

Predict and Prevent Lupus Research Program

REQUEST FOR APPLICATIONS

Purpose: The *Predict and Prevent Lupus* Research Grant (PPLR) is intended to provide funding for novel research aimed at detecting patients at high risk for lupus. We seek studies to further elucidate one or more of the many factors related to determining how high-risk patients may be selected for prevention therapy trials. The goal of Lupus Foundation of America is to prevent the onset of the serious and life-threatening consequences associated with the disease by supporting studies that may reduce the time to diagnosis and lead to early intervention in high-risk patients.

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BACKGROUND

Recent research findings indicate that the incidence and prevalence of systemic lupus erythematosus (SLE) is increasing. There could be many reasons for this including environmental factors, diet altering the gut microbiome, smoking, chemicals in the environment, use of prescribed and over the counter drugs, lifestyle choices, infections with evolving pathogens, and psychosocial stress.

With an increase in the prevalence of SLE, there has been a corresponding interest in the prevention of autoimmune diseases since the medical, social and financial costs are high. There have been positive therapeutic developments for SLE over the past decade, but studies focused on predicting and preventing lupus have lagged behind other autoimmune diseases.

This focus has been hampered by the fact that lupus is relatively rare in the population which is a major challenge with screening and prevention efforts. a lack of a precise definition of lupus based on internationally agreed upon molecular or cellular phenotypes and clinically identifiable manifestations of the disease. Current classification criteria are designed to homogenize clinical research cohorts but have not been thoroughly evaluated for detecting populations with probable, possible or incomplete SLE or to predict which of those people might be at greater risk of developing the disease. The early symptoms of lupus are variable, mimicking many other diseases, and so lupus is often not recognized, leading to delays in diagnosis and treatment. In the latest survey conducted by the Lupus Foundation of America (LFA), the findings conclude that it takes more than five years for patients to receive a definitive diagnosis of lupus.

Novel lupus research in genetics, biomarkers, and the development of new technologies signal we may have entered a new era in the prediction, treatment, and management of lupus. Studies suggest that both serological and clinical evaluations may be able to help predict when high-risk patients will move from a pre-clinical stage of lupus to the beginning of symptoms to clinically identifiable disease that will ultimately enable us to prevent the progression of lupus. Pre-clinical lupus as defined here range from individuals with enhanced genetic risk without current clinical symptoms to individuals with autoantibodies and some clinical features of SLE that do not meet classification criteria or diagnosis. The LFA is interested in adding to the body of knowledge by supporting studies that more precisely allow for selection of high-risk patients who may benefit from participation in prevention therapy trials.

PROGRAM DESCRIPTION

The Lupus Foundation of America is our Nation's largest voluntary health organization dedicated to serving lupus patients and their families at every stage of their disease. From early prevention to management and treatment to finding a cure, the LFA stands ready to address barriers to that mission. This new research initiative, *Predict and Prevent Lupus Research (PPLR)*, represents only one facet of the prevention research initiatives to be undertaken by the LFA.

PROGRAM GOAL:

The PPLR Research program seeks to support studies that will address gaps in the body of knowledge related to early identification of individuals at high risk for developing lupus who are in an early pre-clinical stage. This work, as described in the proposal, should be specifically designed with the long-term goal of preventing progression to the development of symptoms and/or the more serious organ threatening disease common in SLE. With new technologies and research findings on biomarkers, genetics and other biological factors of lupus, researchers believe the time has come to identify those patients who are at high risk for lupus and intervene earlier to prevent the transition to symptoms and serious organ damage. Multiple prevention therapy trials and other studies to identify high risk patients are now underway.

Funding will support projects that aim to: Pursue clinical observational studies to obtain data necessary for predicting and preventing the development of systemic lupus erythematosus in individuals at risk. These studies can include **but are not limited to** biomarker studies that use samples from established cohorts as well as the evaluation of the impacts of the exposome including environmental factors along with the social determinants of health that may increase risk of developing SLE. A study focused on clinical screening of high-risk population subgroups will be considered, especially if the project is a pilot study that will provide preliminary data for R or U-level application submission to the National Institutes of Health.

SPECIAL CONSIDERATIONS:

The Lupus Foundation of America's program, [Research Accelerated by You \(RAY\)](#), may be a supportive resource in studies proposed to predict and prevent lupus. RAY is a patient-powered lupus data platform where lupus and caregivers share information about their lupus experience aimed at helping researchers accelerate the development of new treatments and improve disease outcomes.

RAY collects self-reported data from people with lupus on an ongoing basis and stores it in a centralized location. Through the platform, anonymous data can be shared with researchers to increase understanding of lupus and help drug developers to enhance clinical trials, thus accelerating the potential for new therapies.

We encourage researchers submitting proposals under this new program to consider whether data from the RAY registry may be useful in the conduct of their research. For example, we know that if lupus patients have first-degree relatives with lupus, they may be at higher risk for developing the disease. That information exists in RAY and, depending on the research study proposed, this information, as well as other patient data, may be useful to the researcher. If the proposed project intends to use RAY as a source of information, a statement of intent to use this resource should be referenced in the narrative of the proposal. Consultation with LFA's Director of Research, Dr. Joy Buie, Buie@lupus.org, may be helpful to understanding the available data in the RAY registry.

