



## **Announces**

**The 2010**

### **Request for Applications for Basic, Clinical, and Translational Neuropsychiatric Lupus Research**

**RFA 010-02 (NP)**

**Award Amount: \$100,000**

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**Letter of Intent Deadline: April 19, 2010 at 5 p.m. EST**

**Application Deadline: June 18, 2010 at 5 p.m. EST**

**Award Date: September 6, 2010**



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## **INTRODUCTION**

Neuropsychiatric lupus (NPSLE) refers to manifestations of lupus within the central or peripheral nervous system that contribute to increased morbidity and reduced quality of life. Definitions and diagnostic criteria relevant to NPSLE have been utilized heterogeneously. This makes the reproducibility of findings and direct comparisons of studies from different groups difficult.

In 1999, the American College of Rheumatology (ACR) provided revised nomenclature and case definitions for 19 NPSLE syndromes to help facilitate the adoption of standard language and diagnostic criteria in the study of NPSLE. ACR's report indicates that, according to data published by different groups of investigators, the following NPSLE manifestations are most commonly found: cognitive dysfunction, headache, mood and anxiety disorders, cerebrovascular disease, seizure or seizure disorders, and neuropathy.

This RFA seeks applications whose research outcomes will significantly enhance current understanding of common manifestations of NPSLE in adult and pediatric populations, including cognitive dysfunction, headache, mood and anxiety disorders, cerebrovascular disease, seizure or seizure disorders, and neuropathy, as defined by the 1999 American College of Rheumatology definitions of NPSLE manifestations. This RFA focuses on investigations of these common NPSLE manifestations and assumes the use of case definitions provided by ACR.



## **RESEARCH OBJECTIVES**

This award is intended to provide start-up funds for pilot studies whose outcomes will facilitate the development of large-scale studies of and help springboard researchers toward elucidation of issues relevant to:

- The development and validation of tools (including biomarkers and advanced brain imaging techniques) to measure biological NPSLE disease activity in real time, as well as the etiology, pathogenesis, prognosis, and damage associated with NPSLE, and their impact(s) on quality of life. Of particular interest is the identification and validation of biomarkers that change over time and/or robustly correlate with NPSLE disease activity (as related to one of the aforementioned common NPSLE manifestations of lupus), and appropriate outcome measures.
- The study of NPSLE lupus patients whose common NPSLE manifestations (as described above) are relatively homogeneous, well-defined, persistent, and/or arise from common biological pathways in order to facilitate the development of well-defined biological markers and study endpoints that will aid the movement of research towards clinical trials.
- Identification of the psychological, psychiatric, or behavioral impacts of NPSLE manifestations (as described above) or underpinnings on quality of life, well-being, affect, cognition, and decision-making processes. Studies aimed at detecting risk (such as depression and/or anxiety) and protective factors (such as the role of social support, positive affect, participation in an educational program) relevant to the psychosocial stress of having a chronic illness associated with NPSLE, and the identification of psychiatric comorbidity, are of particular interest.



## **ELIGIBILITY**

Applications will be accepted from tenure-track Principal Investigators possessing the rank of Assistant Professor (or equivalent) or above who directs a laboratory dedicated at least in part to the investigation of lupus at a U.S. academic, medical, or research institution. Applicants should not already possess a substantial grant award (e.g. RO1 or equivalent) to pursue the aims described in their lupus-specific research proposals. Applicants whose home institutions are in Canada or Mexico may apply if collaborating (e.g. co-PI) with a tenure-track Principal Investigators possessing the rank of Assistant Professor (or equivalent) or above who directs a laboratory dedicated at least in part to the investigation of lupus at a U.S. academic, medical, or research institution.

## **FUNDING OPPORTUNITY**

RFA 010-02 (NP) will provide 1 one-year grant award in the amount of \$100,000.



## **LETTER OF INTENT & ONLINE SUBMISSION**

Letters of intent (LOIs) must be submitted online via Altum's proposalCENTRAL by 5 p.m. EST on April 19, 2010. This submission represents a binding letter of intent. The title, abstract, aims, methods, or other aspects of the proposed research cannot be altered during submission of the full application. Responses to LOI submissions will be sent via proposalCENTRAL within two weeks of LOI submission.

