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**2018 Request for Applications for the following two grant mechanisms  
Target Identification in Lupus Program & Novel Research Grant Program**

**Release Date:** November 3, 2017

**Application Due Date:** February 9, 2018

**Earliest Start Date:** August 2018

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

Please note that while the Target Identification in Lupus and 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.

**Target Identification in Lupus (TIL):** up to \$200,000/year total costs for up to 3 years  
Supports highly meritorious research focused on the identification and scientific and/or clinical advancement of therapeutic targets that will lead to new therapies for lupus.

**Novel Research Grants (NRG):** up to \$100,000/year total costs for up to 3 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.

**The same research project may not be submitted for consideration to both grant mechanisms. Any 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. 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. 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.

## **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 promising lead compounds for lupus treatment; and (3) support research that facilitates the clinical evaluation of innovative approaches to the prevention 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, any research funded must be based on realizable goals for translation into therapeutic discovery programs. Targets can include small molecules, biologic agents, vaccines, gene therapy, as well as 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 experience that establishes scientific leadership is necessary to apply. There are no citizenship requirements. The Lupus Research Alliance is willing to appropriately support research in industry or 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 development of innovative therapies under consideration for lupus, or improvements in the abilities to evaluate the outcome of lupus therapies. These proposals must demonstrate a strong orientation to the development and/or evaluation of new therapeutics. Thus, these grants differ from a conventional NIH R01 mechanism where a translational goal is not essential to the success of the grant. 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 development of new treatments of 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 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 development of lead therapeutic compounds for lupus must provide a clear scientific rationale for the compound(s) under investigation, and a research plan that would allow for a definitive decision regarding the viability of the compound(s) as a therapeutic approach to lupus. Clinical studies to improve the ability to evaluate innovative therapies in lupus may focus on 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). 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. *Resubmission Statement* (if applicable): Revised applications are required to include a resubmission statement that addresses the comments of the previous review, and explains how the application has been strengthened or modified. See the *Resubmission Information* section for additional information.
4. *Research Plan*: The 10-page research plan should include the following information: highlight the significance and novelty of the work; describe the relevance of the project to the cause, cure, treatment or prevention of lupus and/or its secondary complications; emphasize the relevance of the project to the goals of this TIL program; provide background information, rationale, hypothesis, and preliminary data; describe the approach, the anticipated outcomes and alternative strategies.
5. *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 Scientific Advisory Board. 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. A suggested format for listing these milestones is a table, listing by priority the goals, along with their respective expected dates of completion and measures. The milestones are part of the proposal narrative but are not included in the 10-page limit. See Instructions for Proposal Narrative in the electronic templates section.
6. *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.

7. *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.
8. *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.
9. *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 whether financially and/or scientifically related to this application.
10. *Facilities & Equipment Description*: A short description of the facilities and equipment available to support the project.
11. *Assurances*: Appropriate institutional assurances regarding human subjects and animals as applicable.
12. *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.
13. *Consultant/Co-Investigator/Collaborator Letters*: Optional, only submit if relevant to the application.
14. *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 to Diomaris Gonzalez ([dgonzalez@lupusresearch.org](mailto:dgonzalez@lupusresearch.org)) no later than two weeks prior to the final review. 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* to the program goals of the Lupus Research Alliance: prevention, treatment, or cure of lupus
- *Feasibility* to accomplish the proposed work within a three-year time frame

- *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?
- *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. All indirect costs or institutional overhead costs are not to exceed 8% of the total amount approved (excluding equipment). Support for a third year of funding will be based on the successful submission of a non-competitive progress report and review by members of the Lupus Research Alliance's Scientific Advisory Board during the second year of the award. Funding decisions for the third year will be made by the Lupus Research Alliance Board of Directors subsequently.

The grant recipient is required to attend the Lupus Research Alliance Annual Scientific Conference 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.

## **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, relevance to lupus, likelihood of success, 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 submission.

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 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 experience that establishes scientific leadership is necessary to apply. 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). 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. *Resubmission Statement* (if applicable): Revised applications are required to include a resubmission statement that addresses the comments of the previous review, and explains how the application has been strengthened or modified. See *Resubmission Information* section for additional information.
4. *Research Plan* (parts a-d may not exceed six pages): A description of the proposed research should include the following:

- a) Background and specific aims
  - b) Preliminary data (if any)
  - c) Experimental design and methods
  - d) 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?
  - e) Milestones: List the expected status of the project at various points in time for the duration of the grant. The list of milestones should reflect the specific aims of the proposal. A suggested format is a table, listing by priority the aims, along with their expected dates of completion and measures. 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 Scientific Advisory Board.
  - f) Literature citations should be listed and are not included in the page limit for the Research Plan.
5. *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.
  6. *Detailed Budget and Summary*: A budget for the project should be prepared in U.S. dollars. The budget should be for up to three years and should not exceed \$100,000 per year. The NRG does not provide funds for institutional overhead, or for major pieces of laboratory equipment.
  7. *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.
  8. *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, signed by an official of the applicant's institution. Ordinarily this would constitute return of funds to all but one granting agency, however, monies granted could be appropriately modified.
  9. *Facilities & Equipment Description*: A short description of the facilities and equipment available to support the project.
  10. *Assurances*: Appropriate institutional assurances regarding human subjects and animals as applicable.
  11. *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.

12. *Consultant/Co-Investigator/Collaborator Letters*: Optional, only submit if relevant to the application.
13. *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)
- Appropriateness of proposed budget

### **Terms of the Award**

The total amount of the Novel Research Grant is up to \$100,000 per year for up to three years. Funds may be used for any appropriate research costs. The grant will pay PI's salary up to 10% or \$10,000 each year which includes fringes. If there are two PIs, the \$10,000 is the limit for both, not each. There is no limitation on the amount for a technical assistant's salary. 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 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.

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### **Resubmission Information for TIL and NRG 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 three times (the original, plus two resubmissions).
- If you include changes to your original proposal, highlight the changes. Explain how the application has been strengthened or modified (additions, deletions, revisions) to address the concerns of the review panel—if a critique had been provided—that considered the previous

application submission.

- Reviewers for applications checked as resubmissions will be provided with the critiques from the previous application cycle, if available.
- If major changes are made to the 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 TIL and NRG 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 review date. Applications not recommended for full review will not receive written critiques. By applying, you are acknowledging your understanding that critiques may not be provided. The Lupus Research Alliance does not provide scores or application's rank to applicants.

### **Key Dates**

RFA Release:	November 3, 2017
Earliest Submission:	November 15, 2017
Application Due:	February 9, 2018
Scientific and Board Reviews:	May-June 2018
Response to Applicants:	July 2, 2018
Earliest Anticipated Start:	August 1, 2018

### **Inquiries**

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**proposalCENTRAL:**

For help with the electronic grant application process, please contact the help desk of proposalCENTRAL [pcsupport@altum.com](mailto:pcsupport@altum.com)  
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