



**On behalf of the Michael Jon Barlin
Pediatric Research Program,
The Lupus Foundation of America, Inc.
Issues the Following**

**Request for Applications for
Basic, Clinical or Translational Lupus Research
In Pediatric HRQOL**

RFA 009-02 (P)

**Lupus Foundation of America, Inc.
2000 L Street, NW, Suite 710
Washington, DC 20036
<http://www.lupus.org>**

**BINDING LETTER OF INTENT MUST BE SUBMITTED BY JULY 13, 2009 (PLEASE NOTE:
DEADLLINE HAS BEEN EXTENDED FROM JULY 3RD)**

ONLINE APPLICATIONS MUST BE SUBMITTED BY AUGUST 7, 2009

AWARD ANNOUNCEMENT DATE SEPTEMBER 18, 2009



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RFA 009-02 (P): INTRODUCTION

On behalf of the Michael Jon Barlin Pediatric Research Program, the Lupus Foundation of America, Inc. (LFA) is issuing this Request for Applications (RFA) that address key understanding of lupus research issues involving health-related quality of life (HRQOL) and disease outcomes of children and young adults with pediatric SLE (pSLE). Lupus in children may develop early and tends to be more severe with multi-organ system involvement.

In public health and in medicine, the concept of HRQOL refers to a person or group's perceived physical and mental health over time. Physicians often use HRQOL to measure the effects of chronic illness in their patients to better understand how an illness interferes with a person's day-to-day life. Similarly, public health professionals use health-related quality of life to measure the effects of numerous disorders, short- and long-term disabilities, and diseases in different populations. Tracking HRQOL in different populations can identify subgroups with poor physical or mental health and can help guide policies or interventions to improve their health.

While medical outcomes of pSLE have been the focus of several recent studies, the effects of pSLE on executive functioning, schooling, and HRQOL in general remain largely unknown. Transition to adult care with pSLE also constitutes a vastly under examined area of research. pSLE in children constitutes a significant burden on their lives, with the potential to decrease HRQOL. Several generic but also disease-specific HRQOL instruments have been developed and initially validated but further validation is needed, with focus on very young children with pSLE and minority groups. The impact of ethnicity, race, of medical interventions on HRQOL has not been well established. Transitioning to adult care appears an especially vulnerable time period for young patients. Additionally, interventions targeted at improving the HRQOL are needed. Such interventions include, but are not limited to, identifying social, medical or therapy-related factors that have a detrimental impact on the lives of children with pSLE, and subsequently plan and test possible interventions using relevant benchmarks.

The LFA is the foremost national nonprofit organization dedicated to finding the causes of and cure for lupus and providing services to people affected by lupus.



RFA 009-02 (P): RESEARCH OBJECTIVES

This RFA seeks applications that address key understanding of pediatric lupus research issues in order to better understand pSLE features and societal factors that affect the HRQOL of children, adolescents and young adults by providing start-up funds to initiate new studies that address one or more of the following areas:

- The development and validation of tools to measure quality of life in children with pSLE.
- Further understanding of the impact of pSLE on HRQOL with focus on the validation of generic and disease specific measures.
- Impact of age, gender, race and or ethnicity on the various aspects of HRQOL with pSLE.
- Determination of risk factors for low HRQOL for various groups of patients with pSLE including, but not limited to, access to care, insurance status and reaching young adulthood.
- Development and testing of clinical interventions that improve the HRQOL with pSLE, such as approaches to health-care delivery, transitioning programs or interventions that improve adherence.

FUNDING OPPORTUNITY

RFA 009-02 (P) will provide one, one-year grant of \$70,000 with a potential for second-year funding. Research projects should either come from investigators at the level of Instructor, Assistant Professor or above *without* substantial funding (e.g. R01 or R01 equivalent) or with a new lupus-specific research proposal which is not or has not been already funded.



RFA 009-02 (P): SUBMISSION DEADLINES

- Binding Letters of Intent (LOI's) must be submitted online no later than 5:00 P.M., E.D.T. on JULY 13, 2009 (PLEASE NOTE: Deadline has been extended from July 3rd).
 - See page xi for full LOI submission instructions.
- Online application packages must be submitted in their entirety and be accompanied by all required documentation and institutional signatures, no later than 5:00 P.M., E.D.T. on AUGUST 7, 2009.
 - See p. xi for full application submission instructions.
- **No extensions will be granted, post-deadline.**
- Notification of grant awards will be made in writing SEPTEMBER 18, 2009
- The first grant award payment will be made on OCTOBER 1, 2009.



**RFA 009-02 (P): ELIGIBILITY REQUIREMENTS AND
CONDITIONS OF APPLICATION ACCEPTANCE**

1. The principal investigator of the research proposal must be an established investigator at the level of Instructor, Assistant Professor or above (e.g. R01 or R01 equivalent), with or without substantial funding, with a new lupus-specific pediatric research proposal.
2. All proposals must be submitted by a U.S.-based Principal Investigator (PI) and be from or in collaboration with a U.S.-based institution.
3. The originally accepted letter of intent (LOI) is binding. The title, proposed work and nature of the research may not be edited or altered without the express advance consent of the Lupus Foundation of America, Inc.



RFA 009-02 (P): METHODS AND CRITERIA FOR APPLICATION EVALUATION

All accepted applications will be reviewed NIH-style and ranked by reviewers representing areas of expertise relevant to the proposed project.

Each proposal will be reviewed using the following criteria:

1. Applicant's past performance and competence to undertake the project.
2. The institution where the project will be done and the proposed collaborations.
3. The feasibility of the project and its relevance to the stated research objectives.
4. The project plan including the design and methods, relevance to all serious forms of lupus and appropriateness of budget.