Please be advised that no special preference will be given to investigators who include RAY as part of their research proposals.

PROGRAM ELIGIBILITY:

Principal Investigators must:

- Hold an MD or PhD from an accredited institution in the U.S.
- Be a citizen or legal resident of the US at the time of application. Collaborators may be from other countries, however no funds from the Lupus Foundation of America may be transferred outside of the U.S.
- Hold an academic appointment at a U.S. University, teaching hospital, or similarly accredited institution (i.e., institution eligible for NIH funding).
- Principal Investigators are permitted to submit up to a maximum of one application per competition.

FUNDING OPPORTUNITY:

One grant award of up to \$200,000 each year for up to two years. Budgets include direct and indirect costs.

REQUIRED APPLICATION COMPONENTS:

LETTER OF INTENT (LOI)

A required, non-binding letter of intent communicating your intent to submit an application should be submitted through Proposal Central using the online template within the system by May 1, 2024. The LOI should be no longer than 2 pages.

The template in Proposal Central will request:

- Descriptive title of proposed research
- Name, address, and telephone number of the principal investigator(s)
- Names of other key personnel
- Participating institution(s)
- Abstract
- Lay Abstract
- Research Aims outlining primary objectives of the project
- Research plan outlining approaches to addresses study aims
- Innovation
- Significance
- Impact on the targeted patient population

- Institutional/personnel resources

This letter of intent will be used to identify the appropriate reviews for the full application.

FULL APPLICATION

Full applications may only be submitted by applicants whose letters of intent have been approved. Completed application packages, with all required attachments and supportive documentation, must be submitted by 5:00 p.m. Eastern Time on July 1, 2024. We will not accept hard copies under any circumstances.

Applications will be reviewed and scored by a review panel of lupus research experts and people living with lupus. Please consider using layperson's language whenever possible when submitting the required documents.

The application must include the following components:

1. Cover letter on institutional letterhead that includes: the applicant's name, date, address, and original signature.
2. Project title and dates of proposed project,
3. Status of Institutional Animal Care and Use Committee (IACUC) and/or Institutional Review Board (IRB) approval.
4. Grant application cover page that includes Project title and dates of proposed project. For the applicant, the institutional official and the signing official: name, highest degree, title, email address, direct phone number and institutional street address.
5. If different from the institutional official and the signing official, the institutional grant administrator's name, highest degree; title, email address, direct phone number and institutional address.
6. IRB and/or IACUC approval date, as well as the Human subjects Assurance Number and/or Animal Welfare Assurance Number.
7. If these are not available at the time of the application, they will be required upon acceptance of the award and prior to the disbursement of any funds to the sponsoring institution.
8. Research proposal abstract and layperson's summary should include Scientific abstract that is no longer than 2,000 characters. The layperson's summary of the proposal for the Lupus Foundation of America's use in press releases should be no longer than 2,000 characters.
9. Biosketches or CVs from the applicant and any other research personnel who have a major role in the design, execution, analysis, interpretation, or writing related to the proposed studies. The CV should include positions and honors, peer-reviewed publications, as well as current and pending research support.
10. The Proposal narrative of no more than twelve (12) pages (single-spaced with one-inch margins, in 12-point Times New Roman font, excluding the Literature cited pages) that includes the following sections:

- a) Background, review of literature, significance
 - b) Research questions and specific objectives
 - c) Research methods and approach
 - d) Knowledge transition plan
 - e) Future plans for grant submission, including a detailed timeline for the study and for intended grant applications
 - f) The potential relevance and potential impact of this work on people with lupus and their families. Note: Appendices are limited to 10 additional pages and could include: reference list, tables and figures and data collection tools.
11. A brief but specific budget and proposed breakdown of how the funds are to be used keeping in mind the following specifications and restrictions. For each category of expense, please provide the dollar amount requested. Please provide a narrative budget justification for each category.
Insert example chart here

ONLINE SUBMISSION:

The Lupus Foundation of America uses an electronic grant submission process. All applicants must submit their full application packages through the ProposalCentral online grants management system. Paper applications will not be accepted.

Applicants must first create a ProposalCentral account and complete the application at <https://proposalcentral.com/GrantOpportunities.asp?GMID=56>

For additional information, visit our Request for Applications page at <https://www.lupus.org/rfa>.

DEADLINES AND REVIEW SCHEDULE

1. Applicants must submit a letter of intent. The LOI will be submitted for the purposes of formulating an appropriate review panel with the expertise necessary to make decisions about the scientific caliber of the proposed studies. The LOI must be submitted by May 1, 2024.
2. The full application package must be submitted in their entirety via ProposalCentral no later than July 1, 2024. No application materials will be accepted after this deadline. Only one proposal per applicant will be accepted. The earliest notification of grant awards will be made by August 15, 2024. Awardee will begin working on their projects no earlier than September 1, 2024.

