



**2019 Request for Applications (RFA) for the following two grant mechanisms:
Novel Research Grant & Target Identification in Lupus**

Release Date: October 1, 2018

Application Due Date: February 1, 2019

Earliest Start Date: September 2019

**FUNDING MECHANISMS
Highlights of Key Features and Differences**

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

Novel Research Grants (NRG): up to \$150,000/year total costs for up to two years. Provides early stage support for highly innovative 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. Early-career investigators are encouraged to apply through this mechanism.

Target Identification in Lupus (TIL): up to \$200,000/year total costs for up to three years. Supports highly meritorious research focused on the identification and scientific and/or clinical investigation of molecular pathways and therapeutic targets that will lead to new therapies or improved management 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 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, there are many unanswered questions regarding the pathogenesis of lupus and a need for new conceptual and therapeutic approaches. To develop more effective and safe lupus therapies, and to address major barriers in lupus research the Lupus Research Alliance has

established the Target Identification in Lupus (TIL) and the Novel Research Grant (NRG) programs.

Novel Research Grant (NRG) Program

Program Goals

Novel Research Grants are intended to support projects that evidence high promise for advancing the understanding of Systemic Lupus Erythematosus. Novel Research Grants provide early stage 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 field forward. Applications will be judged principally on novelty of the hypotheses, scientific quality, strength of approach, likelihood of success, relevance to lupus, and potential impact for those living with lupus. Rationale for the hypotheses proposed rather than amount of preliminary data will be emphasized. Continuations of long-term research projects are not appropriate for this grant mechanism.

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. 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.

The Lupus Research Alliance also 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.

Eligibility

Individuals with a doctoral degree (MD, PhD, DO or equivalent), holding a faculty, or equivalent, position at the Instructor level or above at an academic or research institution are eligible to respond to this RFA. Early-career investigators are encouraged to apply through this mechanism. There are no citizenship requirements. Federal Government Research Laboratories are not eligible for this award.

NRG Application Guidelines

Applications must be submitted electronically, via [proposalCENTRAL](#) by 5pm EST on the stated deadline and should contain the below information (please log into proposalCENTRAL for detailed description). Submissions must be completed using 12-pt. Times New Roman font or equivalent. Paper applications are not accepted.

1. *Lay Abstract*: Summary of the proposed research and its potential significance to the fundamental causes of lupus, written in lay language geared to a twelfth-grade reading level and suitable for use in publications (not to exceed 3,000 characters). Please do not submit a

- scientific abstract in this section.
2. Scientific Abstract: Technical summary of the proposed research, written in scientific terms (not to exceed 3,000 characters).
 3. Research Plan (parts b-e may not exceed six pages): A description of the proposed research should include the following:
 - a) Resubmission Statement (if applicable): Revised applications are required to include a resubmission statement (not to exceed 1 page) that addresses the comments of the previous review and explains how the application has been modified. A copy of the summary statement, for the original application, provided by the LRA must be included in the appendix of the revised application. See the *Resubmission Information* section for additional information.
 - b) Background and specific aims
 - c) Preliminary data (if any)
 - d) Experimental design and methods
 - e) Significance of the proposed work, explanation of the novel nature of the work, and its relevance to lupus. Please include answers to the following questions:
 - i. How is this project novel?
 - ii. How will this project advance the science of lupus?
 - iii. Is there a preference for human tissue use?
 - f) Milestones: List the expected status of the project at various points in time for the duration of the grant. The list of milestones, ideally presented in a table format, should reflect the specific aims of the proposal. The milestones are part of the proposal narrative but are not included in the 6-page limit. These milestones will be used to evaluate progress and to facilitate communication between the principal investigators and the Lupus Research Alliance.
 - g) Literature citations should be listed but are also not included in the page limit for the Research Plan.
 4. Biosketch: A standard NIH 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.
 5. Detailed Budget and Summary: A budget for the project should be prepared in U.S. dollars. The budget should be for up to two years and should not exceed \$150,000 per year, including 10% indirect costs. The NRG does not provide funds for major pieces of laboratory equipment.
 6. Budget Justification: A detailed justification for the budgetary requests must be provided. The information in this section should be divided into two sections. The first section should include the following line items: personnel, consultant costs; equipment and supplies (both office and medical of laboratory). The second section should include all other line items including but not limited to: travel to annual investigator's meeting, patient care, other expenses, consortium and contractual costs. Funds cannot be used to pay for tuition or education expenses. Each section should not exceed 2,000 characters. Any additional information should be included as an appendix to the application.
 7. Other Support: Must indicate current and pending grant applications, their specific aims, amounts and extent of overlap, if any. If overlap exists, a statement regarding intended disposition of funds in the event of dual granting is required.

