

Request for Applications 2023 Lupus Innovation Award \$300,000 over 2 years

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BACKGROUND

The Lupus Research Alliance (LRA) is the largest private funder of lupus research worldwide. The organization aims to transform lupus treatment while advancing towards a cure by funding cutting-edge, innovative research.

At present, therapy for lupus is mostly empiric and involves largely non-specific antiinflammatory and immunosuppressive agents. While these treatments are frequently beneficial, many patients do not respond adequately or 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 Lupus Innovation Award (LIA).

PROGRAM DESCRIPTION

The LIA provides up to \$150,000 per year for up to two years. Early-stage investigators (ESIs) are eligible for a third year of funding (see below for further details). The LIA supports 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.

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 foundational, translational, or clinical research in lupus. However, all studies should have a clear and direct relevance to people with lupus and should offer the potential to improve the standard of care for the disease or usher in a cure.

In keeping with the <u>LRA's strategic priorities</u>, projects that address defining human lupus heterogeneity by molecular pathway or enabling patient stratification based on active disease mechanisms or that facilitate global research collaborations will be given priority consideration.

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.

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. US federal government research laboratories are not eligible for this award.
- There are no citizenship requirements for investigators applying to this program.
- Applicants with total active LRA funding of US\$600,000 or more (NCEs exempted) are not eligible for additional funding from the LRA unless there are exceptional circumstances.
- Applicants who have previously received LRA funding must also be up to date with all progress and financial reports and other Terms and Conditions of the original award(s) at the time of applying.
- Projects with significant overlap with currently active LRA-funded grants will not be considered and may be administratively withdrawn. Applicants are advised to review the <u>LRA research portfolio</u> to determine if overlap exists and may consult with the LRA's scientific staff if necessary.

SPECIAL CONSIDERATIONS

Early-stage Investigators

Early-stage investigators (ESIs) with highly innovative ideas are encouraged to apply to this mechanism. An ESI is a principal investigator who has completed their 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.

ESIs are eligible for a third year of funding of up to \$150,000. If an ESI is interested in receiving the third year of funding, they are required to submit an initial application that includes a three-year research plan. However, the third year of funding will be contingent upon successful completion of the grant milestones proposed to be achieved in the first two years of funding. If an ESI does not include a three-year research plan and instead proposes a two-year research plan in their initial application, they will not be eligible to receive the third year of funding.

APPLICATION PROCESS AND INSTRUCTIONS

A two-stage application process will be employed. A two-page Letter of Intent (LOI) will be used to judge the novelty, significance, and alignment of the proposed project with the LIA funding mechanism. Applicants whose LOIs successfully pass this first review stage will be invited to submit a full application in the second stage of the application process.

KEY DATES

RFA Release: December 20, 2022

Letters of Intent Due: March 1, 2023
Letter of Intent Decision: June 2023
Full Applications Due*: August 1, 2023
Full Application Decision: December 2023
Expected Start Date: March 2024

*By invitation only with an approved LOI

LETTER OF INTENT

LOIs must be submitted electronically, via <u>ProposalCentral</u>, by 11:59pm US ET on the stated deadline. LOIs will not be accepted via any other means.

The following information is required to submit a complete LOI. Numbers correspond to the application sections found on the left side of the ProposalCentral website.

- 1. **Title Page:** Enter the title of the proposed project. Indicate whether the LOI is a resubmission and, if so, select the prior application from the dropdown menu. Indicate whether the applicant is applying as an early-stage investigator.
- 2. **Download Templates & Instructions:** The Request for Applications and Letter of Intent template can be downloaded from this page.

