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## 2022 Lupus Innovation Award (LIA) Request for Applications (RFA)

**RFA Release Date:** December 7, 2021

**Letter of Intent Due Date:** March 1, 2022

**Full Application Due Date:** August 1, 2022

**Earliest Start Date:** March 2023

### **Purpose**

The Lupus Innovation Award (LIA) provides up to \$150,000/year total costs for up to two years. It provides support for pioneering, high-risk, high-reward approaches to major challenges in lupus research. Special emphasis is placed on lupus studies exploring fundamental mechanisms, novel targets and pathways, novel technologies, and interdisciplinary approaches. Both early career and established investigators new to lupus with highly innovative ideas are encouraged to apply. Early-stage investigators are eligible for an additional third year of funding contingent upon successful completion of the original grant.

### **Background**

The Lupus Research Alliance (LRA) is the world's leading private funder of lupus research. The organization's mission is to improve treatments while advancing lupus towards a cure and prevention. At present, therapy for lupus is empiric and involves a variety of mostly non-specific anti-inflammatory and immunosuppressive agents. While these treatments are frequently beneficial, many patients do not respond adequately and suffer significant side effects. Importantly, even patients with low disease activity accrue organ damage over time. There are many unanswered questions regarding the pathogenesis of lupus. Thus, new conceptual and therapeutic approaches are urgently needed. To enable the development of more effective and safer lupus therapies, and to address major barriers in lupus research and translation, the LRA has established the LIA grant mechanism.

**Note: the same research project may not be submitted for consideration to multiple LRA grant mechanisms in the same year. Such submissions will be triaged without review.**

## **Award Goals**

The goals of the LIA are to: (1) promote investigation of underexplored pathways and (2) initiate transformative discoveries in lupus that can drive the development of safer and more effective treatments. The LRA encourages projects based on novel explorations of lupus biology—including innovative studies that use human material to address the physiological, cellular, molecular and/or genetic basis of human lupus. Investigations into the **fundamental mechanisms** of lupus and its complications, explorations of **novel targets and pathways**, and applications involving **novel technologies** and **interdisciplinary approaches** are particularly encouraged. Investigations should be relevant to basic, translational, or clinical research in lupus.

**In keeping with the strategic research objectives of the LRA, priority consideration will be given to projects that address understanding of human lupus heterogeneity or enable patient stratification by active disease mechanism and ideally employ emerging technologies to address these priority areas.** Applicants are encouraged to consult with LRA scientific staff to discuss the responsiveness of their proposal to this program.

## **Eligibility**

Individuals with a doctoral degree (MD, PhD, DO or equivalent), holding a faculty, or equivalent, position and leading an independent research team at an academic, nonprofit, or government research institution are eligible to apply. There are no citizenship requirements. Federal government research laboratories are not eligible for this award.

### ***Special consideration for early-stage investigators***

Early-stage investigators (ESIs), with highly innovative ideas, are encouraged to apply through this mechanism and are eligible for a third year of funding (up to \$150,000) contingent upon successful completion of the original grant goals. ESI is a principal investigator who has completed her or his terminal research degree or medical residency -- whichever date is later -- within the past 10 years and has not yet, as of the date of application submission, competed successfully for a substantial, multi-year NIH R01 or equivalent funding. To be eligible for a third year of funding, the ESI must not have received an R01 or equivalent grant while funded by the LIA grant and must submit an extension request three months prior to the completion of the original grant.

## Application Guidelines

Applications must be submitted electronically, via [ProposalCENTRAL](#) by 11:59 pm ET on the stated deadline. All resubmissions of formerly declined LIA applications must be submitted under the LIA grant mechanism and must follow the general resubmission guidelines below.

A two-stage application process will be employed. A 2-page Letter of Intent (LOI) will be used to evaluate the novelty, significance and alignment of the proposed project concept with the LIA funding mechanism. Applicants whose LOIs have successfully passed this first peer-review stage will be invited to submit full applications.

