



Alliance for Lupus Research

PREVENT. TREAT. CURE.

**TARGET IDENTIFICATION IN LUPUS
COMPETITIVE RENEWAL**

APPLICATION PROGRAM GUIDELINES

Effective - March 30, 2009

Applications Due - July 30, 2009

Applications will be administered by:

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Mission

*The mission of the Alliance for Lupus Research is to prevent,
treat and cure lupus through medical research.*

**ALLIANCE FOR LUPUS RESEARCH: PROGRAM GUIDELINES
TABLE OF CONTENTS**

Section	Page
DESCRIPTION OF TARGET IDENTIFICATION IN LUPUS	
Program Goals	3
Relevance to the mission of the ALR	3
APPLICATION INSTRUCTIONS	
Application Information.....	4
REVIEW PROCESS	
Rating of Applications	5
Review/Notification	5
TERMS OF AWARD	
Award Period	6
Amount of Award	6
Equipment	6
Laboratory Visits	6
Dissemination of Information	6
Sharing of Resources.....	6
Publications.....	7
Internal Revenue Service	7
Scientific Conduct and IRB Approval	7
Principal Investigator Assurance	7
Intellectual Property and Patent Policy.....	7
Cancellation	7
SUBMISSION INSTRUCTIONS AND DEADLINES	
Submission Instructions	8
Deadlines.....	9
Late or Incomplete Packages	10
Change of Applicant Status	10
CONTACT INFORMATION	
ALR Research Administration.....	10
Altum proposalCENTRAL Customer Service.....	10

TARGET IDENTIFICATION IN LUPUS COMPETITIVE RENEWAL

2009 Alliance for Lupus Research Initiative

Description of Target Identification in Lupus Program

The Alliance for Lupus Research (ALR) is an independent, voluntary health agency formed to provide a concentrated effort for the prevention, treatment and cure of systemic lupus erythematosus (lupus or SLE). The purpose of the ALR Target Identification in Lupus (TIL) grants program is to fund highly meritorious and innovative research focused on the identification and scientific and/or clinical advancement of therapeutic targets that will lead to new therapies for the treatment of lupus. Lupus is a complex systemic autoimmune disease that can cause significant morbidity and mortality. At present, therapy for lupus is empiric and involves a variety of non-specific anti-inflammatory and immunosuppressive agents. While these agents are frequently beneficial, many patients do not respond adequately or experience significant side effects. This grant program has been established to develop new approaches to treat lupus more effectively and safely.

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. This research is 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.

Relevance to the mission of the Alliance for Lupus Research: The TIL grants 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 grants should lead to new insights into disease pathogenesis, advances in the development of innovative therapies under consideration for lupus, or improvements in the ability 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 R01 mechanism where a translational component 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.

The ALR has supported a large SLE genetics initiative. This initiative, led by a consortium of investigators, was designed to conduct a whole-genome association study in SLE. The ALR will only review TILR grant applications in genetics that complement this special initiative, or that are unrelated. The ALR has also initiated a program focused on the functional implications of the lupus-associated genetic variants identified in the genome wide association studies. Research proposals aimed at investigation of lupus-associated genetic variants and their molecular pathways are most appropriately submitted through the Functional Genomics in Molecular Pathways program. Projects that can reasonably be construed as duplicative of the initiative should not be submitted.

Application Instructions

Application Information: The TIL program will renew competitive grants that demonstrate substantial progress during the initial phase of funding with a high likelihood that the research will lead to new treatments in lupus. A successful renewal application will: (1) have achieved measurable progress in the initial funding period; (2) focus on target identification in humans; (3) develop a research strategy that will confirm the validity of a particular target; and; (4) create a concept for development of therapeutics (pre-clinical model). As such, these grants should be innovative in direction and utilize state-of-the-art techniques in genetics, immunology, cell biology and molecular biology to identify and characterize molecular systems that will be targeted for drug development. 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.

Application Information:

Each application should contain the following information (please log into Altum proposalCENTRAL for a detailed description of all forms to be completed):

1. **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 3000 characters.
2. **Proposal Narrative:** A research plan highlighting 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; highlight the relevance of the project to the goals of this Request for Proposals; provide background information and brief plans for experiments that can be accomplished within two years.

3. Budget: A detailed budget for the project prepared in U.S. dollars.
4. Budget Justification: A detailed justification for the budgetary requests.
5. Facilities & Equipment: A short description of the facilities and equipment available to support the project.
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 for his/her research endeavors. This should also include a description of currently active support and all projects and proposals pending review and/or award whether or not financially and/or scientifically related to this application.
7. Assurances: A copy of all materials used to obtain the informed consent of project participants and appropriate institutional assurances regarding human subjects and animals.
8. Other Support: Information about other support current and applied for
9. Consultant/Co-Investigator/Collaborator Letters : Optional attachment if relevant to the application
10. Appendix Materials: see instructions for appendix material allowed

Applicants will also have the opportunity to submit to the ALR the following supplemental material:

- Written supplemental material (limited to 2 pages) relating to their research project.
- Publications or manuscripts (limited to 5) submitted for review in order to demonstrate progress (electronic copies preferred).

