



2020 Request for Applications (RFA) for the following two grant mechanisms:

Lupus Innovation Award (LIA) and Lupus Mechanisms and Targets Award (LMTA)

Release Date: November 1, 2019

Due date: January 15, 2020

Earliest Start Date: September 2020

FUNDING MECHANISMS
Highlights of Key Features and Differences

The LIA and LMTA grant mechanisms were formerly known as the Novel Research Grant (NRG) and the Target Identification in Lupus (TIL) grant, respectively. All resubmissions of formerly declined NRG applications must be submitted under the LIA grant mechanism, while all resubmissions of formally declined TIL applications must be submitted under the LMTA mechanism. Failure to do so will disqualify the resubmitted application.

Please note that while the Lupus Innovation Award and the Lupus Mechanisms and Targets Award funding mechanisms follow the same review timeline, they have distinct objectives, application templates, and selection criteria. Applicants are urged to carefully review the individual grant program guidelines detailed in this RFA.

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.

Lupus Mechanisms and Targets Award (LMTA): up to \$200,000/year total costs for up to three years. Supports highly meritorious research focused on the identification and/or investigation of molecular pathways or targets that will lead to new or improved therapies for patients with lupus.

The same research project may not be submitted for consideration to both grant mechanisms. 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 two grant mechanisms: the Lupus Innovation Award (LIA) and the Lupus Mechanisms and Targets Award (LMTA).

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 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 no 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 [proposalCENTRAL](#) by 5pm EST on the stated deadline (please log into proposalCENTRAL for detailed application instructions). The research plan must not exceed five pages. Paper applications are not accepted. Only one LIA application will be accepted per principal investigator in a grant cycle.

All resubmissions of formerly declined NRG applications must be submitted under the LIA grant mechanism and must follow the general resubmission guidelines below.

LIA Review Criteria

To facilitate support of high-risk high-reward projects, 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 not 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.

Lupus Mechanisms and Targets Award (LMTA)

Award Goals

The goals of the LMTA are to: (1) characterize key steps in the pathogenesis of the disease that will allow for the development of new therapeutic agents; (2) promote basic and clinical research studies to identify and/or better characterize molecular pathways and cellular mechanisms that suggest promising approaches for lupus treatment; and (3) support research that facilitates the clinical evaluation of innovative approaches to the prevention, management or treatment of lupus and its complications.

LMTA grants are intended to be highly focused on lupus and, as such, should lead directly to knowledge that will facilitate drug discovery and/or testing of new treatments that may be used to treat systemic or organ-specific manifestations of lupus. As the goal of this program is to advance the treatment of lupus and outcomes of lupus patients, any research funded must be based on realizable goals for ultimate translation into therapeutic discovery programs. LMTA research can lay the groundwork for development of therapeutics that include small molecules, biologic agents, vaccines, gene therapy, as well as predictive biomarkers and novel approaches in public health and risk reduction.

The Lupus Research Alliance encourages applications proposing research that will apply knowledge gained in other disease areas (e.g., other autoimmune and inflammatory conditions, cancer, metabolic diseases) to mechanisms relevant to lupus. These studies can be initiated or conducted in either humans or animals, although any work on animals must include a plan for extension and verification in patient populations. Studies working towards the identification or validation of lead therapeutic compounds for lupus must provide a clear scientific rationale for the compound(s) under investigation, and a research plan that would enable a decision regarding the viability of the compound(s) as a therapeutic approach in lupus. Clinical studies to improve the ability to evaluate innovative therapies in lupus may focus on mechanistic studies and/or the development of systems or processes that enhance the ability to obtain reliable and timely answers to therapeutic questions in lupus. The LRA encourages the use of previously collected longitudinal and/or cross-sectional patient samples and/or data.

Research Priority Areas

In keeping with the strategic research objectives of the LRA, priority consideration will be given to projects that address understanding of lupus heterogeneity or enable patient stratification by active disease mechanism and ideally employ emerging technologies to address these priority areas. Examples of pertinent topics in unranked order include but are **not** limited to:

- Defining pathogenic cell types in human lupus using state-of-the-art approaches;
- Defining the drivers of the type I interferon signature in lupus;
- Developing and applying *ex-vivo* human models of immune cell interactions for disease modeling
- Defining the role of the microbiome in disease pathogenesis and treatment in human lupus
- Identifying racial and ethnic differences in the presence and importance of disease pathways in lupus, such as those underlying lupus nephritis;
- Correlating clinical features of SLE with peripheral biomarkers to define lupus heterogeneity;
- Characterizing the immunologic and molecular factors that differentiate responders from non-responders in each class of biologic therapeutics currently being used or tested in SLE.

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 no citizenship requirements. The Lupus Research Alliance is willing to appropriately support collaborations between academia and industry. Federal government research laboratories are not eligible for this award.

LMTA Application Guidelines

Applications must be submitted electronically, via [proposalCENTRAL](#) by 5pm EST on the stated deadline (please log into proposalCENTRAL for detailed application instructions). Submitted research plan must not exceed ten pages. Paper applications are not accepted. Only one LMTA application will be accepted per principal investigator in a grant cycle.

All resubmissions of formally declined TIL applications must be submitted under the LMTA mechanism and must follow the general resubmission guidelines below.

LMTA Review Criteria

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

- **Relevance:** Is the proposed project aligned with the goals of the LMTA grant mechanism and the mission of the Lupus Research Alliance?
- **Significance** of the project as indicated by the likelihood that the work will:

- characterize key steps in the pathogenesis of the disease that will allow for the development of new therapeutic agents or biomarkers.
- promote basic and clinical research studies to identify and/or better characterize promising lead compounds for lupus treatment.
- support research that facilitates the clinical evaluation of innovative approaches to the prevention or treatment of lupus and its complications.
- **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 two-year time frame?
- **Investigator:** Is the investigator appropriately trained and well-suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?
- **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 useful collaborative arrangements? Is there evidence of institutional support?

LMTA Terms of Award

LMTA grants will be supported for up to \$200,000/year for up to three years. Indirect costs should not exceed 10% of the total budget (excluding equipment) and must be included within the \$200,000 annual budget cap. Support for the third year of funding will be based on the successful submission and review of a non-competitive progress report during the second year of the award.

Grant recipients are 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 Alliance'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 for former NRG and TIL Applications

- A resubmission is considered an application un-funded in 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).
- NRG resubmissions should be submitted under the Lupus Innovation Award (LIA) mechanism. TIL resubmissions should be submitted under the Lupus Mechanisms and Targets Award (LMTA) mechanism.
- A 1-page resubmission statement must be provided at the beginning of the research plan 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 and LMTA 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 1, 2019
Applications Due:	January 15, 2020
Scientific and Board Reviews:	May-June 2020
Response to Applicants:	June 30, 2020
Earliest Anticipated Start:	September 2020

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