

Request for Applications 2025 Lupus Innovation Award \$300,000 over 2 years

CONTENTS

Background	1
Program Description	
Research Emphasis Areas	
Eligibility	
Special Considerations	
Application Process and Instructions	
Key Dates	3
Letter of Intent	3
Application	6
Review Criteria	6
Award Terms and Conditions	7
Lupus Nexus	7
Inquiries	

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 Special Considerations section for further details). Both early career and established investigators new to lupus with highly innovative ideas are encouraged to apply.

The LIA supports pioneering, high-risk, high-reward approaches to major challenges in lupus research. The overarching goals of the LIA are to: (1) promote investigation of underexplored pathways and fundamental mechanisms of lupus and its complications and (2) initiate transformative discoveries in lupus that can drive the development of safer and more effective treatments or novel biomarkers. 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.

RESEARCH EMPHASIS AREAS

Projects must address or be aligned with at least one of the following LRA strategic research priorities:

- 1. Defining human lupus heterogeneity by molecular pathology to stratify patients by active disease mechanisms.
- 2. Integrating the research continuum to bring advances to patients.
- 3. Enabling global research/technology collaborations.

Special emphasis is placed on lupus studies that **use human material**, **humanized models or ex-vivo models** to explore fundamental mechanisms and novel targets and pathways, as well as employ novel technologies or interdisciplinary approaches. Of particular interest are projects that address understudied topics in lupus research such as, but not limited to, neuropsychiatric lupus, the role of the microbiome in lupus, ancestral, environmental and socioeconomic drivers of lupus, pediatric lupus, and molecular signatures of heterogeneity.

Please note that applications involving engineered cell therapies or other potentially "immune re-setting" agents (i.e., bispecific T cell engagers, other B-cell depleting agents) for lupus will <u>not</u> be considered under this RFA. Such submissions will be triaged without review.

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 who have previously received LRA funding must also be up to date with all reporting requirements and other Terms and Conditions of the original award(s) at the time of applying.

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.

Continuations of long-term research projects are not appropriate for this grant mechanism.

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. 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.

Please note that securing the third year of funding will be based on the successful completion of the grant aims for the first two years of the award detailed in the application. An external review of the year two progress report will inform the third-year funding decision.

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 an application in the second stage of the process. Applicants are encouraged to consult with LRA scientific staff to discuss the responsiveness of their proposal to this program.

KEY DATES

RFA Release: February 19, 2025

Letters of Intent Due:

Letter of Intent Decision:

April 2, 2025

June 2025

Applications Due*:

Application Decision:

December 2025

Expected Start Date:

March 2026

*By invitation only with an approved LOI

LETTER OF INTENT

LOIs must be submitted via the <u>LRA Grants Management System</u> by 11:59pm US ET on the stated deadline. LOIs will not be accepted via any other means.

Before accessing the LOI form, the applicant will be required to pass an eligibility quiz. After the applicant clicks the Start LOI button, click the Save Draft button to display the eligibility quiz. Answer the question and click the Submit button, then the Yes button to confirm.

All templates and instructions, including the Request for Applications and the Letter of Intent template, can be downloaded from within the LOI form. **Please note that when a template is provided, it must be used.**

The following information is required to submit a complete LOI:

Applicant

- The Institution Information and Contact Information will be preloaded with information from the organization profile and applicant profile, respectively.
- For Role, select "Applicant/PI" from the dropdown menu.
- Indicate whether the applicant is applying as an early-stage investigator.
- Indicate whether the applicant is currently funded by the LRA and, if so, provide the project title and grant program.
- For Gender and Race and/or Ethnicity, select all that apply. This information is not required and will not be used in any way during the selection process.
- Select from the dropdown menu how the applicant heard about this opportunity.
- Upload, as a PDF, a standard <u>NIH Biosketch</u> for the applicant. 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.
- Upload, as a PDF, an Other Support Page for the applicant. This should detail all other financial support (current as of the date of the submission) available to the applicant for their research endeavors.

