

2014 NEURODEGENERATIVE DISEASES PILOT STUDY GRANTS PROGRAM

Sponsored by

Harvard NeuroDiscovery Center
&
Massachusetts Alzheimer's Disease Research Center
&
MGH Neurological Clinical Research Institute

The MGH Neurological Clinical Research Institute, Massachusetts ADRC and Harvard NeuroDiscovery Center have joined forces to fund the best novel ideas for pilot projects aimed at understanding and developing treatments for neurodegenerative diseases. Together, we are pleased to announce a joint call for pilot study applications from investigators within the Harvard community, including the affiliated hospitals and institutions. Grants with a dollar value up to \$40,000 (direct costs) will be awarded for the duration of one year. Between five and eight awards will be made.

We encourage investigators to examine the shared resources and core facilities available within the **ADRC, MGH Neurology Clinical Trials Unit** and **Harvard NeuroDiscovery Center** and to develop applications that make use of these facilities. AD-related projects are also encouraged to be aware of, and utilize data available from the National Alzheimer's Coordinating Center (NACC) (<http://www.alz.washington.edu>) if appropriate. And where appropriate, relevant ALS projects are encouraged to take advantage of the resources available via the NEALS consortium (<http://www.nealsconsortium.org>).

Applications will be judged on the basis of scientific merit, novelty and the value of the project in obtaining preliminary data that could lead to sponsored research (investigator-initiated R01 research grants, career development awards, industry or foundation support). Availability of appropriate facilities and the technical ability to carry out the project in a relatively short time frame are fundamental. Clinical projects as well as basic research will be considered. Priority will be given first to junior investigators, then to senior investigators who are new to neurodegenerative disease research, and finally, to established investigators with a new line of investigation that lacks funding.

Deadlines

RFP announced:	March 6, 2014
Applications due:	April 21, 2014
Recipients announced:	May 20, 2014
Awards start:	June 1, 2014

Guidelines

1. Applicants should have a doctoral degree (MD, PhD, ScD, PharmD, DO, etc), have undertaken or completed formal research training, and (if the study involves human subjects) have documentation of training in the protection of research participants.
2. An applicant who is a Fellow or Instructor must have a sponsor who is recognized as an independent investigator who is or has been actively involved in neurodegenerative research, has a successful record of providing research training and guidance, and is committed to continued involvement throughout the total award period.
3. Applicants may be U.S. citizens or foreign nationals. Foreign nationals who are not permanent residents are strongly encouraged to identify a U.S. citizen who could serve as Principal Investigator on a sponsored study that could be proposed based on data generated from this grant.
4. It is the responsibility of the applicant to obtain all relevant clearances from the Food and Drug Administration, IRB and animal care agencies. In those instances where an IND is needed, please indicate the status of the IND application in your proposal. At the time of application, any necessary IRB and IACUC approvals must at least have been forwarded to the relevant review committees. Approvals must be completed before awards are made.
5. Funding is intended to be flexible. That is, to be used in a manner most useful to the applicant's project, including the applicant's salary and fringe benefits, other personnel, supplies or other uses. Equipment requests will not be considered. Funding can be made for work that is supplemental to an ongoing funded research project.
6. This program does not seek to support fellows or others in need of bridging salary support. This is not a fellowship program, but instead aims to support pilot projects that will test novel ideas and approaches.

Selection Criteria

1. **Significance.** Does this study address an important problem relevant to our understanding, diagnosis or treatment of neurodegenerative diseases? Please note that it is up to the applicant to **clearly demonstrate** the **clinical significance** of the proposed project.

2. **Prospects.** If the aims of the proposed work are achieved, is it likely that a proposal for additional extramural support (federal, industry, or foundation) will be successfully submitted?

3. **Approach.** Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative approaches?

4. **Innovation.** Does the project employ novel concepts, approaches, or methods? Are the aims original and innovative?

5. **Investigator.** Is the investigator or sponsor appropriately trained to carry out this work? In the case of a proposal by a Fellow or Instructor, might the proposed project lead to a career development award?

6. **Environment.** Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment? Is there evidence of institutional support?

7. **Collaborative potential.** Does the study involve the MGH Neurology Clinical Trials Unit, ADRC or

Harvard NeuroDiscovery Center cores or inter-departmental/inter-institutional collaboration across the community? These criteria will be used to prioritize funding decisions among projects deemed scientifically meritorious.

