Announces

The 2014
Request for Applications for
Clinical and Translational
Pediatric Lupus Nephritis Biomarker Panel Research

RFA 014-02 (PN)
On behalf of the Michael Jon Barlin Pediatric Research Program

Award Amount: $500,000 ($100,000 per year for five years)

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Letter of Intent Deadline: May 30, 2014 at 5 p.m. EST
Application Deadline: June 30, 2014 at 5 p.m. EST
Earliest Award Date: September 5, 2014
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INTRODUCTION

On behalf of the Michael Jon Barlin Pediatric Research Program, the Lupus Foundation of America issues this request for application (RFA) to address a critical need in pediatric lupus nephritis.

Lupus nephritis is one of the most severe and pervasive organ manifestations of lupus, affecting up to 80% of children and adolescents with lupus. Up to 40% of children with lupus nephritis may progress to end-stage renal disease—permanent failure of the kidneys. Thus, lupus nephritis warrants close medical monitoring. Traditional measures used to monitor lupus nephritis are unable to determine disease activity and progression or predict flares while the patient is in the doctor’s office. Thus, clinical decisions may have to be made after the doctor’s visit, which is suboptimal.

The development of a real-time test (or assay), which would allow for more targeted treatment decisions and more personalized care, could change the future for many children living with lupus nephritis. For these reasons, and many more, there is a dire unmet need to develop and test a lupus nephritis biomarker panel that has the potential to monitor, stratify, and predict outcomes of children and adolescents with the disease.

PURPOSE OF RFA

The purpose of this RFA is to bring the pediatric rheumatology community closer to having an in-home or in-office means of capturing the disease status and disease activity of children suffering from lupus nephritis in real-time.
**RESEARCH OBJECTIVES**

This RFA seeks applications that will develop and test a pediatric lupus nephritis biomarker panel that can either be utilized to develop an in-home test, which will allow children and their parents to assess the status of their health on a day-to-day basis, or an in-office test, which will enable physicians to make evidence-based clinical decisions in real-time. The panel must have the potential to closely reflect the degree of kidney inflammation and its change over time, so it can be used to monitor renal disease activity, assess treatment response including lupus nephritis remission, and/or have the ability to predict kidney activity/flares better than currently available measures.

Initial findings in the funded study will be expected to demonstrate that the non-invasive, investigational biomarkers are present in children and adolescents with lupus nephritis. The biomarkers must also show that they are sensitive and specific to disease activity, damage, and/or prognosis.
ELIGIBILITY

Applications will be accepted from 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 an academic, medical, or research institution in the U.S., Canada, or Mexico. Applicants directing laboratories in Canada or Mexico are required to be in collaboration with a US-based investigator. The US-based collaborator must be added as key personnel in proposalCENTRAL.

FUNDING OPPORTUNITY

RFA 014-02 (PN) will provide one (1) five-year award in the amount of $500,000 ($100,000 per year). Continued funding throughout the five years will be dependent upon the awardee’s progress, as indicated in bi-annual reports submitted by the awardee to the Lupus Foundation of America. These progress reports will be reviewed by experts in the field and must be approved for the awardee to continue to receive funding. In addition, it will be required that the awardee seeks additional funding from other institutions (such as NIH and PCORI) throughout the five years of the grant period to move the research closer to the end goal (an in-office or at-home test). Documentation of these efforts will be required during specified reporting periods.
LETTER OF INTENT & ONLINE SUBMISSION

Letters of intent (LOIs) must be submitted online via Altum’s proposalCENTRAL by **5 p.m. EST on May 30, 2014**. 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 a week of the LOI submission deadline.

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 the name(s) of institution(s) where the research will be conducted
- Project title
- Scientific abstract (3000 characters or less) containing the following components: nature of the proposed study, and brief commentary outlining the background and significance of the proposal to lupus research
- Submit the letter of intent via your proposalCENTRAL account at [https://proposalcentral.altum.com/Login.asp](https://proposalcentral.altum.com/Login.asp)
APPLICATION MATERIALS & ONLINE SUBMISSION


The Lupus Foundation of America, Inc. utilizes an electronic grant submission process. All interested grant applicants must submit their full application packages through proposalCENTRAL: [https://proposalcentral.altum.com/Login.asp](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 via phone at 1-800-875-2562 or by email at 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 30, 2014** via Altum’s proposalCENTRAL online system. Hard copies will not be accepted under any circumstances.

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: 10/1/2014 - 09/30/2019
   - 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 - note that this letter cannot be a scanned image file (e.g. JPG) or non-Word file scanned into a PDF document

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 (note that all dated signatures must be obtained on the same grant application cover page)
   - 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 (3000 character max)
   - Lay summary of proposal for LFA’s use in press releases (3000 character max)

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) The applicant’s lay biography

f) 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. These are optional, but no more than five such statements from co-PIs will be accepted - note that such letters cannot be a scanned image file (e.g. JPG) or non-Word filed scanned into a PDF document.

g) 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 literature cited pages), which includes each of the following sections:

- **Specific aims**—the primary goal must be to enable physicians to make evidence-based clinical decisions in real-time

- **Background**

- **Significance to pediatric lupus research or treatment**—successful applications will likely include biomarker panels that demonstrate a strong correlation with lupus nephritis activity, are sensitive to change so it can be used for monitoring disease activity and assessing treatment response including lupus nephritis remission, and/or have the ability to predict kidney activity/flares before an obvious change occurs

- **Methods and experimental design**—applications must be clinical in nature and should include patient representatives in some manner

- **Preliminary results**—successful applications will likely include the Primary Investigator’s preliminary results

- **Plan for obtaining additional project funds over the 5-year grant period**

- **Literature cited** (not included in eight page limit)

- **Appendix** (optional and maximum of ten pages; this section cannot be a continuation of the proposal itself, but rather must be supplementary material)

h) A brief but specific budget and proposed breakdown of how the funds are to be used for each of the five budget periods:

- Period 1 – 10/1/2014 – 09/30/2015
- Period 2 – 10/1/2015 – 09/30/2016
- Period 3 – 10/1/2016 – 09/30/2017
- Period 4 – 10/1/2017 – 09/30/2018
- Period 5 – 10/1/2018 – 09/30/2019
**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 and a 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 30, 2014**. No application materials will be accepted after this deadline. Only one proposal per applicant will be accepted.

Earliest notification of grant awards will be made in writing by September 5, 2014.
EVALUATION CRITERIA

Each proposal will be reviewed by experts in the field according to the new 9-point NIH review. 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
6. Relevance to childhood lupus (note: this is not part of NIH’s review criteria)

See this web page for more detailed information regarding the above categories:
**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 an academic, medical, or research institution in the U.S., Canada, or Mexico. Applicants directing laboratories in Canada or Mexico are required to be in collaboration with a US-based investigator. The US-based collaborator must be added as key personnel in proposalCENTRAL.

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.

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 Anita Roach, MS, LFA Research Program Manager (roach@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. Each award payment will be disbursed only after LFA’s receipt of specific deliverables indicated in the award letter, such as progress reports.

5. All publications (including primary and review-type peer-reviewed journal articles, abstracts, commentaries, magazine articles, as well as national and/or local media coverage, or any such coverage at the home institution or that of a collaborator on the project) 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 provided in U.S. dollars, 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.