8. Facilities & Equipment Description: A short description of the facilities and equipment available to support the project.
9. Assurances: Appropriate institutional assurances regarding human subjects and animals as applicable.
10. Consent Forms: If relevant, copies or drafts of all informed consent forms, to be distributed to participants for signature in this study (or their legal guardians), should be provided.
11. Consultant/Co-Investigator/Collaborator Letters: Optional, only submit if relevant to the application.
12. Signed Cover Page: The signed cover page, which reflects the applicant's agreement to abide by the rules governing grant awards from the Lupus Research Alliance, should be uploaded electronically. Instructions are available on the [proposalCENTRAL](#) website.

Restriction on Number of Applications: Only one NRG application will be accepted per principal investigator in a grant cycle.

NRG Review Criteria

The scientific review group will consider each of the following criteria in assigning the application's overall score:

- Novelty of the hypothesis
- Relevance to lupus
- Scientific merit
- Strength of approach
- Likelihood of success
- Qualification of the investigator(s)

NRG Terms of the Award

The total amount of the Novel Research Grant is up to \$150,000 per year, including 10% indirect costs, for up to two years. Major pieces of laboratory equipment cannot be included in the NRG 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, should 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.

Target Identification in Lupus (TIL) Program

Program Goals

The goals of the TIL grant program 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. TIL 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. These therapies may be used to treat systemic or organ-specific manifestations of lupus, although they may find applicability in the setting of other autoimmune or inflammatory illnesses. 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. TIL 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 particularly welcomes 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.

Eligibility

Individuals with a doctoral degree (MD, PhD, DO or equivalent), holding a faculty, or equivalent, position at the Instructor level and above at an academic or research institution are eligible to apply. Scientific independence, as evidenced by direction of a research program, publication record, or other relevant experience is necessary 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.

Relevance to the Mission of the Lupus Research Alliance

TIL grants should lead to new insights into disease pathogenesis, advances in the discovery or validation of novel therapeutic targets or pathways for lupus, or improvements in the abilities to evaluate the outcome of lupus therapies, as through the identification or testing of novel biomarkers. These proposals must demonstrate a strong orientation towards the evaluation of new therapeutics either in the current proposal or as a logical next step. Applications submitted for the TIL grant program must be relevant to the purpose and goals of the program and the mission of the Lupus Research Alliance.

The TIL grant program will fund research that will accelerate the discovery and validation of new targets and pathways and may thus ultimately lead to new treatments for lupus. As such, these grants should be innovative in direction and utilize state-of-the-art techniques. Fundamental studies in genetics, immunology, cell biology and molecular biology to identify and characterize molecular systems must be oriented towards the ultimate development of drugs that would prevent and/or ameliorate clinical signs and symptoms of 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.

TIL Application Guidelines

Applications must be submitted electronically, via [proposalCENTRAL](#) by 5pm EST on the stated deadline and should contain the below information (please log into proposalCENTRAL for detailed description). Submissions must be completed using 12-pt. Times New Roman font or its equivalent. Paper applications are not accepted.

1. Lay Abstract: Summary of the proposed research and how it will accelerate the development of new treatments for lupus. This must be written in lay language geared to a twelfth-grade reading level and suitable for use in publications (not to exceed 3,000 characters). Please do not submit a scientific abstract in this section.
2. Scientific Abstract: A technical abstract of the research plan that includes the application's long-term objectives and specific aims. Investigators should highlight the relevance of the work to lupus. The abstract should not exceed 3,000 characters.
3. Research Plan (parts b-e may not exceed 10 pages): A description of the proposed research should include the following:
 - a. Resubmission Statement (if applicable): Revised applications are required to include a resubmission statement (not to exceed 1 page) that addresses the comments of the previous review and explains how the application has been modified. A copy of the summary statement, for the original application, provided by the LRA must be included in the appendix of the revised application. See the *Resubmission Information* section for additional information.
 - b. Significance and innovation:
 - i. highlight the significance and novelty of the work;
 - ii. describe the relevance of the project to the cause, cure, treatment or prevention of lupus and/or its secondary complications;
 - iii. emphasize the relevance of the project to the goals of the TIL program.
 - c. Hypothesis and specific aims
 - d. Preliminary data
 - e. Experimental design and methods: in addition to describing the approach for each specific aim, this section should also include the anticipated outcomes and alternative strategies.
 - f. Milestones: A list of milestones (the expected status of the project at various points in time for the duration of the grant). These milestones will be used to evaluate progress and to facilitate communication between the principal investigators and the Lupus Research Alliance. The list of milestones should reflect the specific aims of the proposal and be presented within the context of a pathway for determining or evaluating

