



INVESTIGATOR-INITIATED CLINICAL TRIALS AWARD PROGRAM

2018 REQUEST FOR APPLICATIONS

Lupus Research Alliance
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LUPUS RESEARCH ALLIANCE

The Lupus Research Alliance (LRA) is the world's leading private funder of lupus research. It has committed over \$200 million in support of nearly 500 lupus-related research projects. The organization's mission is to improve treatments while advancing lupus towards a cure. At present, therapy for lupus is empiric and involves a variety of 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, there are many unanswered questions regarding the pathogenesis of lupus and a need for new conceptual and therapeutic approaches. The LRA has established several grant mechanisms aimed to address major barriers in lupus research.

INVESTIGATOR-INITIATED CLINICAL TRIALS (IICT) GRANTS

IICT Grants seek to stimulate exploration of novel therapeutic approaches. This programmatic approach is intended to augment LRA's current research portfolio in an effort to align supported research projects with LRA's affiliate, Lupus Therapeutics and the Lupus Clinical Investigators Network (LuCIN) strategic objectives. The purpose of the Grant is to provide support one or more for well-justified investigator-initiated clinical trials (not fully funded by industry or other sources) designed to determine whether, and to what extent, promising new therapies can improve the lives of lupus patients. A primary focus is the evaluation of drugs that are currently approved for other indications and are available for use, known as drug repurposing, which has been a major focus of the LRA's interest in drug development in lupus. The intention of this program is to eliminate the barriers that typically hinder lupus clinical trials, ensuring that scientifically-sound treatment approaches are tested in lupus patients as quickly as possible.

KEY DATES

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| <i>RFA Release</i> | <i>June 1, 2018</i> |
| <i>Application Due</i> | <i>September 4, 2018 by 8p.m. EDT</i> |
| <i>Application Review</i> | <i>September – November 2018</i> |
| <i>Board Review</i> | <i>December 2018</i> |
| <i>Award Notification</i> | <i>January 2019</i> |
| <i>Earliest Anticipated Start</i> | <i>March 2019</i> |

ELIGIBILITY

Applicants and institutions must conform to the following eligibility criteria to be considered for funding through the IICT Grant. Eligibility requirements must be met at the time of application submission.

The Grant is available to investigators affiliated with a LuCIN center and investigators not affiliated with a LuCIN center; however, the expectation is that the planned clinical trial will utilize LuCIN centers. In addition, the successful applicant (i.e. Principal Investigator) will be required to collaborate with the relevant LuCIN Committees to develop and refine the planned protocol prior to implementation.

APPLICANT

- Must have a doctoral degree, including MD, PhD, DrPH, DO, or equivalent
- Are not required to be U.S. citizen or resident

INSTITUTION

- Must be a non-profit institution or organization anywhere in the world
- Must agree to adhere to LRA's Policies and Procedures for Research Grants including, for example, regulatory assurances, ownership of equipment, intellectual property, liability and insurance and reporting requirements. Copies of the Policies and Procedures will be made available at the time of the Award.

DESIGNATED RECIPIENTS

Grants will be awarded to a single Principal Investigator (PI) or two Co-Principal Investigators (Co-PIs).

FUNDING INFORMATION

Applicants may request either two or three years of funding as follows:

- Up to \$3,000,000 in total over two or three years (inclusive of IDC at 10%) for non-drug study costs

APPLICATION REVIEW PROCESS

Applications proceed through a two-step review process. The first step includes a peer review based on the defined criteria described below. The second step involves evaluation by the LuCIN Executive Committee, which will provide recommendations to the Lupus Therapeutics Board of Directors, which determines the final slate of applications for funding. Un-edited reviewer critiques will be provided to the applicants within 90 days of award notification.

REVIEW CRITERIA

Evaluations for funding consideration are based on each of the following review criteria. Applicants should read the criteria questions carefully and ensure that their application addresses all aspects of each criterion.

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| Scientific Merit | Does the proposed intervention(s) have adequate rationale both mechanistically and clinically? Is the toxicity profile of the intervention(s) considered reasonable? Will the approach effectively evaluate and answer each trial-specific aim? Does the study design use valid research and statistical methods and power calculations? Does the application have the appropriate Protection of Human Subjects safe guards in place? |
| Clinical Impact | What are the advantages of the proposed approach compared to existing therapeutic interventions for lupus? Is the preferred patient population justifiable based on the planned intervention? Will the proposed approach lead to substantial advances and/or contribute to the understanding or knowledge that could improve clinical outcomes in lupus? |
| Research Significance | Does the proposed study address an important question(s) that is not likely to be addressed without LRA funding? Does the proposed study offer a unique opportunity to explore an important issue and/or employ a novel approach to lupus research? Will the study results advance our knowledge of lupus and/or contribute to changes in the focus of future research questions or the way we conduct research in lupus? |
| Feasibility | How likely is it that the study will be achieved within the proposed timeline? How important will the LuCIN collaboration be to ensure success and is there an adequate plan for data sharing? |
| Expertise | Does the PI/Co-PI and his/her research team have the expertise to effectively implement and oversee all aspects of the proposed study? |

SUBMISSION PROCESS

Applicants will be required to submit their applications through proposalCENTRAL. All applications must be submitted electronically through this online system at ***<https://proposalcentral.altum.com/First-time users must register and create a username and password>***. The username and password allows Applicants to develop, modify, and submit applications. Once users have registered, they do not need to re-register in order to apply for other funding opportunities.

A User Guide and detailed submission instructions are available after signing into the application system to help Applicants navigate through the application process.

All scientific inquiries regarding application submission should be directed to Albert Roy at aroy@lupusresearch.org or 646-884-6071.

All administrative inquiries regarding application submission should be directed to:

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