Applicants will be notified by the ALR via e-mail as to the method of delivery and deadline for submission of this information.

Review Process

Rating of Applications: Applications will be evaluated based on the following criteria:

- Relevance to the program goals of the ALR; prevention, treatment, or cure of lupus
- Progress towards meeting benchmarks outlined in the original TIL application
- Feasibility will be evaluated based on the ability to accomplish the work proposed within a two-year time frame and the likelihood that the work will; (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 in humans; and; (3) support research that facilitates the clinical evaluation of innovative approaches to the prevention or treatment of lupus and its complications
- Appropriate research design; originality and scientific rigor

Review/Notification: All grant applications will be peer-reviewed by the Study Section of the ALR. Results from that peer review will be forwarded to the ALR Scientific Advisory Board (SAB). The SAB will consider the recommendations from the Study Section, as well as review the existing ALR portfolio to determine which applications would complement existing grants or

address an unfilled area of research. The SAB will submit their recommendations to the ALR Board of Directors. This 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 ALR Board of Directors will make all final funding decisions. Notification of approval/disapproval will be made to applicants after the ALR Board of Directors meeting in December 2008.

Terms Of Award

Award Period: Renewal grants may be awarded for a two-year time frame. Submitted applications will be evaluated by the ALR Scientific Advisory Board and the ALR Board of Directors in December of 2009 and funded projects will be activated February 2, 2010.

Amount of Award: Individual applicants may request up to \$275,000 per year for a maximum of two years. Collaborative projects, involving other investigators, institutions, government agencies, and/or industry, will be viewed favorably. A detailed budget and justification is required. Documentation of all other support is also required, as the ALR will not provide overlapping support. Total indirect costs are not to exceed 8% of the total amount.

Equipment: Title to all equipment purchased with ALR funds shall vest in the Sponsoring Institution provided that, for the duration of the research grant and for a period not to exceed sixty days from the termination date of the grant, the ALR may, at its option, direct the Sponsoring Institution to transfer title to a new Sponsoring Institution.

Laboratory Visits: As a condition of support, the Principal Investigator agrees that a representative of the ALR may visit the laboratory or other venue where the grant is being funded upon reasonable prior notification.

Dissemination of Information: To disseminate information about the ALR research program to our volunteers and the public, grantees are expected to occasionally give brief presentations of their research to professional audiences or the general public. All applicants are required to provide a summary of their research project in non-technical language. The summary should be brief and should explain the relevance of the project to lupus in such a way that lay advocates involved in the review process can evaluate the potential contribution of the project to the mission of the ALR.

Sharing of Research Resources: Consistent with the policies on intellectual property outlined in the ALR Policy Statement on Research Grants, the ALR strongly encourages the sharing of biomaterials, reagents and data in a timely fashion. Sharing of research resources and timely dissemination of data has been proven to be an essential element in expediting progress in biomedical research. One factor in the ALR's decision of whether to provide renewal funding is the willingness to the investigator to enthusiastically embrace the ALR's philosophy about the importance of sharing research resources.

Publications: It is expected that the results of research supported by the ALR shall be published as rapidly as possible in the open literature, consistent with high standards of scientific excellence and rigor. The responsibility for publication lies exclusively with the Principal Investigator (and his/her collaborators) and the result of any work supported by the ALR may be published without prior review of the ALR. Any publication arising in whole or in part from a research grant funded by the ALR shall acknowledge funding support by the ALR. As soon as a manuscript is accepted for publication (whether during the term of the grant or after it has expired) a copy of the publication along with the name of the journal and expected date of publication should be forwarded to the ALR. As soon as reprints are available, a copy of the reprint should be forwarded to the attention of the Research Administration Department in the ALR office.

Internal Revenue Service Information: Personnel compensated in whole or in part with funds from the ALR are not considered employees of the ALR. Institutions shall be responsible for issuing the appropriate IRS tax filings for all individuals receiving compensation from Grantor's funds hereunder, and shall be responsible for withholding and paying all required federal and state payroll taxes with regard to such compensation.

Scientific Conduct and IRB Approval: The ALR does not assume responsibility for the conduct of the investigation or the acts of the investigator since both are under the direction and control of the grantee institution and subject to the institution's medical and scientific policies. Grantee institutions must safeguard the rights and welfare of individuals who participate as subjects in research activities by reviewing proposed activities through an Institutional Review Board (IRB) as specified by the National Institutes of Health (NIH) Office for Protection from Research Risks (OPRR). In addition, institutions must adhere to current US Department of Health and Human Services guidelines regarding financial conflict of interest, recombinant DNA, biohazards, research misconduct, and vertebrate animals.