### I. *Letter of Intent*

A 2-page LOI, inclusive of text, figures, tables, legends and excluding references, must be submitted electronically, via [ProposalCENTRAL](#), by 11:59 pm ET on the stated deadline. It should contain the following information:

1. *Brief background*: Provide a succinct contextual framework for the proposed project. This section may be particularly valuable to applicants new to lupus and applying knowledge from other scientific areas—that need to be introduced—to bear on lupus.
2. *Objective and Specific Aims*: State the overall objective and outline the specific aims.
3. *Project plan*: Describe the innovation, significance, and approach for the proposed project.
4. *Resource assessment*: Assess your ability to carry out this project and outline resources you may need to accomplish it, such as access to proprietary reagents or technologies and key collaborators. If the applicant's primary scientific expertise is outside of lupus, please describe how you intend to apply your unique knowledge to address a critical issue in the pathogenesis and/or treatment of lupus.

In addition to a 2-page LOI, applicants should submit NIH-style Biosketch for all key personnel working on the project. This should include a description of other financial support available to the applicant(s) for his/her research endeavors. International applicants may submit a copy of their curriculum vitae listing all funding sources.

**Only one LOI may be submitted by the principal investigator per grant cycle.**

### II. *Full Application*

Full applications may be submitted only by applicants whose LOI has been approved and who have been invited by the LRA to advance to the next stage of the review process. Applications must be submitted via [ProposalCENTRAL](#) by 11:59 pm ET on the stated deadline. Submissions must be completed using 12-pt Times New Roman font or equivalent and must contain the following components:

1. Lay Abstract: A summary of the proposed research and its potential significance to the fundamental causes of lupus, not exceeding 3,000 characters and written in lay language geared to a sixth-grade reading level and suitable for use in publications. Please do not submit a scientific abstract in this section.
2. Scientific Abstract: A technical summary of the proposed research, written in scientific terms and not exceeding 3,000 characters. Investigators should highlight the relevance of the work to lupus.
3. Research Plan: A description of proposed research, not exceeding 8-pages excluding references, should be clearly formulated to include, under separate subheadings, justification for and/or explanation of project's:
  - A. Background
  - B. Significance: why is the project important, how is it relevant to lupus, does it have a bench-to-bed site potential, and how it aligns with the strategic goals of the LRA?
  - C. Innovation: how is the proposed work novel and are the findings expected to move the lupus research field forward?
  - D. Hypothesis and Specific Aims
  - E. Preliminary Data (if available)
  - F. Experimental Design and Methods including feasibility, anticipated outcomes, and alternative strategies
  - G. Milestones: List the expected status of the project at various time points for the duration of the grant. The list of milestones, ideally presented in a table format, should reflect the specific aims of the proposal. These milestones will be used to evaluate progress and to facilitate communication between the principal investigators and the LRA.
4. Biosketch: A standard NIH Biosketch for all key personnel working on the project should be provided. International applicants may submit a copy of their curriculum vitae.
5. Detailed Budget and Summary: A budget for the project should be prepared in U.S. dollars. The budget should be for up to two years and should not exceed \$150,000 per year, including 10% indirect costs. The LIA does not provide funds for major pieces of laboratory equipment.
6. Budget Justification: A detailed justification for the budgetary requests must be provided. The information in this section should be divided into two sections. The first section should include the following line items: personnel, consultant costs; equipment and supplies (both office and medical of laboratory). The second section should include all other line items including but not limited to: travel to annual investigator's meeting, patient care, other expenses, consortium and contractual costs. Funds cannot be used to pay for tuition or education expenses. Each section should not exceed 2,000 characters. Any additional information should be included as an appendix to the application.
7. Other Support: A description of other financial support available to the applicant(s) for his/her research endeavors should be provided. Applicants must list current and pending grant applications, their specific aims, funding amounts, percent effort, funding period and the extent of scientific overlap with the proposed research, if any. If overlap exists, a statement regarding intended dispositions of funds in the event of dual granting is required. International applicants

must include all funding sources and clearly explain scientific overlap with the proposed work, if any.

8. Facilities & Equipment Description: A short description of the facilities and equipment available to support the project.
9. Assurances: Appropriate institutional assurances regarding human subjects and animals as applicable.
10. Consent Forms: If relevant, copies or drafts of all informed consent forms, to be distributed to participants for signature in this study (or their legal guardians), should be provided.
11. Consultant/Co-Investigator/Collaborator Letters: Optional, only submit if relevant to the application.
12. Application Signature: The application cover page, which reflects the applicant's agreement to abide by the rules governing grant awards from the LRA, should be signed electronically by the applicant and a representative from the sponsoring institution before it is submitted in proposalCENTRAL.

