

LUPUS RESEARCH ALLIANCE

POLICY STATEMENT FOR RESEARCH GRANTS

Research Awards

All Research Grants funded by the Lupus Research Alliance (LRA) are subject to the terms and conditions outlined in this Policy Statement and the accompanying Funding Letter. Deviations from the policies outlined in this document are valid only if made in writing and approved by an official of the LRA. Research performed under LRA 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 ensuring that all research activities are conducted in a safe, responsible and ethical manner.

Grant Period and Payments

Target Identification in Lupus Grants are funded for up to three years, unless a shorter funding term is recommended during the review process. This will be reflected in the funding letter. The third year of funding is dependent upon the successful completion of the prior years' work and the approval of a noncompetitive progress report by the LRA. Grants are typically activated on the date listed in the grant funding letter. Alternate activation dates are strongly discouraged. All acceptance materials must be submitted via the Award Management System of proposalCENTRAL by the date indicated in the grant funding letter. The Principal Investigator is responsible for ensuring that the activation materials are submitted in a timely fashion. Grant payments are disbursed to the Sponsoring Institution on a semi-annual basis.

William J. Paul Distinguished Innovator Awards are funded for up to four years, unless a shorter funding term is recommended during the review process. Grants are typically activated on the date listed in the grant funding letter. Alternate activation dates are strongly discouraged. All acceptance materials must be submitted via the Award Management System of proposalCENTRAL by the date indicated in the grant funding letter. The Principal Investigator is responsible for ensuring that the activation materials are submitted in a timely fashion. Grant payments are disbursed to the Sponsoring Institution on a semi-annual basis.

Novel Research Grants are funded for up to three years, unless a shorter funding term is recommended during the review process. This will be reflected in the funding letter. Grants are typically activated on the date listed in the grant funding letter. Alternate activation dates are strongly discouraged. All acceptance materials must be submitted via the Award Management System of proposalCENTRAL by the date indicated in the grant funding letter. The Principal Investigator is responsible for ensuring that the activation materials are submitted in a timely fashion. Grant payments are disbursed to the Sponsoring Institution on a semi-annual basis.

Sponsoring Institutions located outside of the United States should be aware that all LRA awards are made in U.S. dollars and all grant payments are disbursed in U.S. dollars. The LRA understands that fluctuations in the relative value of the dollar versus the local currency where the Sponsoring Institution is located may, in some circumstances, impair the value of the grant. In instances where dollar depreciation impairs the value of the grant in local currency, the LRA is not able to consider supplemental funding to restore the purchasing power of the award to its original value.

Research Protocol

The Principal Investigator shall commence the research described in the Research Protocol within four weeks of the date the first grant payment is received by the Sponsoring Institution. If the Principal Investigator is unable to commence the project at that time, the LRA should be promptly notified and the LRA, in its discretion, may choose to terminate the grant. Funds provided by this grant are for the purposes of conducting the research described in the Research Protocol and may not be used for any other purpose without the express written consent of the LRA. Funds that are unexpended or uncommitted at the termination of the grant shall be remitted to LRA within ninety days.

Progress and Financial Reports

Progress Reports

Annual progress reports are due at the end of each year of the project and will be requested by the LRA if a no-cost extension is requested. Final progress reports must be submitted to the LRA no later than ninety days after the final termination date of the grant. The Final Progress Report should delineate the objectives and significant findings of the research, future directions suggested by the research and a listing of publications in preparation, submitted or in press stemming from the research. All progress report submissions must be made electronically using the LRA's progress report template in proposalCENTRAL (a copy of the template is available in the deliverables section in proposalCENTRAL).

Financial Reports

Annual financial reports are due at the end of each year of the project and will be requested by LRA if a no-cost extension is requested. Final financial reports must be submitted to the LRA no later than ninety days after the final termination date of the grant. All financial report submissions must be made in the Award Management System of proposalCENTRAL. A Final Financial Report signed by the responsible administrative official at the Sponsoring Institution should accompany the Final Progress Report along with a refund of any unexpended balance in excess of 500 USD.

No-Cost Extension Request

Requests for no-cost extensions will be considered only if made in writing. This request should include: (1) an explanation of why the extension is needed; (2) the scope of the scientific work to be completed during the no-cost extension; (3) date by which the project will be completed (this cannot exceed 12 months from the original grant completion date); and (4) a budget for the no-cost extension period.

Budget Modifications

The funding letter, for a TIL grant, stipulates an itemized budget for the grant. Grantees may reallocate funds from one budget category to another without prior LRA approval, as long as the reallocation does not exceed 5 percent of the total amount approved for the grant. Please note that under no circumstances may indirect costs exceed 8 percent of direct costs excluding equipment. In addition, funds may not be reallocated to the travel budget without prior LRA approval. In the second and third years of an award, funds may not be reallocated to the equipment

budget without prior LRA approval. If the Principal Investigator wishes to reallocate funds from one category to another in an amount that exceeds 5 percent of the total grant amount LRA approval must be requested in writing.

Awarded funds may not be used to pay for tuition, computers or membership fees for the Principal Investigator or other key personnel.

Forum for Discovery - Annual Scientific Conference

Recipients of Research Grants are required to attend LRA's Annual Scientific Conference, called Forum for the Discovery, and may be asked to present the progress of their work at that meeting. Grant recipients will be notified of the meeting logistics well in advance of the event. Travel funds provided as part of this grant must be used to pay for all travel expenses related to attending this meeting. Please see the additional travel policy section below.

