



SUMMARY OF POLICIES GOVERNING DR. WILLIAM E. PAUL DISTINGUISHED INNOVATOR AWARDS IN LUPUS AND AUTOIMMUNITY APPLICATIONS

RFA Launch: March 10, 2017

Deadline for Applications: May 24, 2017

Funding to begin: January 2018

Administered by: Lupus Research Alliance, 275 Madison Avenue, 10th Floor, New York, NY 10016; lupusresearch.org.

Program Goals: Lupus Research Alliance Distinguished Innovator Awards provide outstanding scientists with substantial support for up to four years to conduct novel research into the fundamental causes of systemic lupus erythematosus and so provide new directions towards a cure. We welcome novel, hypothesis- or discovery-driven proposals in human and/or animal-model based lupus research. The research proposal must aim to uncover the fundamental causes of lupus and present a compelling vision of how the discovery would lay the groundwork for a cure, prevention, or highly effective therapy. Applications will be judged primarily on the novelty and potential of the research proposal, and the strengths and track record of the investigator. Emphasis will be on the rationale for the hypothesis rather than the amount of preliminary data. Continuations of long-term research projects will not be considered. Successful applicants will be outstanding investigators who have demonstrated creativity and productivity in their field of research. We encourage applications from investigators in diverse disciplines including, but not limited to, immunology, genetics, molecular-, cell- and systems biology.

1. **Authority:** Grants are awarded by the Lupus Research Alliance, Inc. upon recommendation of the Distinguished Innovator Award Task Force and approval of the Lupus Research Alliance Board of Directors.

2. **Eligibility Criteria:** Applicants must hold an established position, at assistant professor level or higher, at an academic institution. The Lupus Research Alliance does not impose geographic restriction on its applicants and researchers working outside of the US are also encouraged to apply.

3. **Selection Criteria:** Grant applications will be judged by the Distinguished Innovators

Task Force assisted by an international panel of reviewers. Scoring will be based on the following criteria:

- a) Novelty of research proposal
- b) Scientific merit of research proposal
- c) Relevance to fundamental causes of lupus
- d) Potential to lead to lupus cure, prevention or highly effective therapy.
- e) Strengths and track record of investigator
- f) Strength of approach
- g) Likelihood of success
- h) Appropriateness of the proposed budget

4. **Administration:** Administration of grants is a joint responsibility of the Lupus Research Institute's Alliance's Board of Directors and its Distinguished Innovators Task Force. When two or more proposals of equal merit are received, it will be at the sole discretion of the Board of Directors to determine the recipient(s) of the grant

5. **Terms of the Award:** The total amount of the Distinguished Innovators Award is up to US \$250,000 per year for up to four years. Funds may be used for any appropriate research costs and up to 10% of the total annual budget (US \$25,000) may be allocated to salary of the principal investigator. No portion of the research grant may be used to pay institutional overhead or other indirect costs.

Progress reports are required at the end of each year. The progress reports due at the end of the second year and third years will be used to determine if the applicant should receive the third and final years of funding.

The award recipient is required to attend the Lupus Research Alliance Annual Scientific Conference each year.

6. **Payment:** Grants are paid in eight installments.

7. **Reviewer Comments:** Reviewer comments will not be provided to applicants.

RULES GOVERNING GRANTS

1. **Applications:** Grant applications are evaluated by the Lupus Research Alliance's Scientific Task Force on Distinguished Innovator Awards, which makes recommendations to the Board of Directors. The Lupus Research Alliance reserves the right to consult qualified third parties in particular cases. All applications awaiting action will be held in confidence.

2. **Terms of Grant:** Unless otherwise specified in writing, Distinguished Innovator Awards are given for terms of up to four years.

3. **Purpose of Funds:** Grants are not made to individuals, but to institutions for the support of specific projects. They are not intended to subsidize normal institutional budgets or staff, nor to pay institutional overhead charges. Up to 10% of the annual award budget may be used to pay the salary of the principal investigator (not to exceed US \$25,000 including fringes). Grant funds may be used to pay the salaries of technical assistants and the cost of equipment, supplies and materials necessary for carrying out the purpose of the grant. Funds are not available for journal subscriptions, construction or renovation of buildings, nor for the purchase of office equipment and furniture. Similarly, dues and membership in scientific societies will not be underwritten.