## **Review Criteria**

### LOIs

The most important LOI review criterion is innovation. Another chief consideration is the alignment of the proposed project with the LRA's strategic research objectives. Priority consideration will be given to ESIs.

### Full Applications

To facilitate support of high-risk, high-reward projects, full applications will be evaluated using a tripartite scoring system focused on the following components:

1. *Innovation*, which will be the most heavily weighted aspect;
2. *Project*, including relevance, significance, approach and feasibility;
3. *Investigator and environment*, including consideration of the PI's track record, area of expertise, career stage and training.

The rationale for and the novelty of the proposed research rather than the amount of preliminary data will be emphasized. Continuations of long-term research projects are not appropriate for this grant mechanism.

Applications that are not aligned with the goals and the mission of the LRA will not be peer-reviewed.

## **Terms of the Award**

LIA grants will be supported for up to \$150,000/year for up to two years. Indirect costs should not exceed 10% of the total budget and must be included within the \$150,000 annual budget cap.

The LRA is committed to the publication and dissemination of all information and materials developed using the LRA's resources. All recipients of LRA awards must agree to this principle and must submit a data sharing plan.

The grant recipient is required to attend the LRA annual scientific conference, Forum for Discovery, each year. Travel funds, provided by the grant award, must be used to attend this meeting.

ESIs are eligible for a third year of funding (up to \$150,000) pending successful completion of the original grant aims. ESI is a principal investigator who has completed her or his terminal research degree or medical residency -- whichever date is later -- within the past 10 years and has not yet, as of the date of application submission, competed successfully for a substantial, multi-year NIH R01 or equivalent funding. To be eligible for a third year of funding, the ESI must not have received an R01 or equivalent grant while funded by the LIA grant and must submit an extension request three months prior to the completion of the original grant.

## **Resubmission Information**

- A resubmission is considered an application that was not selected for funding in the previous application cycle. An applicant may resubmit the revised application only once.
- A brief .5-page resubmission statement (up to 300 words) must be provided at the beginning of LOI for all resubmissions. It should highlight the changes and explain how modifications address the reviewers' concerns. The resubmission statement does not count towards the overall LOI page limit.
- A 1-page resubmission statement (up to 500 words) must be provided at the beginning of the Research Plan if an applicant is invited to submit full application. The resubmission statement should highlight the changes and explain where (additions, deletions, revisions) and how the revised application has been modified to address the reviewers' concerns.
- A copy of the summary statement for an application that has not been selected for funding must be included in the appendix of the proposal. If you have not received a summary statement, please contact the LRA research staff.
- If major changes are made to the original application or if the applicant is planning to submit an entirely different/new project, the proposal should not be submitted as a resubmission.
- Applicants should contact the LRA research staff with any questions.

## **Review Process**

All grant applications will be peer-reviewed by a Study Section of the LRA. Results from that peer review will be forwarded to the LRA Scientific Advisory Board (SAB). The SAB will consider the recommendations from the Study Section, in the context of the existing LRA grant portfolio and LRA's

strategic research priorities. The SAB will submit their recommendations to the LRA Board of Directors. The Board will consider all the previous recommendations and will also provide a lay perspective. This perspective will include patients' concerns and expectations, as well as deliberations on the business aspect of funding the recommended grants. The LRA Board of Directors will make all final funding decisions.

### **Review Feedback**

For applications receiving a full review, a summary statement containing the reviewers' critiques will be provided. Applications not recommended for full review will receive abridged feedback. The LRA does not provide application scores or rankings to applicants.

### **Key Dates**

RFA Release:	December 7, 2021
Letter of Intent Due:	March 1, 2022
Letter of Intent Decision:	June 15, 2022
Full Applications* Due:	August 1, 2022
Response to Applicants†:	December 2022
Earliest Anticipated Start:	March 2023

\*By invitation only with an approved LOI

†Full applications only

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#### **proposalCENTRAL:**

For help with the electronic grant application process, please contact the help desk of [ProposalCENTRAL pcsupport@altum.com](mailto:ProposalCENTRAL_pcsupport@altum.com); +1-800-875-2562, extension 227.