

Request for Applications

Clinical Research and Intervention Investigator Awards for Parkinson's Disease 2011

Issued by:

The National Parkinson Foundation
1501 NW 9th Avenue
Miami, Florida 33136

1. Introduction

1.1. Program Goal

The National Parkinson Foundation (“NPF”) is pleased to issue the following Request for Applications (“RFA”) with the goal of funding clinical investigations in several specific areas of Parkinson’s disease research led at NPF Centers of Excellence (“COE”). This RFA will provide support for well-designed clinical research that addresses comparative effectiveness of treatment, current unmet needs, and/or clinical controversies. Starting with the FY2010 grant cycle, NPF revised its model of grant funding in order to ensure that funding goes to the best research addressing the greatest unmet needs. In keeping with this model, this RFA will fund programs based on scientific merit, as determined by the NPF’s Clinical and Scientific Advisory Board (“CSAB”) in a peer-review process.

1.2. Eligibility and Funding Considerations

Applications will be accepted from any principal investigator affiliated with a currently certified NPF COE or a member of the NPF Care Consortium (“Applicant” from an “Eligible Institution”). Investigators not from Eligible Institutions are invited to participate as collaborators. Total grant funding is dependent upon quality of applications; however, NPF anticipates funding between \$1-\$2 million over a two-year period. Individual grants will be limited to a maximum of **\$250,000 over a period of up to two years.**

1.3. Dates and Deadlines for Applicants

The following are the key dates for this RFA:

Release date.....	August 12, 2010
First conference call.....	12:00 noon EDT, September 24, 2010
Second conference call.....	12:00 noon EST, October 29, 2010
Application deadline.....	6:00 pm EST, December 10, 2010
Review process.....	January 2011 – March 2011
Anticipated award announcement.....	On or before April 15, 2011

Between issuance and the deadline for submission, there will be two conference calls during which questions related to the format will be addressed. Dial-in numbers and call details will be distributed to COE directors and coordinators and also posted to the e-mail list at NPFProgramAnnouncements@groups.yahoo.com (collectively, the “Announcement List”). All applicants are invited to subscribe to this list. A summary of questions and answers posed during the conference calls and all announcements relevant to this RFA will be distributed on the Announcement List. While Applicants are not required to subscribe to it, the posting of an announcement to the Announcement List will be considered sufficient for any clarification of terms of this RFA.

2. Program Details

Investigators from Eligible Institutions are invited to submit grant applications to conduct novel or critical clinical research offering the promise of improving care for or understanding of PD. Proposals should focus on well-designed and rigorous hypothesis-driven research conducted in a clinical setting. As mentioned above, applications will be primarily evaluated on clinical relevance and a proposal to meaningfully test a clearly articulated and well supported hypothesis. A power analysis and review of potential avenues for the introduction of bias and mechanisms for its reduction should be included. The proposed research should attempt to: (a) resolve a clinical controversy, (b) advance a promising therapy, or (c) establish a methodology that will result in a better understanding of PD in a clinical setting. Applications should include detailed references and, should they draw upon unpublished data, should include such data (with confidential or proprietary data specifically identified as such in the header of each page on which it is included).

2.1.Proposal Focus Areas

Applications are preferred that either (1) contrast the comparative effectiveness of a therapy, intervention, or technique versus an existing standard, or (2) compare the effectiveness of a therapy, intervention or technique between two different populations. For studies of sub-populations of patients with PD (such as those of a specific ethnicity or with a particular comorbidity), reviewers will evaluate clinical relevance based on (a) the number of individuals represented and (b) the relative underrepresentation of that segment in the literature. Areas of interest to NPF include (but are not limited to):

1. Clinical interventions in sleep, speech, pain, sexual function, gastro-intestinal distress, or cardiac function.
2. Clinical interventions in mood or cognition.
3. Clinical interventions in swallowing and/or therapies to prevent or treat aspiration pneumonia.
4. Clinical interventions in averting or reducing trauma from falling.
5. Biomarkers and clinically applied genetics with relevance to a broad clinical population.
6. New or novel studies of gender, genetic, cultural or ethnic differences in the incidence, presentation or course of PD or responses to therapies or interventions that address an issue of clinical importance at NPF COEs (i.e., in a population regularly seen at several NPF COEs).

Studies of interventions should investigate new or novel approaches.

2.2 Areas Not Appropriate for this Program

Proposals for research without direct clinical relevance will not be considered. All research should be conducted in a clinical setting and should involve patients. All proposals must include data-driven evaluation of the study topic, and proposals without data collection and statistical evaluation will not be considered.

