Request for Applications

Research and Intervention Investigator Awards for Parkinson's Disease 2014

Issued by:

The National Parkinson Foundation
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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. This RFA will provide support for well-designed clinical research that addresses comparative effectiveness of treatment, current unmet needs, and/or clinical controversies. All investigators, both at NPF Centers of Excellence and in the scientific community overall, are invited to apply. This RFA will fund programs based on scientific merit in three focus areas, as determined by the NPF's Clinical and Scientific Advisory Board ("CSAB") in a peer-review process.

1.2. Eligibility and Funding Considerations

Challenges in mid-career funding opportunities are widely believed to be limiting the careers of the next generation of leaders in neuroscience. For this reason, applications to this RFA will be limited to individuals who are assistant or associate professors (or equivalent) at a non-profit research institution ("Applicants"). Applicants should have been previously been the Principal Investigator on one or more NIH, NSF, or PCORI competitive research grants or contracts (at the discretion of the NPF, similar competitive funding from a foreign government or prestigious private foundation may be considered). For applications over US$100,000, the Applicant must have received an R01 or P50 grant prior to applying for funding. Applicants may request in advance of submission that NPF consider another funding mechanism equivalent. Prospective applicants may contact NPF in advance of submission to verify their eligibility.

Applicants must be affiliated with a non-profit research institution with a history of administering scientific grants/contracts from NIH, NSF, PCORI, or other funding agencies with similar grant structures

("Eligible institutions"). 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 by the limits specified under each focus area.

1.3. Dates and Deadlines for Applicants

The following are the key dates for this RFA:

Release date……..10 December 2013

Application deadline…….. 3 March 2014, 6:00 pm EST

Anticipated award announcement…….. On or before 2 May 2014

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. As mentioned above, applications will be primarily evaluated on clinical relevance and a proposal to meaningfully test a clearly articulated and well supported hypothesis. 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. 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

This RFA includes funding opportunities in three focus areas. Applications under focus areas one and three and focus area two will be evaluated separately in two groups.

Focus area one: Cell to cell transmission studies.

Funding of up to $250,000 over two years per award will be available to investigators who wish to conduct research on mechanisms of cell-to-cell transmission of alpha synuclein in Parkinson's disease or models of Parkinson's disease. Such studies must be based on a well-supported hypothesis that the research will directly provide insight into clinical mechanisms of disease.

Focus area two: Database studies.

Funding of up to $50,000 over one year per award will be available to investigators who wish to conduct research of Parkinson's disease by performing hypothesis-driven analyses joining data from multiple data sources, where at least one data source is a well-designed prospective cohort study such as a registry or follow-up study of a RCT cohort. Examples of allowable projects include joining NPF's

Parkinson's Outcomes Project data to information from chart review and combining insight from two studies, especially if there are overlapping populations. Hypotheses must have specific relevance to Parkinson's disease and/or care for Parkinson's disease.

Focus area three: Cognitive change in Parkinson's disease.
Findings from the Parkinson's Outcomes Project have shown that significant differences in two-year cognitive change can be achieved through better care. Cognitive change is for many patients the most troubling aspect of Parkinson's. Funding of up to $250,000 over two years per award will be available to investigators who apply to study a well-supported hypothesis to (a) identify biological mechanisms of cognitive change that may be responsive to interventions, or (b) study the comparative effectiveness of interventions to improve cognition.

2.2. Areas Not Appropriate for this Program

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 approximately $1-2 million over a two-year period. As always, funding is dependent 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. 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; however, a line item for facilities fees may be included under direct costs for up to 13% of the total grant amount.

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 two milestones per year of the project (the final milestone being project completion, and other milestones could be completion of subject recruitment, completion of clinical phase, etc.). Each milestone will require the timely filing of a report upon achievement. A detailed report will be required upon each anniversary of the award date.

3.2. Eligibility to Receive Funds

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 ethical review (either through an IRB or IACUC) approval shortly after the award date and applications should include the date of or an estimated date for approval in the timeline.

4. RFA Process

4.1. Application Submission Process

Applications will be submitted electronically by e-mail to npf-grants@parkinson.org. The 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, and budget. NIH style biosketches for each investigator and references should be attached in an appendix. Each application will be reviewed administratively to ensure that the application conforms to these guidelines. 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 will not be reviewed. Any appendices other than those mentioned above will not be included in the review.

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 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 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. Applications selected based on scientific merit but where the budget is insufficiently justified in the opinion of the reviewers will have the grant amount reduced at the discretion of the reviewers.

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, their co-investigators and/or their institutions (collectively, "Investigators"), accept full responsibility for executing research funded by NPF via this RFA. Such responsibility includes execution of the research in manner consistent with the ethical standards required of clinical research and that all risks associated with this research shall be disclosed to and evaluated by the institutional review board at the institution at which this work will be completed. All Investigators recognize that NPF, its CSAB, and any other individuals involved in reviewing the application (collectively, "Review Panel") are not responsible for evaluating the risks to participants and ethical implications of the research. Investigators accept full responsibility for evaluating and addressing the ethical consequences of their research and also the risks to participants and affirm that a formal process for evaluating these issues exists at their institution and that they will accept responsibility for securing approval to perform their research through this process. By submitting an application, Investigators acknowledge that they accept responsibility for evaluating and addressing risks to participants. Further, Investigators acknowledge that they conceived the experiment and wrote the proposal themselves and that the Review Panel, individually or collectively, did not commission, conceive or design the proposed effort. (Any proposal submitted by a member of the Review Panel does so independent of his or her role as a member of the Review Panel and shall not be considered to be part of the Review Panel for the purposes of this section.) Any feedback received or changes to the protocol requested during the review process shall be considered to be exclusively addressing study design and/or the use of grant funds. For avoidance of doubt, any ethical or safety issues and the possibility of loss, injury or death in the conduct of any project funded under this RFA, whether or not such issues or possibilities were foreseeable based on information submitted in the application, are exclusively and without limitation the responsibility of the Investigators and not the Review Panel. Investigators agree to reimburse the Review Panel, individually or collectively, for reasonable costs including attorneys' fees associated with defending claims against it which are herein defined as responsibilities of the Investigators.

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* 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 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]