Please note that for grant award applications under \$100,000, the Lupus Foundation of America, Inc. does not provide written commentary or feedback to applicants. Applicants may, however, review raw scoring data online through proposalCENTRAL, post review period.



RFA 009-02 (P): CONDITIONS OF AWARD

1. No institutional overhead or other indirect costs will be paid and shall not be supported as part of any grant request.
2. All funds awarded shall be used in accordance with the submitted and approved application and accompanying budget. Any unused portion thereof shall be returned to the Lupus Foundation of America. All required deliverables as outlined Interim progress reports and financial reports must be submitted periodically throughout the award period, and will coincide with funding disbursement. A final report must be submitted within (30) days following the expiration of the grant period in order to receive disbursement of final award installment.
3. The Principal Investigator (PI) must assure the LFA of his or her intended work location.
4. The 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 funded period only with the advance of the LFA.
5. All publications and presentations resulting from funded research must include the LFA in a footnote or credit line. Copies of any such publications must be also provided within (30) days of publication to the LFA. All publicity and information disseminated about such research must acknowledge LFA support.
6. Within the grant period, the recipient agrees to work with the LFA and/or its local chapter in a public/professional lupus awareness activity, as requested by the LFA.
7. You agree to allow the LFA to videotape an interview with you regarding your research.
8. You complete an LFA research profile where you will provide a 1-2 paragraph biography and answer several questions about your research, which will be utilized on the LFA website and potentially in other materials highlighting the LFA National Research Program.
9. The recipient of any research grant awarded must certify that any research will be conducted according to the rules and regulations of the United States Department of Health and Human Services. The recipient agrees to hold the LFA harmless from any and all claims which may arise from such research.
10. All work involving human subjects must show documented compliance with DHHS and NIH guidelines for human subjects as provided by the sponsoring institution's committee for clinical investigation.
11. All work involving animal experimentation must comply with DHHS and NIH guidelines for care and use of laboratory animals. Evidence of Compliance with Government Requirements and human/animal subjects mandated upon funding award notification. Evidence of IRB and/or IACUC approval must be supplied before funds will be disbursed.



RFA 009-02 (P): CONDITIONS OF AWARD (CONT.)

12. Any grant awarded by the LFA is for one-time only, including multi-year awards. If the applicant desires further funding, a new application must be submitted if/when additional grant funding may become available.
13. Any discovery made under a program supported by the LFA must be reported promptly to the LFA, and any application for a patent may not be made without the prior written consent of the LFA, in accordance with the LFA's policy on Discoveries & Inventions.



RFA 009-02 (P): ONLINE APPLICATION PROCESS

The Lupus Foundation of America, Inc. utilizes an electronic grants submission process. All interested grant applicants must submit LOI's and full application packages through proposalCENTRAL: <https://proposalcentral.altum.com/>.

RFA 009-01 (S) grant applicants are encouraged to register and complete a professional profile at proposalCENTRAL as soon as possible. Applicants should also ensure that their grants and contracts office has registered their institution and signing officials with proposalCENTRAL.

A proposalCENTRAL helpline is available for questions from applicants during normal business hours (8:30 a.m. – 5:00 p.m.), Monday-Friday, EST. Phone: 1-800-875-2562 x227 (toll free) or 301-916-4557 x227, E-mail: pcsupport@altum.com



RFA 009-02 (P): INSTRUCTIONS FOR ONLINE LETTER OF INTENT (LOI) SUBMISSION

- Letters of Intent (LOI's) must be submitted prior to 5:00 P.M., E.S.T. on JULY 13, 2009. (PLEASE NOTE: Deadline has been extended from July 3rd).
- **Please note: this submission represents a “binding” letter of intent. The title, abstract(s) and nature of the proposal cannot be amended during the full application process.**

Letters of Intent must contain the following information:

- Title of proposed study.
- Scientific Abstract (300 words or less) containing the following components:
 - Nature of the proposed study
 - Brief data/commentary outlining the background (if any) of proposal
 - Proposal's relevance to potential impact on lupus research.
 - All PI and co-PI contact information (full mailing address at institution, email, phone, fax).
 - Institution where proposed research will be conducted.
- Visit <https://proposalcentral.altum.com/> to submit a Letter of Intent for this grant opportunity.



RFA 009-02 (P): INSTRUCTIONS FOR ONLINE GRANT
APPLICATION SUBMISSION

Complete online application packages (with all required attachments, institutional signatures and supportive documentation) must be submitted prior to 5:00 P.M., E.S.T. on AUGUST 7, 2009.

The online application must include the following components:

- a) Applicant/Institutional data
- b) Lay-language Abstract: (250) words or less:
 - A brief description in simple lay language summarizing the proposed research and its significance.
- c) Required Uploads:
 - *Biographical Sketch for P.I./Applicant.*
 - Applicant can use biosketch template provided or upload NIH biosketch, *in addition to a 2-4 paragraph lay biography.*
 - *Signature pages* which must be signed by applicant and institutional signing official
 - *Proposal Data:* Not more than (8) pages, total (does not include literature cited):
 - Introduction
 - Specific Aims
 - Significance
 - Preliminary Data
 - Experimental Design
 - Methods
 - References/citations
 - *Proposed Budget:*

Please provide itemized costs and narrative budget justification. A detailed justification of all proposed budget items must be uploaded and submitted.

Visit <https://proposalcentral.altum.com/> to submit an application for this grant opportunity. A proposalCENTRAL helpline is available for questions from applicants during normal business hours (8:30 a.m. – 5:00 p.m.), Monday-Friday, EST. Phone: 1-800-875-2562 x227 (toll free) or 301-916-4557 x227, E-mail: pcsupport@altum.com