- a potential target for lupus treatment. The milestones are part of the research plan but are not included in the 10-page limit. See Instructions for Proposal Narrative in the electronic templates section.
- g. Literature citations should be listed, but are also not included in the page limit for the Research Plan
4. Biosketch: A standard NIH 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.
 5. Detailed Budget and Summary: A budget for the project prepared in U.S. dollars. The budget should be for three years and should not exceed \$200,000 per year, including indirect costs, which should not exceed 10% of the total budget (excluding equipment).
 6. Budget Justification: A detailed justification for the budgetary requests must be provided. The information in this section should be divided into two sections. The first section should include the following line items: personnel, consultant costs; equipment and supplies (both office and medical of laboratory). The second section should include all other line items including but not limited to: travel to the annual investigators' meeting, patient care, other expenses, consortium and contractual costs. Funds cannot be used to pay for tuition or education expenses. Each section should not exceed 2,000 characters. Any additional information should be included as an appendix to the application.
 7. Other Support: Applicants must include accurate and complete information regarding all other sources of grant support from the main PI (current and pending), including title, abstract, annual and total amount of the grant, inclusive funding period, and percent effort of the applicant. It is not necessary to include this information for all Key Personnel. This should also include a description of currently active support and all projects and proposals pending review and/or award regardless of financial and/or scientific relevance to this application.
 8. Facilities & Equipment Description: A short description of the facilities and equipment available to support the project.
 9. Assurances: Appropriate institutional assurances regarding human subjects and animals as applicable.
 10. Consent Forms: If relevant, copies or drafts of all informed consent forms, to be distributed to participants for signature in this study (or their legal guardians), should be provided.
 11. Consultant/Co-Investigator/Collaborator Letters: Optional, only submit if relevant to the application.
 12. Signed Cover Page: The signed cover page, which reflects the applicant's agreement to abide by the rules governing grant awards from the Lupus Research Alliance, should be uploaded electronically. Instructions are available on the [proposalCENTRAL](#) website.

Supplemental Material Applicants can submit supplemental material (limited to 1 page), which: 1) was acquired following the submission of the grant application; and 2) substantially bolsters the proposal. Examples of appropriate supplemental information include an accepted relevant manuscript or additional preliminary data. This must be submitted via e-mail to Diomaris Gonzalez (dgonzalez@lupusresearch.org) no later than April 26, 2019. Please do not submit a cover letter or mail any documents to the Lupus Research Alliance.

Restriction on Number of Applications: Only one TIL application will be accepted per principal investigator in a grant cycle.

TIL 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* of the proposed project to the goals of the TIL program 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
 - 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* to accomplish the proposed work within a three-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?

TIL Terms of Award

TIL 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, should 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 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).
- 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 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 Lupus Research Alliance staff with any questions.

Review Process for NRG and TIL Programs

All grant applications will be peer-reviewed by the Study Section of the Lupus Research Alliance. Results from that peer review will be forwarded to the Lupus Research Alliance Scientific Advisory Board (SAB). The SAB will consider the recommendations from the Study Section, as well as review the existing Lupus Research Alliance portfolio to determine which applications would complement existing grants or address an unfilled area of research. The SAB will submit their recommendations to the Lupus Research Alliance 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 Lupus Research Alliance 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 may be able to receive abridged feedback and should contact LRA staff to request such. The Lupus Research Alliance does not provide application's scores or rankings to applicants.

Key Dates

RFA Release: October 1, 2018
Earliest Submission: October 15, 2018
Application Due: February 1, 2019
Scientific and Board Reviews: May-June 2019
Response to Applicants: July 2, 2019
Earliest Anticipated Start: September 2019

Inquiries

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