HNDC, MGH Neurology Clinical Trials Unit and ADRC Resources

- ADRC Clinical Core – subject referral
- ADRC Neuropathology Core – access to human tissues
- ADRC Data Management and Statistical Core – longitudinal data and analysis
- ADRC Neuroimaging Core – neuroimages and image analysis
- ADRC Outreach, Recruitment and Education Core – assistance with subject recruitment
- HNDC Enhanced NeuroImaging Core – confocal, multi-photon and wide-field microscopy
- HNDC Advanced Tissue Resource Center – access to laser capture microscopy, DNA/RNA expression analysis, real-time PCR, and miRNA core
- HNDC Bioinformatics Core – access to informatics consultation, training and support.
- HNDC Biostatistics Consultation – statistics consultation and collaboration
- HNDC Clinical Trials innovation Core (support for novel technologies in clinical trials)
- HNDC Laboratory for Drug Discovery in Neurodegeneration (assays/screening/med.chem.)
- HNDC Biomarkers Discovery program repository
- HNDC NeuroBehavior Lab – providing a wide range of behavioral/cognitive tests
- HNDC Research Instrumentation Core
- NCTU/NEALS Clinical Trials Cores:
 - Data management
 - Biostats
 - Project management
 - Study Monitoring
- NCTU/NEALS Biosample Repository

Please visit our websites for further details and core leadership contact information:

Massachusetts ADRC: www.madrc.org

MGH Neurological Clinical Research Unit: www.massgeneral.org/research/researchlab.aspx?id=1255

Harvard NeuroDiscovery Center: www.neurodiscovery.harvard.edu

NOTE: Letters of support from core managers and/or collaborators confirming the availability of the necessary resources for the proposal should be included in the application.

Applications Must Include the Following

1. Research plan (maximum of 4 pages, in a mini-NIH style format). No appendix materials are allowed. Any necessary figures, tables etc must be incorporated into the text.

- Specific Aims (~ 1/2 page)
- Background and Significance (~ 1/2 page)
- Preliminary Studies (~ 1 page)
- Research Design and Methods (study design; description of subjects; data to be collected; analysis plan) (1 page)
- References (1 page max)

2. Ancillary Documents

Applications must include the following pages:

- Detailed Budget (direct costs only) and detailed budget justification (1page)

- Biographical Sketch (for all key personnel)
- Letters of support (if applicable)

Rules and Requirements

1. Applications will be treated as confidential documents.
2. The deadline for the receipt of the application is **5:00 pm on April 21, 2014**.
3. Applications must be submitted electronically to neurodiscovery@hms.harvard.edu. You will receive notification of receipt. In order to preserve the line spacing, figure location and the overall appearance of your application, you must submit your entire package as a **single PDF document. Word files will not be accepted.**
4. Format restrictions:
 - a. Application text must be in Arial or Times New Roman font and can be no smaller than 12-point type. Figures, charts, tables, figure legends, and footnotes must be readily legible.
 - b. Single-spacing is allowed.
 - c. Margins, in all directions, must be at least 0.5 inches.
5. Decisions of the peer-review committee will be final and will be announced mid May 2014.
6. Awardees must participate in the Massachusetts ADRC/Boston University ADC/HNDC annual poster symposium, typically held in January/February each year.

For questions concerning the application process or administrative issues, please contact Nancy Maher at nancy_maher@hms.harvard.edu 617.432.3370.

For questions of a scientific nature, please contact:
Adrian J. Ivinson, PhD at 617.525.5510 adrian_ivinson@hms.harvard.edu or
Brad Hyman, MD, PhD at 617.726.2299 bhyman@partners.org or
Merit Cudkowicz, MD at 617.726.9122 Mcudkowicz@partners.org

Applications must be submitted to neurodiscovery@hms.harvard.edu by 5pm April 21, 2014.

Conditions of the Grant and Funding Sources

1. This joint program draws on funds from three sources:

Massachusetts ADRC funds: To support two or three AD or AD-related projects.

MGH Neurological Clinical Research Institute funds: To support two or three ALS or ALS-related projects.

HNDC funds: To support three projects on any neurodegenerative diseases.

Despite the three funding sources, all applications should be prepared according to the same rules and criteria and submitted electronically to neurodiscovery@hms.harvard.edu by the April 21st deadline.

2. Budget

A draft budget that includes only direct costs is requested. If awarded, a final budget page with indirect costs, if available for a specific project, will be negotiated.

3. Salary and Fringe Benefits

Salary and fringe benefits of the recipient are to be actual costs or for TBN.

4. Reporting

A separate financial report must be maintained by the sponsoring institution for each recipient, and this account must be available for audit.

A final scientific report will be required within 90 days of the end of the grant period.

5. Poster Session

Awardees must participate in the Massachusetts ADRC - Boston University ADC – HNDC annual poster symposium.

6. Publications

All publications, abstracts, posters and other forms of publication that result from a project supported by this award must carry the following acknowledgement: “This research was in part supported by a grant from the Massachusetts Alzheimer’s Disease Research Center (5 P50 AG005134), the MGH Neurology Clinical Trials Unit, and the Harvard NeuroDiscovery Center.”

7. Stipulations

Funding is contingent on the following, where applicable:

- Activation of the study by the investigator’s Institutional Review Board/IACUC.
- IND approval.
- Receipt of certificates indicating human subjects protection training by the PI and all key personnel involved in human subjects research.

9. If the applicant’s project is funded by another source, the applicant is expected to inform us (at nancy_maher@hms.harvard.edu). Funding will be withdrawn unless the funding from another source is used for a supplemental research project.

10. Should a recipient discontinue the research project or leave the designated institution, he or she must notify us within two weeks, and must indicate the reason(s) why.