Give Other Users Access to Proposal

To provide co-applicants and institutional administrators with access to the LOI form:

- 1. Click the Collaborators icon .
- 2. Enter the required information.
- 3. Clicking on the plus sign button will add additional rows.
- 4. Click the Save button at any time to save your work.
- 5. Click the Invite button. An email with the subject line "Invitation to Collaborate on LRA Grant Proposal" will be sent inviting them to work on the grant proposal. They will be asked to click a link to accept or decline the invitation. Users who accept but are not yet registered in the system will need to do so.
 - NOTE: A user added as a co-applicant, financial administrator, research/grants administrator or signing official will be able to edit the LOI form but will not be able to submit it. Only the applicant and any users added as institutional administrators will be able to both edit and submit the LOI form. In addition, only one user can edit the LOI form at a time.

Project Information

- Enter the title of the proposed project.
- Indicate whether the LOI is a resubmission and, if so, provide the title of the prior application.
- Indicate whether the proposed project involves the use of human samples and/or data
- Keywords: Select all that apply.

Attachments

Upload the **Letter of Intent** as a PDF. The Letter of Intent template provided on the LRA Grants Management System 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.

vii. References: List all citations.

Upload, as a single PDF, standard **NIH Biosketches for all key personnel** working on the project. A curriculum vitae may be submitted for key personnel not based in the United States.

Electronic Signatures

When the applicant is ready to submit the LOI:

- 1. Click on the checkbox next to, "By signing, the applicant certifies that the information contained in the LOI is true, complete, and accurate to the best of their knowledge."
- 2. Enter the applicant's name in the LOI Signature Box.
- 3. Click on the LOI Signature Date box and click the Now button. This will automatically insert the current date and time.
- 4. Click the Submit button to submit the LOI, then the Yes button to confirm.

LOI Restrictions

Only one LOI will be accepted per applicant in a grant cycle.

APPLICATION

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 via the LRA Grants Management System by 11:59pm US ET on the stated deadline. Detailed instructions for the application form will be available in the LRA Grants Management System. The application form 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. Applications that are not aligned with the goals and the mission of the LRA will not be peer-reviewed. Priority consideration will be given to ESIs.

Application Review

To facilitate support of high-risk, high-reward projects, 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.

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 applications, a summary statement containing the reviewers' critiques will be provided. Applicants not recommended to advance to the application stage will receive abridged feedback. The LRA does not provide scores or 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 will be based on the successful completion of the grant aims for the first two years of the award detailed in the application and an external review of the year two progress report.

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 Final NIH Policy for Data Management and Sharing.

LUPUS NEXUS

We strongly encourage applicants to incorporate Lupus Nexus (LNx) data and biosamples into their research projects when applying for this grant.

The Lupus Nexus (LNx) is a comprehensive registry, biorepository, and data knowledge platform designed to facilitate information exchange and empower researchers to address critical questions in lupus research. The LNx includes an observational, longitudinal study enrolling up to 3500 participants in 4 cohorts (new onset, extra-renal flare, active lupus nephritis, and prevalent) and contains medical data, clinician- and patient-reported outcomes, and an extensive range of linked biosamples (e.g., whole blood, blood derivatives, urine, saliva, and stool). These resources are housed in the **Data Repository, Exchange, and Analytics platform (DREAM)**, a centralized data hub with high-performance computing capabilities available to researchers worldwide.

For detailed information about the LNx, visit <u>LupusNexus.org</u>. The "For Researchers" link at the bottom of the homepage leads to the Researcher Landing Page, where users can submit both general inquiries and apply for access to biosamples and DREAM data.

INQUIRIES

Scientific:

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Administrative:

Diomaris Gonzalez Director of Grant Programs Lupus Research Alliance dgonzalez@lupusresearch.org +1-646-884-6056

LRA Grants Management System:

For assistance with the electronic grant application process, please contact Erin McLaughlin, Manager, Grant Programs, at emcLaughlin@lupusresearch.org.