4. **Expenditures:** All charges must conform to the budget submitted by the grantee. The Lupus Research Alliance reserves the right to a refund on demand of all grant funds expended in an unauthorized manner.

5. **Annual Meeting:** The Lupus Research Alliance (LRA) is keenly committed to furthering research into the cause, cure, treatment and prevention of lupus and its complications. We know that you share our aspirations in this area. Forming partnerships with our grant recipients is one of the cornerstones of our funding philosophy. Towards this end, we ask our grant recipients to participate in an annual collaborative meeting to share the concept and progress of their research. ***You will be notified of the logistics of this meeting once the dates have been finalized. Funds provided through this grant should be used to pay for your attendance at this meeting***

6. **Accounting:** Financial commitments against all grants must be liquidated as soon as possible after the grant period has ended, and the grantee must submit a final accounting of all expenses and return all unexpended funds. The Lupus Research Alliance will not be responsible for any financial commitment against the grant. The grantee shall be responsible for any unauthorized expenditure or over-expenditure.

7. **Materials:** All equipment or instruments purchased, prepared, manufactured, and paid for with funds from the grant for specific items named in the application shall, unless otherwise specified, become the property of the grantee's institution.

8. **Salaries:** Personnel compensated under the grant will not be considered employees of the Lupus Research Alliance, but as employees of the grantee institution.

9. **Other Financial Support:** Additional funding must not duplicate grant support from the Lupus Research Alliance for the same project. If the applicant is awarded additional support during the term of a Lupus Research Alliance grant, the grantor must be notified as soon as possible.

10. **Program Changes:** Change of the purpose or personnel for which a current grant was made, without the prior written approval of the Lupus Research Alliance, will automatically terminate the grant; return of funds on a pro-rated basis will be required.

11. **Reports:** Progress reports are required at the end of each year. The progress reports due at the end of the second year and third years will be used to determine if the applicant should receive the third and final years of grant funding.

12. **Discoveries:** Any discovery made under a program supported by the Institute must be reported promptly to the Lupus Research Alliance, and application for patent may not be made without the prior written consent of the Lupus Research Alliance. (See Patent and Intellectual Property Policy attached herewith.)

13. **Publicity:** The Lupus Research Alliance has a strong interest in tracking the discoveries that result from its grant funding. Therefore, the grantee must advise the Lupus Research Alliance in writing prior to publishing/publicizing, in any manner, discoveries made or developed under a grant. The communication should explain fully the nature of the information to be divulged, the time, the place, and the manner of its presentation. From time to time, grantees may be asked to give brief presentations of their research to professional and lay audiences.

14. **Publication and Exhibits:** The Lupus Research Alliance should be notified immediately upon acceptance for publication of any article resulting from Institute-funded research. Any article or exhibit prepared by anyone associated with the work covered by a grant and dealing with the project should bear the credit line: "Supported in part/in entirety by a grant from the Lupus Research Alliance." An electronic version of any publication bearing this credit line should be sent to the Institute for their files.

15. **Transfer of Grant:** Grants may not be transferred from one individual or institution to another individual or institution without the prior written approval of the Lupus Research Alliance.

16. **Deviation From Rules:** Failure to abide by any rule governing grants will be considered sufficient reason to cancel the grant or refuse to consider any application a grantee has pending.

17. **Change of Rules:** The Lupus Research Alliance reserves the right to change or amend its rules governing grants at any time. Unless implementation of the project for which the grant was given has already commenced, the grantee agrees to abide by such changes or terminate the grant at the time it goes into effect.

18. **Human Subjects:** If human subjects are to be used in the research, written, informed consent must be obtained, and the research protocol must be approved by the appropriate committee of the grantee institution concerned with human safeguards. The investigator bears full responsibility for obtaining such approval and, further, certifies by agreeing to these rules that the investigator and/or the institution will be fully responsible for any financial liability and legal expenses resulting from research supported by the Lupus Research Alliance. This ruling will also pertain to animal research and the use of radioisotopes and biohazardous materials.