- 3. **Enable Other Users to Access this Proposal:** Enter the information for any other users who will need to work on the LOI.
- 4. Applicant/PI: The applicant's information is pre-loaded with the contact information from their ProposalCentral profile. Click the Edit Professional Profile button if any changes need to be made. Upload a standard NIH Biosketch and Other Support Format Page, which should detail all other financial support (current as of the date of application submission) available to the applicant for their research endeavors. Applicants who are not based in the United States may submit a copy of their curriculum vitae, which must be limited to five pages in length.
- 5. **Institution:** The institution will be pre-loaded with the applicant's institution.
- 6. Letter of Intent & Other Attachments: Upload the Letter of Intent, including Resubmission Statement (if applicable), and biosketches/CVs for all key personnel as PDFs.
 - A. Letter of Intent (LOI): The Letter of Intent template provided on ProposalCentral must be used. Margins must not be less than .5 inches on each side and 12-point Times New Roman or the equivalent should be used for the text. The LOI, excluding the resubmission statement (if applicable) and references, should not exceed two pages. Figures, tables, and legends are included in the page limit. The information listed below must be included in the indicated order.
 - i. **Resubmission Statement (if applicable):** Revised applications are required to include a resubmission statement, not to exceed a half page (300 words). The statement should highlight any major changes and explain how the modifications address the concerns of the original review panel.
 - A resubmission is an application that was not funded in one of the previous two application cycles.
 - An applicant who is unsuccessful may revise their original application only once.
 - If substantial changes are made to the original application, the application should not be submitted as a resubmission.
 - ii. **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.
 - iii. **Objective and Specific Aims:** State the overall objective and outline the specific aims.
 - iv. **Impact Statement**: Provide a succinct statement about the potential of the proposed research to improve the standard of care or quality of life of people with lupus.

- v. **Project Plan:** Describe the innovation, significance, and approach for the proposed project.
- vi. **Resource Assessment:** Assess your ability to carry out this project and outline the resources needed, 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 the applicant's unique knowledge will be applied to address a critical issue in the pathogenesis or treatment of lupus, and, importantly, how the applicant will leverage the expertise of their lupus collaborators to maximize the lupus impact of the project.
- B. **Biosketch(es):** Submit a standard NIH-style biosketch for all key personnel working on the project. A curriculum vitae may be submitted for key personnel not based in the United States.
- 7. **Validate:** Click the "Validate" button to check for any missing required information or attachments.
- 8. **Sign:** Click the "Sign" button to electronically sign the LOI. By signing, the applicant certifies that the information contained in the LOI is true, complete, and accurate to the best of their knowledge.
- 9. **Submit:** After successfully passing the validate check, click the "Submit" button. An e-mail will be sent confirming submission.

LOI Restrictions

- Only one LOI will be accepted per applicant in a grant cycle.
- Applicants with total active LRA funding of US\$600,000 or more (NCEs exempted) are not eligible for additional funding from the LRA unless there are exceptional circumstances.

FULL APPLICATION

Full applications may be submitted only by applicants whose LOIs have been approved to advance to the next stage of the review process. Applications must be submitted electronically, via ProposalCentral, by 11:59pm US ET on the stated deadline. Detailed instructions for the full application will be available on ProposalCentral. The full application site will only be accessible to applicants with approved LOIs.

REVIEW CRITERIA

LOI Review

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 Application Review

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

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

The **Impact Statement** will be used by the LRA Scientific Advisory Board to prioritize funding among the top scoring applications.

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.

Review Process

All eligible grant applications will be peer-reviewed by a panel of external reviewers, the results from which will be considered by the LRA Scientific Advisory Board (SAB) in the context of the LRA grant portfolio and LRA's strategic research priorities. The SAB will make funding recommendations to the LRA Board of Directors, which will, in turn, consider all previous recommendations and provide a lay perspective including patients' concerns and expectations, as well as deliberations on the business aspects of funding the recommended grants. The LRA Board of Directors will make all final funding decisions.

Review Feedback

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

AWARD TERMS AND CONDITIONS

The LIA provides up to US\$150,000 per year for up to two years. For ESIs proposing a three-year research plan, the LIA provides a third year of funding of up to US\$150,000, which is contingent upon the successful completion of the research milestones proposed to be achieved in the first two years of funding.

Indirect costs must not exceed 10% of the total budget and must be included within the \$150,000 annual budget cap.

Grant recipients must attend and present at Forum for Discovery, the LRA annual scientific conference, each year. Travel funds (up to \$2,000 per year) provided by the

grant must be used to pay for travel expenses related to attending Forum for Discovery meetings.

The LRA is committed to the publication and dissemination of all data/information and materials developed using the organization's resources. All recipients of LRA awards must facilitate availability of data and materials by executing a Data Sharing Plan based on the 2023 NIH Data Management and Sharing Policy.

INQUIRIES

Scientific:

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Administrative:

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ProposalCentral:

For assistance with the electronic grant application process, please contact ProposalCentral at pcsupport@altum.com or 800-875-2562, extension 227.