3. Funds Available

NPF anticipates funding between \$1-\$2 million over a two-year period. As always, funding is dependant upon the quality of applications received and an assessment of their impact on the field.

3.1.Funding Considerations

NPF will consider proposals seeking funding for periods of two years or less. Applications should include detailed budgets and each budget item should be clearly described. There are no limits on the number of grants by any one institution but each grant is limited to no more than \$250,000 over the two-year period. The grants cannot be used to purchase equipment or support conference fees or travel except for travel to an Eligible Institution collaborating on the research project. Indirect costs will not be funded.

Applicants should submit project plans, including a detailed budgetary timeline and critical milestones for completion over the course of the research. Projects should include at least three milestones prior to project completion (e.g., completion of subject recruitment, completion of clinical phase, etc.). Each milestone will require the timely filing of a detailed report.

3.2.Eligibility to Receive Funds

The principal investigator must be a clinical investigator associated with an Eligible Institution and the management of the grant budget and reporting must be done at the institution. Principal investigators must meet their institution's criteria for eligibility to receive grants and oversee expenditures. Post-

doctoral fellows, fellows, and students cannot serve as a principal investigator. Further, each application must be co-signed by the institutional officer responsible for grants and contracts. Applicants must reasonably expect to have Institutional Review Board (IRB) approval shortly after the award date and applications should include the date of or an estimated date for IRB approval in the timeline.

4. RFA Process

4.1. Application Submission Process

Applications will be submitted electronically at www.npfgrants.org. Registration is required. After registering, applicants will receive e-mails acknowledging registration and containing the user ID and password. After authenticating, users can change their password in the My Profile section of the main menu. General information, such as institution, contracting contacts, IRB approvals, and such, will be entered directly into the online form. Also, information for the payment of grants will be provided via the form. All the remaining application should be assembled and uploaded as a single PDF document formatted in accordance with NIH guidelines (http://grants.nih.gov/grants/writing_application.htm) and should include no more than ten continuous pages including the budget. Applications should provide at most one page for specific aims and the remainder of the application (nine pages), should cover background, preliminary data, details of proposed experiments, budget, and references. NIH style biosketches for each investigator should be attached in an appendix. Note that applications will be reviewed on the basis of the content of the first ten pages of the application and that content included in appendices will not be included in the review. Investigators are responsible to ensure that the first ten pages of the PDF application include all the relevant information for review. Applications submitted that exceed length limits or include any appendixes other than the biosketches of key personnel will not be reviewed.

Note:

- Use an Arial, Helvetica, Palatino Linotype, or Georgia typeface, a black font color, and a font size of 11 points or larger. (A Symbol font may be used to insert Greek letters or special characters; the font size requirement still applies.)
- Type density, including characters and spaces, must be no more than 15 characters per inch. Type may be no more than six lines per inch. Use standard paper size (8 ½" x 11). Use at least one-half inch margins (top, bottom, left, and right) for all pages. No information should appear in the margins.

4.2. Review Criteria

Applications will be reviewed first to ensure compliance with the application guidelines including an evaluation of the proposed process with consideration of the milestones as appropriate check-points for progress against budget. Applications that meet these structural requirements will be evaluated for scientific merit. This review of scientific merit will consider the depth of understanding of the state of the field, an evaluation of the likely impact of the study, and the study design. Proposals should provide

sufficient detail to facilitate each review. Impact of the study on the management of PD will be an important component of review.

4.3. Review Process

Applicants are welcome to ask questions on the conference calls or submit questions to NPF regarding developing applications that will meet the RFA's administrative requirements, including the selection of milestones. While NPF will hold all project details in confidence, general details of any answered question may be made available to the entire applicant pool. NPF's goal in this is to maximize the number of applications that qualify for consideration in the scientific evaluation and therefore questions are welcome. Applicants are requested to first review the FAQs prior to submitting a question. As they are posted, FAQs will be published on the Announcement List.

After receipt of applications, an administrative review will be conducted in which compliance with the requirements will be assessed. At the same time, the chair of the CSAB will review the subject matters of applications. The CSAB will schedule a meeting in February, 2011, and ad-hoc members will be invited to provide necessary expertise to cover the subjects of applications that fall outside the expertise of the standing members of the panel or if the appropriate member has a conflict of interest. Applications that pass the administrative review will be scored by the CSAB for relevance and merit. Awards will be based on the relative scoring of applications based on this review. Note that scoring will include consideration for applications that advance NPF's priorities for research.

All award decisions made by the NPF or its designated agents under this RFA will be final.

