The MGH Neurological Clinical Research Institute (NCRI) and The ALS Association are pleased to announce a call for phase II clinical trial applications for novel, high-potential treatments in Amyotrophic Lateral Sclerosis. The call for clinical study proposals is intended for academic-industry partnerships, including pharmaceutical, biotherapeutic/biotechnology companies, academic members of the Northeast ALS Consortium (NEALS), and ALS scientists throughout the world. A total of USD $800,000 (direct costs only) in NCRI/ALS Association clinical research support is available.

Potential Phase II clinical trials should include interventions that have:

A. a pharmacodynamics marker that can measure whether pathway of interest has been affected, and
B. a plan to collect samples for biomarker studies.

Applications will be reviewed by a joint NCRI and ALS Association steering committee and will be judged on:
- Scientific rationale and merit, novelty, and the value of the project.
- Availability of appropriate facilities and the technical ability to carry out the clinical study.

Funds will be awarded in the form of infrastructure support provided by NEALS and its Coordination Center, the NCRI, and funds for per subject fee, sample collection, pharmacodynamic marker testing and other trial related costs as needed. Applicants may apply for a combination of any of the following clinical research support services available through NEALS and the NCRI:
- Project Management
- Grants & Contracts Management
- Data Management
- Study Monitoring
- Outcome Measure Development and Training
- Biostatistical Support
- Site Selection, Start Up, Regulatory Document Review, and Ongoing Site Management
The successful applicant will retain control of the trial as well as intellectual property relating to the therapeutic agent being investigated. The NCRI and The ALS Association are extremely well-positioned to work with both academic and industry partners to rapidly bring the best ALS science into clinical testing. Since infrastructure support is provided by this grant, applicants are required to contact NEALS/ALS Association prior to their grant submission to collaborate on the budget portion. Applicants may request the full $800,000 in NCRI/ALS Association research support or may request a smaller amount, depending on the appropriate needs of the proposed study.

**Deadlines:**

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<tr>
<td>Letter of Intent:</td>
<td>May 20, 2013</td>
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<td>Notification to submit full application</td>
<td>June 20, 2013</td>
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<td>Full Application:</td>
<td>August 15, 2013</td>
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<td>Recipients Announced:</td>
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**Background:**

There is an urgent need for better ALS treatments and therapeutic agents. In the United States, ALS affects one in approximately 40,000 people, with 5,000 new diagnoses each year. There is currently one FDA-approved treatment for ALS, Riluzole (Rilutek). The goal of this Request for Proposal is to expedite the process of bringing new treatments forward for testing in people with ALS and to measure if that therapeutic agent is reaching its target.

**About Neurological Clinical Research Institute (NCRI)**

The NCRI at Massachusetts General Hospital serves as a Coordinating Center for NEALS, a non-profit, research consortium committed to the cooperative implementation, timely completion, analysis, and reporting of clinical trials and other research studies aimed at improving patient care and understanding of the disease process of ALS. The SUNY at Upstate NCTU serves as the Outcome Measure and Monitoring Center for NEALS. Together, the three entities have supported/conducted 22 clinical trials in ALS.

**About NEALS**

The Northeast ALS Consortium (NEALS) is an international, independent, non-profit group of researchers who collaboratively conduct clinical research in Amyotrophic Lateral Sclerosis (ALS) and other motor neuron diseases. NEALS mission is to translate scientific advances into new treatments for people with ALS and motor neuron disease as rapidly as possible. NEALS has over 100 member sites in the United States, Canada, Ireland, and Israel.

**About The ALS Association**

The ALS Association is the only national non-profit organization fighting Lou Gehrig’s Disease on every front. By leading the way in global research, providing assistance for people with ALS through a nationwide network of chapters, coordinating multidisciplinary care through certified clinical care centers, and fostering government partnerships, The Association builds hope and enhances quality of life while aggressively searching for new treatments and a cure. For more information about The ALS Association, visit our website at [www.alsa.org](http://www.alsa.org)
Selection Criteria
NCRI and The ALS Association joint steering committee will evaluate proposals based on the following criteria:

1. **Significance:** Does the proposed study bring forward a new potential therapy for people with ALS? Can the proposed clinical trial be initiated expeditiously? Does the study have a pharmacodynamics marker that can measure whether pathway of interest has been affected? Is there a proposed plan to collect samples for biomarker studies? Applicants should demonstrate that there is sufficient preclinical data (pharmacology and toxicology) to support initiation of the proposed trial.

2. **Approach:** are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the study? Have potential problem areas and alternative approaches been considered?

3. **Innovation:** Does the clinical trial employ novel concepts, approaches, and/or methods?

4. **Investigator/Sponsor:** Is the investigator or sponsor appropriately trained/qualified to carry out the study?

5. **Environment/Collaborative Potential:** does the scientific environment in which the work will be done contribute to the probability of success? Does the proposed study take advantage of useful collaborative arrangements? Will the study utilize resources available through available the clinical trial cores?

Available NEALS Clinical Trial Cores
- Project Management
- Grants & Contracts Management
- Data Management
- Study Monitoring
- Outcome Measure Development and Training
- Biostatistical Support
- Site Selection, Start Up, Regulatory Document Review, and Ongoing Site Management
- Site Trainings: Good Clinical Practice, Regulatory Compliance, and Site Management

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

NCRI: [http://ncrinstitute.org/](http://ncrinstitute.org/)

**Should you be invited to submit a full application, application forms will be provided and applications must include the following:**

1. **Research Plan** (maximum of 7 pages)
Abstract

Specific Aims

Background and Significance

Preliminary Studies

Research Design and Methods (study design; participant description; data to be collected; plan of analysis)

Supportive Documentation including a proposed timeline demonstrating that the trial will be conducted expeditiously

References

Appendix materials are allowed including material to demonstrate that the treatment is ready for testing in humans. For studies requiring an IND, please indicate the status of the IND application in the Request for Proposal application.

2. Budget and Ancillary Documents

- Applicants are strongly encouraged to contact NCRI/NEALS prior to submission to discuss budget planning. Tara Lincoln (617) 724-7398 tlincoln@partners.org
- Budget and budget justification – direct costs only
- Biographical Sketch of key personnel

Rules and Requirements

1. The application deadline is 5pm EST on August 15, 2013. Applicants must be submitted electronically in a single PDF document to researchgrants@alsa-national.org

2. 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.

3. Decisions will be final and announced by October 2013.

Awardees will be invited to present their proposal at the NEALS Annual Meeting on October 3rd, 2013 in Clearwater Beach, FL.

Applications will be treated as confidential documents.

Questions about the RFP, NCRI, NEALS or The ALS Association capabilities are encouraged. Inquiries may be directed to:

Tara Lincoln
NEALS Program Manager
tlincoln@partners.org
617-724-7398

And
Conditions of the Grant

1. Proprietary Rights
   The Principal Investigator/Sponsor will maintain full control of scientific work and all corresponding responsibilities. A scope of work will be agreed upon by all parties prior to initiation of funding. If necessary, confidentiality agreements will be incorporated.

2. Reporting
   For all projects, quarterly reports and a final report are required.

3. Presentation
   Awardees are invited to make a platform or poster presentation at the 12th Annual NEALS Meeting on October 3rd, 2013.

4. Publications
   All publications, as well as abstracts of presentations at scientific meetings, posters, or any other form of publication that results from a study supported by this award must carry the following acknowledgement: “This research was in part supported by a grant from the ALS Association, NCRI and the Northeast ALS Consortium (NEALS).”

5. Funds
   Funds will be restricted until evidence of IND (or IND exemption) is presented. Additional restrictions will be in place until IRB approval is obtained.