Letters of intent must contain the following information:

- Full contact information (name, highest degree, title, full mailing address, phone number, fax number, and email address) for the applicant and co-PI(s), and the name(s) of institution(s) where the research will be conducted.
- Project title and dates of proposed project.
- Scientific abstract (250 words or less) containing the following components: nature of the proposed study, and brief commentary outlining the background and significance to lupus research of the proposal.
- Submit the letter of intent via your proposalCENTRAL account at <https://proposalcentral.altum.com/Login.asp>.



## **APPLICATION MATERIALS & ONLINE SUBMISSION**

Click here to visit the LFA National Research Program homepage:

<http://www.lupus.org/research>.

The Lupus Foundation of America, Inc. (LFA) utilizes an electronic grant submission process. All interested grant applicants must submit their full application packages through proposalCENTRAL: <https://proposalcentral.altum.com/Login.asp>.

Applicants are encouraged to register and complete a professional proposalCENTRAL profile as soon as possible. Applicants should ensure that their grants and contracts office has registered their institutional, financial, and signing officials with proposalCENTRAL.

A proposalCENTRAL helpline is available to answer questions from applicants, Monday through Friday, 8:30 a.m. – 5:30 p.m. EST. Customer support is available via phone at 1-800-875-2562 or by email at [pcsupport@altum.com](mailto:pcsupport@altum.com).



## **REQUIRED COMPONENTS OF GRANT APPLICATION**

- Complete online application packages (with all required attachments and supportive documentation) must be submitted by 5:00 P.M. EST on June 18, 2010 via Altum's proposalCENTRAL online system. Hard copies will not be accepted under any circumstances. However, in order for a submitted application to be considered complete, each applicant must mail a CD containing electronic copies of all required application documentation to the Research Program Manager by 5:00 P.M. EST on June 18, 2010.
- The online application must include the following components:
  - a) Cover letter (printed on institutional letterhead), including:
    - Name, date, address, and original signature of the applicant
    - Project title and dates of proposed project
    - Status of Institutional Animal Care and Use Committee (IACUC) and/or Institutional Review Board (IRB) approval
    - Statement that all proposed research will be conducted according to the rules and regulations of the U.S. Department of Health and Human Services.
  - b) Grant Application cover page, including:
    - Project title
    - The following must be provided for the applicant, as well as the institutional official and signing official: name, highest degree, title, email address, direct phone and fax numbers, and institutional street address
    - Dated original signatures from the applicant and institutional signing official
    - Dates of proposed project
    - IRB and/or IACUC approval date, as well as Human Subjects Assurance Number and/or Animal Welfare Assurance Number (If these are not available at the time of application submission, they will be required upon acceptance of the award and prior to disbursement of any funds to the sponsoring institution)
    - Institutional grant administrator's (if different from the institutional official and signing official) name, highest degree, title, email address, direct phone and fax numbers, and institutional street address

- c) Research proposal abstract and lay summary:
- Scientific abstract (250 words or less)
  - Lay summary of proposal for LFA's use in press releases (250 words or less)
- d) NIH-formatted Biosketches from the applicant, co-PI(s), and any other research personnel that will have a major role in the design, execution, analysis, interpretation, or writing related to the proposed studies (these should include Positions and Honors, Peer-Reviewed Publications, as well as Current and Pending Research Support)
- e) A statement from the co-PI(s) indicating the nature, workings, and extent of collaborative interactions and research efforts to be implemented to accomplish the proposed research.
- f) A single-spaced proposal narrative (with one-inch margins, typed in 12-point Times New Roman font) of no more than eight pages (excluding the abstract and literature cited pages), including each of the following sections:
- Specific aims
  - Background
  - Significance to lupus research or treatment
  - Methods and experimental design
  - Preliminary results, if any
  - Literature cited (not included in 8-page limit)



## **SUBMISSION DEADLINE**

- Online application packages must be submitted in their entirety via proposalCENTRAL and must be accompanied by all required documentation, including a signed and dated cover letter from the applicant (printed on institutional letterhead; see cover letter requirements on p. 8), grant application cover page with dated original signatures from the applicant and institutional signing official, no later than 5:00 P.M. EST on June 18, 2010. No application materials will be accepted after this deadline. Only one proposal per applicant will be accepted.
- Notification of grant awards will be made in writing by September 6, 2010.