Principal Investigator Assurance: All research grants funded by the ALR are subject to the terms and conditions outlined in this document and the funding letter. Deviations from the policies outlined in this document are valid only if made in writing and signed by an official of the ALR. Research performed under ALR grants is the sole responsibility of the Principal Investigator of that grant and the Sponsoring Institution. The Principal Investigator and Sponsoring Institution are both responsible for insuring that all research activities are conducted in a safe, responsible, and ethical manner.

Intellectual Property and Patent Policy: The ALR's policy on intellectual property and patent ownership will be shared upon request.

Cancellation: Any grant may be terminated or cancelled by the ALR upon written notice to the Principal Investigator and responsible Administrative Official at the Sponsoring Institution if in the sole discretion of the ALR; (1) the Principal Investigator is unable to carry out the research for any reason; (2) the Principal Investigator or any member of his/her research team is found by an institutional investigation to have committed scientific misconduct or fraud; (3) the Principal Investigator has failed to comply with any of the terms and conditions of this award; (4) the ALR concludes that the Principal Investigator has received overlap funding for the award or that the

funds are not being used for the purposes originally outlined in the research protocol, or; (5) the IRB approval for the grant has been rescinded.

SUBMISSION INSTRUCTIONS AND DEADLINES

Submission Instructions: Applications are to be submitted electronically through the Altum proposalCENTRAL online application system. Altum proposalCENTRAL can be accessed directly at: <https://proposalcentral.altum.com>. Instructions and application forms should be downloaded from the Altum proposalCENTRAL site and the completed proposal must be submitted electronically.

In addition to this electronic submission, applicants are required to submit an original and two paper copies of the grant application to:

Alliance for Lupus Research
Attention: Research Administration Department
28 West 44th Street, Suite 501
New York, NY 10036
Phone: 212-218-2840
Fax: 212-218-2848

The original application carries the signatures of both the applicant and the applicant's institution. These documents represent the official application.

After all the application information has been entered, please complete the following steps to print the online application:

Step 1: Click the ‘**Validate**’ button from Section 11 of the online application. ‘**Validate**’ checks for missing required entries on all pages of the application, and any missing attachments.

Step 2: After successfully passing the validate check you are ready to print the signature pages. This is done by clicking on the ‘**Print Signature Pages**’ section of the application. This information will serve as the title page for the paper copy of your application. The signature pages need to be signed by the PI and the institutional representatives prior to the electronic submission of the application.

Step 3: Print all completed templates required for the grant application. In Section 12 click on the **Print Signature Pages and Attached PDF Files**. This will allow you to the signature page and all related .pdf attachments in the file.

Step 4: Assemble the application packet in the following order (after completing the above all attachments should print in the following order):

1. Signature Pages (from Altum proposalCENTRAL)
2. Abstract – Technical only
3. Proposal Narrative
4. Budget Summary
5. Budget Justification
6. Biosketch- PI and Key Personnel
7. Facilities and Resources
8. Key Personnel
9. Other Support
10. Consultant/Co-Investigator/Collaborator Letters (optional)
11. Appendix Materials (optional)

Additional notes:

- Cover letters are not necessary but if you wish to include a cover letter, clip it to the original application.
- All attachments and completed templates must be in PDF format prior to uploading to Altum proposalCENTRAL site.
- The original and two copies must be complete and legible.

Deadlines: The electronic application must be received by the close of business (5:00 PM Eastern time) on July 30, 2009. Do not submit your application electronically before obtaining the required institutional signatures.

The signed original and two paper copies, including any appendix material, must be postmarked by July 30, 2009 and received in the ALR office within seven business (7) days. If the deadline falls on a weekend or national holiday, use the first postal workday following the deadline as the submission/postmark day.

DATE	
March 30, 2009	TIL RFA Distributed
July 30, 2009	TIL Renewal Grant Application Due
November 2009	Grant Review Meeting
December 2009	Scientific Advisory Board Meeting & Board of Directors Meeting – grant approval
January 2010	Funding notification to all applicants
February 2, 2010	Grant activation date

Late or Incomplete Packages: An application will not be reviewed if; (1) it arrives after the deadline; (2) is incomplete; (3) the principal investigator is ineligible; (4) it exceeds the page limit, or; (5) uses a printer font smaller than standard type size (Arial 12 pt.). An application will be considered incomplete if it fails to follow the instructions or if the material presented is insufficient to permit an adequate review without the solicitation of a substantial amount of additional information. The principal investigator bears the responsibility for submission of a complete application by the designated deadline date.

Change of Application Status: Any change in application status after submission including a withdrawal of application, a change of address, etc. should be communicated to the ALR's Research Administration Department via e-mail immediately at grant.administration@lupusresearch.org.

Contact Information

ALR Contact Information: Questions concerning the application submission process, or the administration of TIL Renewal grant applications, should be directed to the ALR Research Administration Department at (212) 218-2840 or grant.administration@lupusresearch.org.

Altum proposalCENTRAL Contact Information: For help with the electronic grant application process, please contact the help desk of proposalCENTRAL by email at pcsupport@altum.com. You may also contract them by phone at 1-800-875-2562, extension 227.