans.

#### **Relevance**

*Relevance for the research programme and work field of the Netherlands Brain Foundation*

- It fulfils the needs of the target group, and representatives are involved in advising on and writing this application.
- It is expected to have a relevant positive effect (clinical) for the intended target group, and the intervention is expected to have a clear added value compared to the existing interventions.
- It focuses on a large target group or has a considerable positive effect on a small target group.
- It provides for taking the next step / safeguarding / implementation of the results.

#### **Feasibility**

*Feasibility of research and intended subsequent trajectory to clinical practice*

- The project is feasible in terms of time, money and other means.
- The implementation plan presents a realistic step-by-step plan of the trajectory from the study to the patient.
- The applicant and the project are well embedded in the relevant field.

### Criteria for lay experts/patients

- Usefulness of the result for lay experts/patients.
- Involvement of lay experts/patients in formulating the research question and study design and the extent to which their advice and needs were taken into account.
- Societal and clinical relevance; relevance of the research and the intended intervention for the patient's needs.
- Planned involvement of lay experts in conducting the research.
- Burden of the study for lay experts/ patients.
- The laymen's summary is short and concise and written in easily understood Dutch.

### 3.3 Criteria for conducting the project

This section contains information about the Netherlands Brain Foundation's procedure for initiating and following up projects.

Please refer to the manual for researchers for the general subsidy conditions. Applicants receive the manual once their project is granted a subsidy.

- The research must start within 9 months of the subsidy being awarded, otherwise it will be withdrawn.
- The research can only start after the Netherlands Brain Foundation has received a copy of the approval from the Medical Ethics Committee or Central Committee for Animal Testing. Please apply for this in time.

#### Milestone planning

The Netherlands Brain Foundation wants project leaders to work with a milestone planning, because it is an effective project management tool. A milestone planning:

- gives insight into the end result and the path to be followed by anyone implementing it and the office of the Netherlands Brain Foundation;
- gives insight into critical decision moments and interim results during the project, e.g. how different activities are linked;
- provides an overview for monitoring the progress with the project and the budget, allowing effective adjustment or guidance where necessary.

The achieved deliverables in the milestone planning ultimately determine the payment of the subsidy instalments.

#### Implementation plan *(see also third bullet point on page 4)*

The Netherlands Brain Foundation wants project leaders to work with an implementation plan, because this is a tool for the continuing development of the project results, distributing knowledge and achieving an impact. It does not want the results to be left on a shelf after the end of the research project, but brought closer to application in patients. It has prepared a template which, by completing it together with the relevant stakeholders, can facilitate further development (see below; users' committee).

After you have outlined the different target groups, investigate for each one:

- what benefit does implementation have for them?
- what will the implementation cost them?
- what do they need to know, think and do?
- how will you manage to achieve this?

By answering these questions, you can determine which **actions** are desirable or necessary for which **target groups** at what **moment** for a sound implementation of the project results.

#### Users' committee *(see also third and fourth bullet points on page 4)*

The Netherlands Brain Foundation wants project leaders to set up a users' committee to improve the chance of applying the project results. Users are people who can apply the results of a project. They could be patients or informal carers, or professional users such as caregivers or researchers. The Users' committee will meet several times during the course of the project. The frequency of these meetings will be set before the start of the project. Members of the Users' committee are meant to ensure that the implementation of the results is always kept in mind during the conduct of the project. They may also be asked to encourage the application of the results after the study. The Users' committee has an advisory role, not an evaluating role.

### **Publication and open science**

The results of research subsidized by the Netherlands Brain Foundation must be published in international scientific journals. The Netherlands Brain Foundation expects even neutral or negative results from effectiveness studies to be published (or the researchers must show that they made a demonstrable effort to have them published). The preferred route is for results from this research to be published on an open access basis

( <http://www.gezondheidsfondsen.nl/wordpress/wp-content/uploads/2018/09/Open-Access-standpunt-okt-2018.pdf> ).

### **Communication**

In addition, the applicant must be prepared to communicate about the results through other channels in agreement with the Netherlands Brain Foundation and raise joint funds for the Netherlands Brain Foundation. The aim is to augment the societal impact by distributing the results, scientific education (acquainting a broader public with scientific insights and enthusiasm for science), fund-raising, accountability and transparency (making it clear to target groups how the money is being spent, what the intended result is). Feedback and transparently providing information about the study in laymen's terms is especially important in this case because this research is being financed by an earmarked gift.

## 4 Appendices

### 4.1 Appendix I Tips for writing for lay experts

When preparing a Dutch application for lay experts (patients and their informal carers), it is important to ensure that they understand your project proposal so they can make a proper judgement of its feasibility and relevance. Answer the questions briefly and concisely in laymen's language. Here are some useful tips:

- **Use active sentences (subject, finite verb, remainder):** *'We want to investigate/ our research group is going to examine the effect of..'* instead of *'The effect of xxx will be investigated using...'*
- **Use short sentences:** Make the sentences as short as possible. Try to keep to an average sentence length of 10 to 15 words.
- **Avoid inserted phrases:** *'The protein plays a prominent role in frontotemporal dementia, and is also involved in Alzheimer's disease'* instead of *'The protein, that is also involved in Alzheimer's disease, plays a prominent role in frontotemporal dementia.'*
- **Avoid text in parentheses:** *'Almost all cases of dementia arising before 65 years of age are caused by hereditary factors'* instead of *'Research has revealed that (almost) all cases of dementia at a young age (<65 years) are caused by hereditary factors.'*
- **Explain medical/scientific terms in laymen's language:** like *'protein'* instead of *'Amyloid-Beta-42'*, *'mental faculties'* instead of *'cognition'*, *'link'* instead of *'correlation'* and *'has an effect'* instead of *'statistically significant'*.
- **Use visual language or recognisable examples:** *'This process is comparable to a chain letter with which the sender (APP) sends one message to the recipient (tau) through a series of letters (message proteins).'*
- **Do not explain the method or results in too much depth:** *Do not explain how it works exactly in chemical, physical or statistical terms. Explain the method briefly: we do 'this' test to show 'that'.*
- **Finally:** Let someone who is not scientifically trained have a look at the completed application form: do they understand it?

### 4.2 Hints for recruiting participants for brain research

Are you looking for Dutch patients or healthy persons for a scientific study or questionnaire? Hersenonderzoek.nl brings you in contact with a variety of suitable participants for your study. Hersenonderzoek.nl is an online register with over 15.000 people that have applied and are interested to participate in research. For academical researchers access to this facility of free! More information: [info@herenonderzoek.nl](mailto:info@herenonderzoek.nl)

Link: <https://herenonderzoek.nl/voor-onderzoekers/>