## **EVALUATION CRITERIA**

Each proposal will be reviewed by experts in the field according to the new 9-point NIH review system.

Each proposal will receive an overall impact score (1-9) based on the current NIH grant review criteria, as determined by the reviewers' assessments of the following aspects of the proposal:

1. Significance
2. Investigators
3. Innovation
4. Approach
5. Environment

See this web page for more detailed information regarding the above categories:  
[http://grants.nih.gov/grants/peer\\_review\\_process.htm](http://grants.nih.gov/grants/peer_review_process.htm).



## **USE OF FUNDS & CONDITIONS OF AWARD**

1. Funds from this award must be utilized to support research-related activities of the awardee. Funds from this award cannot be used for any other reason, including indirect costs. Any unused funds shall be returned to LFA.
2. Applications will be accepted from tenure-track Principal Investigators possessing the rank of Assistant Professor (or equivalent) or above who directs a laboratory dedicated at least in part to the investigation of lupus at a U.S. academic, medical, or research institution. Applicants should not already possess a substantial grant award (e.g. RO1 or equivalent) to pursue the aims described in their lupus-specific research proposals.
3. Each Principal Investigator must assure LFA of his/her home institution and intended work location. LFA must be advised at the time of application of all moves, contemplated or real. The institution at which the proposed project will be completed must be given at the time of application. Projects may be moved during a funding period only when LFA is given advanced notice of a possible move.
4. An interim and final progress report (originally signed and dated by the applicant, but not the co-PI(s)) documenting the nature and outcomes of the research conducted must be submitted electronically to Dario Dieguez, Jr., Ph.D., LFA Research Program Manager ([dieguez@lupus.org](mailto:dieguez@lupus.org)) by the mid- and end-points of the grant award, respectively. A formatted progress report form will be provided to awardees simultaneously with award letters.
5. All publications (including peer-reviewed journal articles, abstracts, as well as national and/or local media coverage) resulting from research funded either wholly or partially by this grant award must acknowledge financial contributions from the Lupus Foundation of America, Inc. In addition, copies of such publications must be provided to the LFA within 30 days of final production. Moreover, all publicity and information disseminated by the home institution of the awardee or co-PI(s) about such research must acknowledge financial contributions from the Lupus Foundation of America, Inc.

6. Each applicant must indicate on his/her cover letter (printed on institutional letterhead, as well as originally signed and dated by the applicant) that all proposed research will be conducted according to the rules and regulations of the U.S. Department of Health and Human Services. Also, each applicant's institution must agree to hold the LFA harmless from any and all claims which may arise from research-related activities funded either wholly or partially by the Lupus Foundation of America, Inc.
7. Applicants proposing to conduct research on animals must provide the LFA with a letter (printed on institutional letterhead, as well as originally signed and dated by an appropriate university official) from the sponsoring institution's IACUC documenting current approval of the proposed research and its compliance with NIH guidelines for the care and use of animals in research. Applicants proposing to conduct research involving human subjects must provide the LFA with a letter (printed on institutional letterhead, as well as originally signed and dated by an appropriate university official) from the sponsoring institution's IRB documenting current approval of the proposed research and its compliance with NIH guidelines for the use of human subjects in research. IRB and/or IACUC approval are not required upon the date of application submission, but are required upon LFA's offer of the award. No award funds will be disbursed until written IRB and/or IACUC approval have been received by LFA.
8. Each award is for one-time use only and cannot be postponed, extended, modified, renewed, or transferred to another individual or institution. In addition, no additional funds will be provided beyond the amount stipulated in the award letter. Moreover, eligible applicants desiring LFA funds beyond the dollar amount or period of time stipulated in the award letter are encouraged to submit a new application in response to an LFA National Research Program funding opportunity announcement.
9. Each award payment will be provided, in the form of a check, to a designated institutional grant official authorized to receive, deposit, and appropriately manage funds from such a check at the sponsoring institution. Under no circumstances will a check be made payable or available to an applicant, co-PI, or other individual associated with the proposed research.
10. Any patentable discoveries resulting from research funded either wholly or partially by LFA must be reported to the LFA Research Program Manager as soon as any relevant decisions to pursue a patent are made. A patent application resulting from any such research-related activities cannot be made without the prior written consent of the LFA.