

Request for Applications 2024 DIVERSITY IN LUPUS RESEARCH CAREER DEVELOPMENT AWARD \$600,000 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 and fostering diverse scientific talent. Addressing the challenges of lupus requires a talented and tenacious workforce capable of decoding the inherent complexity of the disease and devising innovative medicines.

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.

PROGRAM DESCRIPTION

The LRA Diversity in Lupus Research Career Development Award (DLR CDA) is designed to foster the development and productivity of outstanding independent, early-career underrepresented minority (URM) investigators, who will ideally bridge the gap between the bench and the bedside in lupus research. The DLR CDAs provide robust and sustained support (US\$150,000 per year for up to four years) for awardees to establish a competitive research program in areas that reflect the LRA's strategic priorities, which include 1) defining human lupus heterogeneity and 2) stratifying patients by active disease mechanism to advance new therapeutics.

ELIGIBILITY

At the time of submission of the letter of intent, applicants must hold an MD, PhD, DO, or equivalent academic degree with a faculty or equivalent position and lead an independent research team at an academic, nonprofit, or government research institution in the United States or Canada.

Applicants must be Early-Stage Investigators. For the purposes of this grant mechanism, an Early-Stage Investigator (ESI) is a Program Director (PD) or Principal Investigator (PI) who has completed their terminal research degree or post-graduate clinical training, whichever date is later, within the past ten years. PDs/PIs holding R01-type awards are eligible to apply.

The LRA recognizes that personal circumstances can impact career timelines (e.g., care of a parent/spouse/child/dependent or personal health issues). Applicants who have taken leave from their career and thus fall outside the eligibility timeline should contact LRA staff before applying to confirm eligibility.

Applicants must be members of a racial or ethnic group underrepresented in the science and engineering fields compared to their representation in the US population. For the purposes of this grant mechanism, these racial and ethnic groups are Blacks or African Americans, Hispanics or Latinos, Indigenous American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders.

There is no citizenship requirement.

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.

APPLICATION PROCESS AND INSTRUCTIONS

A two-stage application process will be employed. At the first step of the application process applicants must submit a Letter of Intent (LOI) indicating their intention to apply. The LOI is required and will be used for the purposes of convening an appropriate review panel. Applicants 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: June 20, 2023 September 12, 2023 October 10, 2023 December 5, 2023 April 2024 June 1, 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.
- 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 as a single document a standard <u>NIH Biosketch and Other Support Format Page</u>, which should detail other financial support 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 lead institution will be pre-loaded with the applicant's institution.
- 6. Letter of Intent: Upload the Letter of Intent. 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 should include the applicant's name, degree, position, institution, the project's title and specific aims, an impact statement explaining how the proposed research could improve the standard of care or quality of life of people with lupus, and the names of three references for the applicant. Please note that the applicant's primary and secondary mentors cannot serve as referees (see Mentoring Team and Mentoring Plan information below). The LOI should not exceed two pages.
- 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. Applications will not be accepted via any other means.

The following information is required to submit a complete full application. 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 application is a resubmission and, if so, select the prior application from the dropdown menu.
- 2. **Download Templates & Instructions:** The Request for Applications, Research Plan Template, Milestones Template, Mentoring Team Form, Primary Mentor Plan Form, Secondary Mentor Plan Form, and Mentor's List of Past Trainees 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 application.
- 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 as a single document a standard <u>NIH Biosketch and Other Support Format Page</u>, which should detail all other existing financial support (institutional, federal, commercial, etc.) available to the applicant for their research endeavors as well as a clear explanation of research overlap between the proposed and funded research projects. 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 & Contacts:** The lead institution will be pre-loaded with the applicant's institution. Enter the requested information for the Signing Official and Financial Officer.
- 6. Key Personnel: Enter the requested information for all key personnel, including the applicant's primary and secondary mentors. For the primary and secondary mentors, upload as a single document a standard <u>NIH Biosketch and Other Support Format Page</u>. For each co-investigator, upload a standard <u>NIH Biosketch</u>. For co-investigators and mentors not based in the United States, a copy of their curriculum vitae, which must be limited to five pages in length, may be submitted.
- 7. Letters of Reference: Enter an e-mail address for each referee submitting a letter of reference. Please note that the applicant's primary and secondary mentors cannot serve as referees. Three letters of reference are required. Letters of reference are to be limited to two pages in length and should describe the scientific

abilities and potential of the applicant. These letters are confidential and will not be released to the applicant. The letters of reference are uploaded directly by the referees to ProposalCentral. Please be aware that applications cannot be submitted without the three letters of reference.