4.4. Conflicts of Interest

Committee members with a conflict of interest will be excluded from discussions of the conflicted application and, at the discretion of NPF and the chairman, other applications. NPF will have sole discretion in resolving issues of conflict of interest. NPF's goal is to eliminate the appearance of a conflict of interest as well as actual conflicts of interest and will endeavor to take steps to do so; however, it retains its discretion as sole arbiter of any conflicts that arise.

5. Agreements between Applicants and NPF

5.1. Confidentiality

All applications and all information supplied with applications (collectively, "Confidential Information") will be treated by NPF with the same care with which it handles its own confidential information. NPF will destroy this Confidential Information for unsuccessful applications upon the completion of the review; this will be no later than that date that accepted grants are awarded. Confidential Information cannot be either disclosed or used to create or influence derivative works without the permission of the Applicant. Notwithstanding the foregoing, the definition of Confidential Information shall not include information that can be demonstrated (i) was generally known to the public through no unlawful or unauthorized act by either NPF or its agents prior to disclosure by either NPF or its agents, (ii) was independently developed by any recipient prior to the submission deadline for applications under this

RFA or the demonstrable disclosure of such information to NPF, or (iii) was disclosed to NPF or its agents by another party who has the right to make such a disclosure.

Recipients of Confidential Information under this RFA will be required to take reasonable and lawful steps to keep that information confidential. If disclosure is required to comply with any legal, governmental, or lawful administrative proceeding, the disclosing party will take steps to limit the disclosure, ensure that the party receiving the disclosure will maintain confidentiality, and to inform the Applicant of the disclosure, to the extent reasonable and lawful.

The submission of Confidential Information under this RFA indicates acceptance of a requirement to indemnify NPF for any unauthorized disclosure of Confidential Information provided (a) NPF has taken the steps outlined above as specifically required of it to ensure confidentiality, (b) NPF provides reasonable assistance in efforts to achieve a reasonable settlement with any party reasonably believed to have violated confidentiality, and (c) that NPF has not agreed to indemnify the disclosing party.

5.2.Special Requirements

All Applicants and their co-investigators shall agree to indemnify NPF from any liability for consequences arising out of their research, including, without limitation, safety issues and the possible injury or death of patients regardless of whether or not such risks were foreseeable based on information submitted in their applications. Applicants will indemnify NPF and members of the CSAB acting in their role as members of the grant review committee (the “Indemnified Parties”) and hold them harmless of any liability and any costs and damages associated with Applicants’ work and, without limitation, reasonable attorneys’ fees. Further, Applicants agree to defend, indemnify, and hold Indemnified Parties harmless from and against any such liability, costs, and damages.

5.3.Sharing of Research and Findings

NPF is a public charity and research funded by NPF must be conducted in the public interest. Applicants shall have a right to ownership of the research funded by NPF, but each Applicant shall acknowledge NPF’s right to publish a *summary* of all research findings (“Announcement”) funded under this RFA after completion. Applicants will report on progress (milestones) and issue a separate, final report to the NPF upon the successful completion or the termination of the awarded grant. NPF will publish the Announcement within twelve months of completion of the research or later if requested by the Applicant with reasonable justification for the delay. Reasonable justifications will include that the study was part of a larger, on-going research project that would be affected by the release of the data or that release of the information must be withheld to allow publication in a major journal. Any conflict or disagreement between investigators and NPF will be resolved by NPF at its sole discretion.

The results of the research funded under this RFA will be published as rapidly as reasonably possible. Any public presentation of the research or results by the Applicant or any co-investigator will acknowledge the funding provided by NPF prominently and in such a manner as to make clear that NPF had provided meaningful support for the research, subject to any requirements for acknowledgements in the forum in which the presentation is made. No organization providing less direct funding for the specific research shall be given a more prominent acknowledgement and the acknowledgement of NPF

support shall be done at the same time and/or in the same section, page, or slide as acknowledgement of other funders unless it is done more prominently.

Commercialization of intellectual property arising from research funded under this RFA, including perfecting intellectual property rights, will not be funded through this RFA.

5.4. Clinical Trial Registration

Any clinical trial funded under this RFA will be required to be registered with *clinicaltrials.gov*, *pdtrials.org*, and other appropriate public registries. Registration must be done before recruitment of subjects start.

6. Inquiries

Please do not hesitate to make inquiries to NPF should you have any questions regarding this RFA. Inquiries should be made on the scheduled conference call or via e-mail at programs@parkinson.org.

7. Acknowledgement upon submission

Applicants are required to submit a signed complete copy of this RFA as an appendix to their applications to indicate their acceptance of its terms. If the RFA is signed by only the Applicant, the Applicant is indicating through his or her signature that he or she has secured or will secure the acceptance of these terms by each proposed participant.

Signed,

[Signature]

[Printed name]

[Affiliation]

[Date]

