

Request for Applications 2023 William E. Paul Distinguished Innovator Award in Lupus and Autoimmunity \$1,000,000 over 4 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. There are many unanswered questions regarding the pathogenesis of lupus, and new conceptual and therapeutic approaches are urgently needed.

To address these critical knowledge gaps and markedly advance lupus research, the Lupus Research Alliance (LRA) established the William E. Paul Distinguished Innovator Award in Lupus and Autoimmunity (DIA). This grant mechanism is intended to attract exceptionally creative scientists from all relevant scientific disciplines and provide them with robust and sustained support to explore bold and paradigm-shifting ideas that could lead to ground-breaking discoveries in lupus research. Investigators working in areas outside of lupus are strongly encouraged to apply.

PROGRAM DESCRIPTION

The DIA provides outstanding scientists with substantial support (up to \$250,000 per year for up to four years) to conduct novel research into the fundamental causes of systemic lupus erythematosus and so provide new directions towards a cure. The LRA welcomes novel hypothesis- or discovery-driven proposals using clinically relevant models in lupus research. Proposals must aim to uncover the fundamental causes of lupus and present a compelling vision of how the discovery could lay the groundwork for a cure, prevention, or highly effective therapy.

Applications will be judged primarily on the novelty and potential of the research proposal, with particular emphasis on the rationale for the hypothesis and the supporting preliminary data and on the track record of the investigator. Continuations of long-term research projects will not be considered.

Successful applicants will be outstanding investigators who have demonstrated creativity and productivity in their field of research. We encourage applications from investigators in diverse disciplines including, but not limited to, immunology, genetics, and molecular, cell, and systems biology.

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.

Applicants are encouraged to consult with LRA scientific staff to discuss the responsiveness of their proposal to this program.

ELIGIBILITY

- At the time of submission of the letter of intent, applicants must hold a PhD, MD, or equivalent academic degree with a <u>faculty position at the level of assistant professor</u> <u>or above</u> at an academic institution.
- The LRA does not impose geographic restrictions on its applicants. Researchers working outside of the US are also encouraged to apply.
- Applicants with total active LRA funding of US\$600,000 or more (NCEs exempted) are not eligible to receive 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.

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 significance, novelty, and alignment of the proposed project with the DIA 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: Letters of Intent Due: Letter of Intent Decision: Full Applications Due*: Full Application Decision: Expected Start Date: December 20, 2022 February 6, 2023 May 1, 2023 June 14, 2023 October 2023 December 2023

*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.
- 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 <u>NIH Biosketch and Other Support</u> <u>Format Page</u>, which should detail all other financial support available to the applicant for their research endeavors as of the date of LOI submission. 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 considered to be 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. **Overall 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 significance, innovation, 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.

Restriction on number of LOIs

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

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 <u>ProposalCentral</u>, **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

The scientific review committee will consider each of the following criteria in assigning an application's overall score, weighting them as appropriate for each application.

- **Novelty of the proposed research:** Does the project (1) employ novel concepts or approaches, (2) contain original and innovative aims, (3) challenge existing paradigms or develop new methodologies or technologies?
- Scientific merit of the proposed research: Is the question to be studied significant? Is the rationale for the hypothesis supported by strong evidence with sufficient preliminary data?
- **Approach:** Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Has the applicant proposed alternative strategies to address the project's potential challenges?
- **Relevance** of the proposed project to the fundamental causes of lupus.
- **Therapeutic potential** of the proposed project to lead to lupus care, prevention, or a highly effective therapy.

- **Investigator:** Has the investigator demonstrated a track record of innovation, shifting scientific paradigms, and opening new areas of research?
- **Environment:** Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ beneficial collaborative arrangements? Is there evidence of institutional support?

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

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 within three months of the review date. Applications not recommended to advance to the full proposal stage will not receive written critiques. The LRA does not provide scores or application rankings to applicants.

AWARD TERMS AND CONDITIONS

The DIA provides up to US\$250,000 per year for up to four years. Indirect costs must not exceed 10% of the total budget and must be included within the \$250,000 annual budget cap. Funds may be used for any appropriate research costs, and up to 10% of the total annual budget (US\$25,000) may be allocated to salary of the principal investigator. Any equipment costs need to be strongly justified and, if approved, are only allowed in the first year of the award.

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 all 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 <u>2023 NIH Data Management and Sharing Policy</u>.

INQUIRIES

Scientific: Hoang Nguyen, PhD Senior Scientific Program Manager Lupus Research Alliance hnguyen@lupusresearch.org +1-646-884-6086

Administrative:

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

ProposalCentral:

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