- 8. Lay & Scientific Abstracts: Provide both lay and scientific abstracts, limited to 3,000 characters each, for the proposed project. The lay abstract should be suitable for public distribution. Provide an impact statement, limited to 1,000 characters, explaining the potential of the proposed project to translate to the clinic and how the proposed research will impact people with lupus.
- 9. **Budget Period Details:** Enter the budget periods for each year of the grant and complete the budget information for each budget period. Please keep the following in mind:
 - DLR CDA grants will be supported for up to US\$150,000 per year for up to four years.
 - Funds may be used for any appropriate research costs.
 - The LRA follows the NIH salary limitation guidelines for principal investigators and post-doctoral fellows.
 - Indirect costs may not exceed 10% of the total amount budgeted.
 - Funds cannot be used to pay for equipment or tuition or education expenses.
- 10. **Budget Summary & Justification:** A detailed budget justification, limited to 5,000 characters, must be provided.
- 11. **Organizational Assurances:** Answer all organizational assurance questions and provide their status, if applicable.
- 12. Research Plan & Other Attachments: Upload the Research Plan, Summary Statement (if applicable), Milestones, Diversity Statement, Institution's Diversity, Equity and Inclusion Policy, Mentoring Team Form, Primary Mentor Plan, Secondary Mentor Plan, Mentors' List of Past Trainees, Letter of Institutional Support, and Letters of Collaboration (if applicable). Please note that when a template or form is provided, it must be used. Indicated page limits must be strictly adhered to. All documents should be uploaded to ProposalCentral as PDFs.
 - A. **Research Plan:** The Research Plan 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 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 one page. The statement should highlight changes from the original submission and explain how the application has been modified to address the concerns of the original review panel. A copy of the summary statement provided by the LRA for the original application must be uploaded as a separate document.

- 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. **Career Goals:** The candidate should describe their current and long-term research and career objectives as well as their plan for career development activities during the award period. The candidate should explain how this award will enhance their research productivity, facilitate the development of new approaches or directions for investigation, and ensure their commitment to a career in lupus research or translation. (2 pages)
- iii. **Research Plan:** List specific aims and state the relevance, significance, feasibility, innovation, and approach of the proposed research. Provide a detailed rationale, experimental approach, and expected and alternative outcomes for the proposed studies. The applicant should also describe their current research and its relation to the proposed research, including any preliminary supporting data. The plan should include objectives, milestones, and associated timelines for the award period. (8 pages, excluding references)
- iv. Facilities and Resources: Specify the facilities to be used for the conduct of the proposed project. Indicate the performance sites and describe capacities, pertinent capabilities, relative proximity, and the extent of availability for the project. Under "Other" identify support services (machine shop, electronics shop, etc.) and specify the extent to which they will be available to the project. List all major equipment items already available for the proposed project, noting the location and pertinent capabilities of each. (2 pages)
- B. **Milestones:** Using the template provided on ProposalCentral, list all aims and subaims necessary to complete the proposed project. Indicate during which months of the grant term each aim and sub-aim are proposed to be completed by filling the corresponding cells with a light color. Upload as a PDF document.
- C. **Diversity Statement:** The applicant's institution should describe how support of this specific applicant will address the issue of diversity within the national scientific workforce and explain how mentoring is conducted at the institution. (1 page)
- D. **Diversity, Equity, and Inclusion Policy:** A copy of the institution's Diversity, Equity and Inclusion Policy must also be uploaded.
- E. **Mentoring Team and Mentoring Plan:** The DLR CDA requires a primary mentor and a secondary mentor who will provide counsel and direction to the applicant. The mentors should 1) have a prior history of successfully mentoring early career investigators to independence, 2) have a track record of high-quality investigations and academic accomplishments, and 3) be invested in the career progress of the applicant. The primary mentor must be from the applicant's institution and an active

investigator in the area of the proposed research. The secondary mentor can be from the applicant's or an outside institution or department and be an active investigator in an area complementary to the proposed research. The mentors' primary functions are to work with the applicant to develop the application, make necessary arrangements with the institutions to conduct the proposed research, enforce the appropriate timelines to accomplish the work, and guide the applicant toward a productive career in their chosen field, including publishing their research findings and applying for an NIH RO1 or equivalent grant.

- i. Mentoring Team Form: Provide the requested information. (1 page)
- ii. **Primary Mentor Plan Form:** The primary mentor should provide a clear and focused mentoring plan that 1) details how the applicant will be mentored, 2) outlines project timelines and milestones that must be achieved by the applicant to successfully complete the proposed research, and 3) explains whether and how the research proposed by the applicant differs from the research endeavors of the primary mentor. (1 page)
- iii. **Secondary Mentor Plan Form:** The secondary mentor, in conjunction with the mentee, should provide a plan to guide the applicant toward a productive career in their chosen field that would include, but not be limited to, the critical review of the applicant's manuscripts and applications for funding, and career advancements. (1 page)
- iv. **Mentors' List of Past Trainees:** Each mentor should list up to five trainees (predoctoral or postdoctoral) from the past 10 years who, following training in the mentors' groups, successfully advanced their careers to the next level in academia, the private sector, or government. (1 page each)
- F. Letter of Institutional Support: The applicant's department head must provide a letter affirming the institution's commitment to the applicant's academic career and the research project proposed in the application. (2 pages)
- G. Letters of Collaboration (if applicable): Signed letters from each co-investigator or consultant stating their role in the project and confirming their agreement to participate in the project must be provided. These letters should include a detailed explanation of the programmatic, fiscal, and administrative arrangements made between the applicant institution and collaborating organizations and individuals. The letters should be combined into one PDF document.
- 13. **PI Data Sheet:** Please verify the applicant's gender, race, and ethnicity. This information will not be used in any way during the selection process.
- 14. **Validate:** Click the "Validate" button to check for any missing required information or attachments.
- 15. **Sign:** Click the "Sign" button to electronically sign the application. By signing, the applicant certifies that the information contained in the application is true, complete,