19. Scientific Conduct and IRB Approval: The Lupus Research Alliance provides grant-in-aid support for research projects including those that may involve human subjects. Lupus Research Alliance will not act as the Sponsor of any research as that term is defined by Food and Drug Administration nor take on any of the responsibilities of a Sponsor. *See* 21 C.F.R. §§ 312.3, 812.3. Lupus Research Alliance does not provide management support for the projects that it funds and does not assume responsibility for the conduct of the investigation or the acts of the investigator or others since all persons undertaking the funded research are acting under the direction and control of the grantee institution and subject to the institution's medical and scientific policies. As a condition of receiving Lupus Research Alliance grant funding for research, a Grantee institution and the investigator each agrees (i) to safeguard the rights and welfare of any individual who may participate as a human subject in any research funded in whole or in part by Lupus Research Alliance and (ii) to seek and obtain approval from Grantee's institutional review board, where human subjects are involved, and to comply with the provisions of 45 C.F.R. pt. 46 to the same extent as each would were the research funded by the National Institutes of Health ("NIH"), (iii) to comply with United States Department of Health and Human Services regulations or guidelines regarding financial conflicts of interest (*see* 42 C.F.R. pt. 50, subpt. F), recombinant DNA, biohazards, research misconduct (*see* 42 C.F.R. pt. 93), and vertebrate animals, all to the same extent as each would were the research funded by NIH; and (iv) such other federal regulations as may pertain to the particular research funded in whole or in part by the Lupus Research Alliance grant.

20. Animal Welfare: It is the responsibility of the applicant to assure proper care and treatment of all laboratory animals used in any Lupus Research Alliance sponsored research. Any application involving laboratory animals must be reviewed and approved by the appropriate institutional review committee.

21. Cancellation: The Board of Directors, in consultation with the Distinguished Innovators Task Forces of the, may, for cause, cancel a grant at any time upon 90 days notice, and require the return of any unused funds.

22. Governing Rules: By the act of applying for a grant, the applicant certifies that he/she has read and will abide by the accompanying rules governing Research Grants.

GENERAL INFORMATION AND INSTRUCTIONS FOR DISTINGUISHED INNOVATOR AWARDS IN LUPUS APPLICATIONS.

Application Details: Applications must be submitted electronically by May 24, 2017, 5:00pm US Eastern time to <http://proposalcentral.altum.com/>. Only electronic applications submitted through proposalCENTRAL will be accepted. No paper applications will be accepted.

The information below is required. Each section must be completed. If not applicable, please indicate this. Incomplete applications will not be reviewed. Review of applications is facilitated if the outline given below is followed as closely as possible. Supplementary material will not be accepted after the submission deadline.

1. Name and address of institution, including department, phone number, email address, division, if any, and location of the laboratory where research is to be conducted.
2. Name and title of principal investigator and co-PI if applicable. A curriculum vitae and selective bibliography for PI should be appended to the application, and should, as a minimum, include: degrees held (with dates and schools), daytime telephone number, awards and honors, membership in professional organizations, board eligibility or certification, and positions held, including, in addition, any relevant research experience not otherwise listed. National Institutes of Health biosketches are acceptable.
3. Brief title of proposed research project (<120 characters, including spaces).
4. Proposed period of award (beginning and termination dates). Note: estimated award start date is January 2018.
5. Lay Abstract: Brief summary of the proposed research and its potential significance for 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 3000 characters).
6. Scientific Abstract: Technical summary of the proposed research, written in scientific terms (not to exceed 3000 characters).
7. Proposed Budget:
 - Each item of equipment costing more than US \$5000.00 should be listed separately.
 - Supplies should be listed by major types, such as glassware, chemicals, animals, etc.
 - **Note:** The Lupus Research Alliance policy does not provide funds for institutional overhead, or for major pieces of laboratory equipment.

8. Budget Detail and Summary: A budget for the project prepared in U.S. dollars. This information should be entered directly into the electronic application. The budget should be for four years.
9. Budget Justification: A detailed justification for the budgetary requests. This information should be entered directly into the electronic application. 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 2000 characters. (See 'Purpose of Funds- page 3).
10. Other Support: Indicate other pending grant applications, their specific aims, amounts and extent of overlap, if any. If overlap does exist, 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.
11. Proposal Narrative: A research plan with a description of the proposed research should include the following: (Note: Research Plan, parts a-d, may not exceed six pages. Research Plan may not contain an appendix section).
 - a) Background and specific goals of proposal being submitted.
 - b) Experimental design and methods.
 - c) Significance of the proposed work: explanation of the novel nature of the work, and its relevance to the fundamental causes of lupus.
 - d) Impact of the proposed work: explanation of how the work has the potential to lead to a cure, prevention, or highly effective therapy for lupus.
 - e) Estimated time required for the proposed studies, giving the approximate sequence of experiments.
 - f) Facilities available for this project, including laboratory space and major equipment
 - g) Literature citations should be listed and are not included in page limits for the Research Plan.
12. Consultant/Co-Investigator/Collaborator Letters: Optional, only submit if relevant to the application. Can be uploaded in Proposal Section 11.
13. 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). Can be uploaded in Proposal Section 11.
14. Include at the end of the application a letter with the following statement:

“I have read and accept the current rules governing grants of the Lupus Research Alliance, Inc.” followed by the signature of the principal investigator, along with name, title and date. For ALL applications, the name and signature of the Dean of the Institution or equivalent is required on this statement

15. Signed Signature Page: The signed cover page should be uploaded electronically in Proposal Section 11 can be added by selecting the appropriate attachment “Signed Cover Page”

PATENT AND INTELLECTUAL PROPERTY POLICY

- 1) All inventions or intellectual property made with support in whole or in part by research or training grants or awards from the Lupus Research Alliance, must be reported at the earliest practical time to the Grants Division of the Lupus Research Alliance. The grantee institution or individual awardee agrees to notify the Institute immediately of the decision to apply for letters patent or other legal protection for intellectual property, and to consider seriously and in good faith, any comments or objections the Lupus Research Alliance may have concerning such applications. The Institute agrees to keep all information confidential and to not release any information relating to such inventions, intellectual property or applications. All patenting expenses shall be borne by the grantee institution or individual awardee.
- 2) Title to any invention or intellectual property shall reside in the grantee institution to the extent that such title is claimed by the institution under its patent policy or procedure and paragraphs 3 through 8 shall apply. If a grantee institution has no established patent policy or procedure for administering inventions or intellectual property, or if the institutional patent policy or procedure does not claim rights for the institution or individual inventor, then the Lupus Research Alliance, shall have the right to determine the disposition of invention or intellectual property rights and paragraphs 3 through 6 shall not apply.
- 3) Distribution of income derived from an invention or intellectual property which might include equity disposition shall be according to the policies of the grantee institution, although the Lupus Research Alliance, would expect to participate in income derived from the invention or intellectual property to the extent and at a rate of remuneration determined by mutual agreement between the grantee institution and the Lupus Research Alliance no later than six months after first receipt of income. Such agreement shall be guided by the principle that the Institute’s proportion of sharing in the income shall be reasonably related to the Institute’s proportion of support for the invention or intellectual property.
- 4) If any invention or intellectual property is made with the joint support of the Lupus Research Alliance, and other organizations, it is expected that income distribution shall be in accordance with the provisions of this policy. Should an exception be taken to this

provision, the grantee institution, The Lupus Research Alliance, and other sponsoring agencies will confer to reach a mutually satisfactory disposition of invention or intellectual property rights.

- 5) No patent, patent application, or other type of protection shall be abandoned without first notifying the Grants Program Department of the Lupus Research Alliance. At such time, the grantee institution and individual awardee shall give the Lupus Research Alliance the opportunity to take title to the invention or other intellectual property.
- 6) The grantee institution shall agree that when it licenses any invention or intellectual property it will obligate the licensee as follows: The licensee agrees to exert its best efforts to commercialize or cause to be commercialized the invention or intellectual property as rapidly as practical, consistent with sound and reasonable business practices and judgment. In the event that the licensee has failed to commercialize the invention or property, the grantee institution within a number of years determined to be reasonable for the invention or intellectual property, the grantee institution upon conferring with the Institute shall have the right to convert an exclusive license to a non-exclusive license or to terminate a non-exclusive license. If the licensee or grantee institution has an ongoing and active research, development, manufacturing, marketing or licensing program as appropriately directed toward the production and sale of the invention or intellectual property, the same would be deemed to be sufficient evidence that the licensee or grantee institution has commercialized the invention or intellectual property.
- 7) The Lupus Research Alliance reserves the right to public acknowledgment for inventions or intellectual property resulting from support by the Institute; however, the Lupus Research Alliance, name and logo may not be used in association with an invention or intellectual property without prior approval of the Institute.
- 8) The Lupus Research Alliance may have use of inventions or intellectual properties without payment of royalties or fees, but solely for use with the Institute for intramural purposes and not for any of its grantee institutions or individual awardees.