EVALUATION CRITERIA:

Each proposal will be reviewed according to a modified version of the 9-point NIH review system (see this page: https://grants.nih.gov/grants/peer_review_process.htm by experts in lupus research. Each proposal will receive an overall impact score (1-9) as determined by the reviewers' assessments.

- Significance
- Investigator(s)
- Innovation
- Approach, including feasibility and timeline for future funding
- Environment
- Institution
- Relevance to lupus

Additional Review Criteria

- Protections for Human Subjects
- Study Timeline
- Inclusion of Men, Minorities, Individuals Across the Lifespan (where appropriate)

The Lupus Foundation of America reserves the right to make final award decisions following the completion of the scoring process, based on research subject matter needs.

USE OF FUNDS AND CONDITIONS OF AWARDS:

1. Applications will be accepted from adult rheumatology, nephrology, and dermatology investigators with academic appointments, i.e., Assistant, Associate, or Full-Professor at a U.S. Institution. This investigator's NIH-formatted Biosketch must be added in ProposalCentral. (See #9 under Required Application Components.)
2. Funds from this award must be used to support only the proposed research activities of the awardee. Funds can be used to cover indirect costs at a rate of 12%. Any unused funds must be returned to the Lupus Foundation of America.
3. This award will fund one applicant for a maximum of 2 years. The funds may be spent on salary, fringe benefits, supplies/equipment technical personnel, travel to a scientific meeting to deliver an abstract or presentation, and/or to submit a manuscript of the research to a journal.
4. Each applicant must inform the Lupus Foundation of America of their home institution and intended work location as well as the institution at which the proposed project will be completed if different. Applicants must indicate on their

application if they plan to change their institution or work location. Once granted, awardees are required to notify the LFA immediately if they decide to change institutions. Awards are not automatically transferrable and will be reviewed on a case-by-case basis.

5. Awardees must electronically submit signed, dated progress and final reports documenting the nature and outcomes of the conducted research. Reports must be submitted to ProposalCentral by the mid-and end points of the grant award, respectively. The Foundation will provide the formatted reports to the awardees.
6. All publications resulting from research funded either wholly or partially by this grant award must acknowledge financial contributions from the LFA's Predict and Prevent Lupus Research Grant Program. This includes primary and review-type peer-reviewed journal articles, abstracts, commentaries, magazine articles, national and/or local media coverage, as well as any such coverage at the home institution or the institution of a collaborator on the project. In addition, copies of such publications must be provided to the Foundation within 30 days of final production. All publicity and information disseminated by the home institution of the awardee or sponsor/mentor about such research must acknowledge financial contribution from the Lupus Foundation of America, Inc.
7. Each applicant must indicate in his-her cover letter that all proposed research will be conducted according to the rules and regulations of the U.S. Department of Health and Human Services relevant to the ethical conduct of research on humans and animals. Also, each applicant's institution must agree to hold the Foundation harmless from any and all claims that may arise from research-related activities funded either wholly or partially by the Lupus Foundation of America, Inc
8. Applicants proposing to conduct research on animals must provide the Foundation with a letter from the sponsoring institution's IACUC documenting approval of the proposed research and its compliance with NIH guidelines for the care and use of animals in research. The letter must be on institutional letterhead, originally signed and dated by an appropriate university official. Applicants proposing to conduct research involving human subjects must provide the Foundation with a letter from the sponsoring institution's IRB documenting approval of the proposed research and its compliance with NIH guidelines for the use of human subjects in research. The letter must be on the institution's letterhead, originally signed and dated by an appropriate university official.
9. IRB and/or IACUC approval are not required on the date of application, but they are required when the Foundation offers the award. No award funds will be disbursed until the Foundation receives written IRB and/or IACUC approval. All IACUC and IRB approval documents must contain the full name, title, address, phone number, and email for the IACUC or IRB Chair in order for the Foundation to disburse funds.

10. Each award is for one-time use only and may only be postponed, extended, modified, or transferred to another individual or institution upon review by the LFA, on a case-by-case basis. No additional funds will be provided beyond the amount stipulated in the award letter.
11. Each award payment will be made in the form of a check payable in USD, or electronic transfer to a designed institutional grant official who is authorized to receive, deposit, and appropriately manage funds from such a payment at the sponsoring institution. Under no circumstances will a disbursement be made payable or available to an applicant, sponsor/mentor, or other individual associated with the proposed research.
12. Any patentable discoveries, abstracts, publications resulting from research funded either wholly or partially by the Foundation must be reported to Jaren Crump at crump@lupus.org as soon as any relevant decisions to pursue a patent are made.

For questions about project suitability for this call for applications, please email VP, Research Dr. Joy Buie at buie@lupus.org.

For questions about the application submissions process, please email our Grants and Contracts Manager at crump@lupus.org.

**Thank you for your interest in the PPLR program and your commitment to
*Solving the Cruel Mystery.***