and accurate to the best of their knowledge and agrees to facilitate the availability of data and materials by executing a Data Sharing Plan based on the <u>2023 NIH Data</u> <u>Management and Sharing Policy</u> should the proposed project be funded by the LRA. The institution's signing official must also sign.

16. **Submit:** After successfully passing the validate check, click the "Submit" button. An e-mail will be sent confirming submission.

Resubmission information

Applicants resubmitting full applications that were not funded in the last award cycle must include a one-page resubmission statement highlighting the planned overall modifications to address the concerns of the original review panel. A copy of the summary statement must be included in the appendix of the resubmission. If you have not received a statement, please contact LRA research staff.

Change of Institution or Position

If you change your institution or professional position after submitting your application, you are required to promptly contact the LRA to present and discuss your new circumstances.

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.

- **Applicant:** Is the applicant appropriately trained and well suited to carry out this work? Is the work proposed appropriate to their experience level? Do they demonstrate a commitment to a career in lupus research and the enhancement of diversity, inclusion, and equity in the field? Do the letters of recommendation align with the overall impression of the candidate presented in the application and are they supportive of the investigator's application for a DLR CDA?
- **Career Plan:** Will the proposed career plan enhance the scientific and professional development of the applicant? Does the career plan include an intention to augment the appropriate research skills and training to facilitate continued success as an independent investigator?
- **Relevance:** Is the proposed project aligned with the goals of the DLR CDA grant mechanism, as well as the mission and strategic priorities of the LRA?
- **Significance:** Will the work stimulate investigation of underexplored pathways and initiate transformative discoveries in lupus that can drive the development of safer and more effective treatments? Is the project based on novel explorations of lupus biology, including innovative studies that use human material to address the physiological, cellular, molecular, or genetic basis of human lupus? Does this project prompt investigations into the fundamental mechanisms of lupus and its complications, explorations of novel targets and pathways, and the use of novel technologies and interdisciplinary approaches?

- **Approach:** Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?
- **Innovation:** Does the project employ novel concepts, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?
- **Feasibility:** Can this project be accomplished within a four-year time frame?
- Mentoring Team and Mentoring Plan: Do the mentors provide a clear and focused mentoring plan that will guide the applicant toward a productive career in their chosen field? Do mentors have a record of successfully mentoring early career investigators to independence? Does the primary mentor propose reasonable milestones that need to be achieved by the applicant to complete the project?
- **Institutional Support:** Does the applicant's institution provide, through the Department Head's Statement, strong assurance of academic commitment to the applicant, their research project, and their career development?
- **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?

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 proposals, 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 receive abridged feedback. The LRA does not provide scores or application rankings to applicants.

LRA MENTORSHIP RESOURCES

Mentors and peer support play a critical role in the development of scientists. In addition to an applicant-selected mentoring team, DLR CDA recipients will benefit from critical mentoring resources provided by the LRA and the support of other members of their

cohort. The mentoring program includes all LRA CDA recipients and is guided by two established lupus investigators appointed by the LRA. The group will meet twice a year—once in person during the LRA annual scientific conference—to discuss questions or issues related to publications, grant applications, laboratory and grant management, collaborations, career advancement, etc. The LRA may also offer awardees exposure to relevant industry contacts and opportunities, as necessary.

AWARD TERMS AND CONDITIONS

The DLR CDA provides up to US\$150,000 per year for up to four years. Indirect costs must not exceed 10% of the total budget and must be included within the US\$150,000 annual budget cap. Funds may be used for any appropriate research costs, including participation in a grant writing/coaching program if not already offered by the awardee's institution. Any equipment costs need to be strongly justified and, if approved, are only allowed in the first year of the award.

The PI must spend at least 60% of their time and effort on research relevant to lupus during the grant period. Grant recipients must attend and present at Forum for Discovery, the LRA annual scientific conference, each year. Travel funds (up to US\$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 PI's mentoring team is expected to meet with the PI every six months during the grant period. At each meeting, the PI should give a formal presentation of the work accomplished to date and detail future plans. The PI and their mentors should also discuss how the PI will achieve their stated career goals and successfully complete the funded project. Mentoring team meetings should be recorded by completing a Meeting Record Form. Documentation of these meetings must be included with each annual progress report.

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

For all administrative and scientific questions, please contact the LRA at <u>grants@lupusresearch.org</u>.

ProposalCentral:

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