

2021 Request for Applications (RFA) for the Lupus Innovation Award (LIA)

Release Date: November 10, 2020

Letter of Intent Due Date: February 16, 2021 Full Application Due Date: June 15, 2021

Earliest Start Date: December 2021

Highlights of Key Features

The LIA grant mechanism was formerly known as the Novel Research Grant (NRG). All resubmissions of formerly declined NRG applications must be submitted under the LIA grant mechanism. Failure to do so will disqualify the resubmitted application.

Lupus Innovation Award (LIA): up to \$150,000/year total costs for up to two years.

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.

The Lupus Mechanisms and Targets Award (LMTA) will not be offered in 2021.

The same research project may <u>not</u> be submitted for consideration to multiple LRA grant mechanisms in the same year. Such submissions will be triaged without review.

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 Lupus Innovation Award (LIA) grant mechanism.

Lupus Innovation Award (LIA)

Award Goals

Lupus Innovation Awards provide support for exceptionally creative and innovative approaches to major challenges in lupus research. Successful proposals will advance novel hypotheses and/or technologies that have the potential to stimulate new research directions and propel the lupus field forward.

The program goals are to stimulate investigation of underexplored pathways and initiate transformative discoveries in lupus that can drive the development of safer and more effective treatments. The Lupus Research Alliance 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 <u>no</u> citizenship requirements. Federal government research laboratories are not eligible for this award.

Special consideration for early stage investigators

Early stage investigators, 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. Early stage investigators are defined as principal investigators who have completed their terminal research degree or end of post-graduate clinical training, whichever date is later, within the past 10 years (as of the date of application submission) and have not received significant, R01-level, funding. To be eligible for a third year of funding, the early stage investigator must not have received an R01 during the course of the LIA term and must submit an extension request three months prior to the completion of the original grant.

LIA Application Guidelines

Applications must be submitted electronically, via <u>proposalCENTRAL</u> by <u>5 pm ET on the stated deadline</u> (please log into proposalCENTRAL for detailed application instructions). All resubmissions of formerly declined NRG 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 LOI will be used to judge the novelty, significance and alignment of the proposed project concept with the LIA funding mechanism. Applicants whose LOIs have successfully passed this first review stage will be invited to submit full applications. It is anticipated that about 40% of the applicants invited to submit full applications, following the LOI review stage, will be funded.

I. Letter of Intent

A Letter of Intent (LOI) is required and must be submitted electronically, via proposalCENTRAL, by 5 pm ET on the stated deadline. It should contain the following information:

(Items 1–4 should not exceed 2 pages. Figures, tables and legends are included within the page limit. However, citations are not counted towards the page limit.)

- 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. Overall objective and preliminary Specific Aims: State the overall objective and outline the preliminary 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.
- 5. *Biosketch*: A standard 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. Applicants who are not based in the United States may submit a copy of their curriculum vitae.

Restriction on number of applications: Only one LOI will be accepted per principal investigator in a 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 Lupus Research Alliance to advance to the next stage of the review process. Applications should be submitted via proposalCENTRAL (please log into this site for detailed instructions). The full application site will only be accessible to applicants with approved LOIs.

LIA 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 Early Stage Investigators.

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 hypotheses rather than the amount of preliminary data will be emphasized. Continuations of long-term research projects are <u>not</u> appropriate for this grant mechanism.

Applications that are not aligned with the goals of the LIA and the mission of the LRA will not be considered.

LIA Terms of the Award

The total amount of the Lupus Innovation Award is up to \$150,000 per year, including 10% indirect costs, for up to two years. Early stage investigators are eligible for a third year of funding (up to \$150,000) pending successful completion of the original grant aims. Early stage investigators are principal investigators who have completed their terminal research degree or end of post-graduate clinical training, whichever date is later, within the past 10 years (as of the date of application submission) and have not received significant, R01-level funding. To be eligible for a third year of funding, the early stage investigator must not have received an R01 during the course of the LIA term and must submit an extension request three months prior to the completion of the original grant.

Major pieces of laboratory equipment cannot be included in the LIA budget. Funds may be used for any appropriate research costs. The award cannot be used for a graduate student's tuition and/or stipend.

The grant recipient is required to attend the Lupus Research Alliance Annual Scientific Conference, Forum for Discovery, each year. Travel funds, provided by the grant award, must be used to attend this meeting.

The Lupus Research Alliance 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 take steps to facilitate availability of data and materials.

Resubmission Information

- A resubmission is considered an unfunded application from one of the previous two
 application cycles. An applicant who is unsuccessful in a competition may resubmit a revised
 application two times (the original, plus two resubmissions).
- Novel Research Grant (NRG) resubmissions should be submitted under the LIA mechanism.
- A brief (no more than 1-page) resubmission statement must be provided at the beginning of the LOI for all resubmissions. It should highlight the changes and how these modifications address the concerns of the original reviewers. The resubmission statement does not count towards the overall LOI page limit.
- A 1-page resubmission statement must be provided at the beginning of the research plan (for invited full applications) for all resubmissions. It should highlight the changes and explain how the application has been modified (additions, deletions, revisions) to address the concerns of the original review panel.
- A copy of the summary statement for the unsuccessful application must be included in the appendix of the new one. If you have not received a statement, please contact the LRA research staff.
- If major changes are made to the original application or if this is an entirely different/new project, the application should not be submitted as a resubmission.
- Applicants should contact the LRA research staff with any questions.

Review Process for LIA Applications

All grant applications will be peer-reviewed by the 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 within three months of the decision notification date. 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: November 10, 2020

<u>Letter of Intent Due</u>: February 16, 2021 <u>Letter of Intent Decision</u>: April 15, 2021 <u>Full Applications* Due</u>: June 15, 2021

Scientific and Board Reviews: September 2021 Response to Applicants†: September 30, 2021 Earliest Anticipated Start: December 1, 2021

*By invitation only with an approved LOI †For full applications only

Scientific Inquiries:

Shayla Shorter, PhD Scientific Program Manager Lupus Research Alliance <u>sshorter@lupusresearch.org</u> +1-646-884-6015

Administrative Inquiries:

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

proposalCENTRAL:

For help with the electronic grant application process, please contact the help desk of proposalCENTRAL <u>pcsupport@altum.com</u>; +1-800-875-2562, extension 227.