Publication Policy

Consistent with the high standards of scientific excellence and rigor the LRA upholds, it is expected that the results of the research supported by the LRA shall be published, as rapidly as possible, in peer-reviewed journals. The responsibility for publication vests exclusively with the Principal Investigator (and his/her collaborators). Any publication arising, in whole or in part, from a Research Grant funded by the LRA shall acknowledge funding support by the LRA. As soon as a manuscript is accepted for publication (whether during the term of the grant or after it has expired), an electronic copy of the paper along with the name of the journal and expected publication date should be forwarded to the LRA's Research Director, Teodora Staeva, at tstaeva@lupusresearch.org. As soon as reprints are available, an electronic copy should be forwarded to the LRA's Research Department at publications@lupusresearch.org.

Media Responsibility

Investigators funded by the LRA may, from time to time, be called upon to work with science writers, media and development specialists for the purpose of promoting the research activities of the LRA.

LRA shares the accomplishments of its supported investigators with numerous segments of the lupus community. Therefore, prior to grant activation, all investigators are asked to provide a lay summary of their work in non-technical language that can readily be understood by a competent lay person making reference to a standard medical dictionary. This summary should be 400 words or less and should highlight the main goal of the project, the expected outcomes of the project and how this project might eventually lead to either an improved understanding of the causes of lupus or the development of therapies.

Data Sharing

LRA is committed to sharing the results and accomplishments of the projects that it funds with the general public and the research community. The wide dissemination of data results in expedited translation of research results into knowledge, products and procedures that hold the promise of improving human health. LRA endorses the sharing of final research data to serve these and other important scientific goals and requires the timely release and sharing of final research data from

LRA supported studies for use by other investigators. “Timely release and sharing” is defined as no later than the acceptance for publication of the main findings from the final data set.

LRA recognizes that data sharing may be complicated or limited, in some cases, by organizational policies, policies pertaining to the protection of intellectual property, local IRB rules, local, State and Federal laws and regulations, including privacy and confidentiality policies.

The rights and privacy of individuals who participate in LRA sponsored research must be protected at all times. Thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

A variety of institutional based and government organized data bases (e.g. dbGaP, ImmPort) are now being made available to expedite the sharing of data. Where possible, subject to HIPPA regulations, data from LRA funded studies should be submitted to these publicly available repositories.

Sharing of Research Resources

Investigators conducting biomedical research frequently develop unique research resources. Categories of these resources include synthetic compounds, organisms, cell lines, viruses, cell products, and cloned DNA, as well as DNA sequences, mapping information, crystallographic coordinates, and spectroscopic data. Specific examples include specialized or genetically defined cells, including normal and diseased human cells; monoclonal antibodies; hybridoma cell lines; microbial cells and products; viral products; recombinant nucleic acid molecules; DNA probes; nucleic acid and protein sequences; certain types of animals, such as transgenic mice; and intellectual property, such as computer programs.

LRA considers the sharing of such unique research resources (sometimes called research tools) an important means to enhance the value of LRA sponsored research. Restricting the availability of unique resources can impede the advancement of further research. Therefore, LRA requires that resources developed with the LRA funds be made available for research purposes to the scientific community.

Investigators submitting LRA proposals that are expected to result in the development of a research resource must include a plan for sharing these resources or clearly explain why sharing of the research resource is not possible.

Termination of the Grant

This grant may be terminated or cancelled by the LRA upon written notice to the Principal Investigator and Responsible Administrative Official at the Sponsoring Institution if in the sole discretion of the LRA: (a) the Principal Investigator is unable to carry out the research for any reason, (b) the Principal Investigator or any member of his/her research team is found by an institutional investigation to have committed scientific misconduct or fraud, (c) the Principal Investigator has failed to comply with any of the terms and conditions of this award, (d) the LRA 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 (e) the IRB and/or the IACUC approval for the grant has been rescinded or has not been renewed.

The Principal Investigator and Sponsoring Institution are responsible for notifying the LRA immediately and in writing of any institutional investigation into the conduct of the Principal Investigator or any member of his/her research team and for keeping the LRA informed, on a timely basis, of the progress and outcome of the investigation. The LRA must also be notified if the IRB and/or the IACUC approval for the grant is suspended or terminated.

Transfer or Retirement of the Principal Investigator

If prior to the termination of the grant, the Principal Investigator's employment, affiliation or other relationship with the Sponsoring Institution is terminated, the grant will be terminated, and all unexpended or uncommitted funds shall be returned to LRA within 90 days. Grant awards may not be transferred to another individual working at the Sponsoring Institution without the express written consent of LRA.

If the Principal Investigator transfers institutions, he/she must submit a formal request to transfer their LRA award to the new Sponsoring Institution. The request must be made, via proposalCentral, at least one month prior to the official transfer date, and must include the following information: 1) letter of acceptance of the grant award signed by the new Sponsoring Institution and the Principal Investigator ; 2) updated budget for the remainder of the budget year; 3) assurance of continued availability of study subjects at the new location, should the study involve human subject research; 4) IRB and/or IACUC approvals for the LRA project from the new Sponsoring Institution; and 5) Facilities description for the new Sponsoring Institution, highlighting the continued access to any key equipment/resources required for the project that were available at the former institution.

Ownership of Equipment

Title to all equipment purchased with LRA 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 LRA may, at its option, direct the Sponsoring Institution to transfer title to a new Sponsoring Institution.

Indemnification

By accepting this grant, the Sponsoring Institution agrees to indemnify and hold harmless the LRA, its officers, directors, trustees, employees, and agents (each as an "indemnified party") from and against any and all claims asserted against or losses incurred by an indemnified party arising out of or relating to the research funded by this grant even if the aspect of the research giving rise to the claim or loss was not funded by the LRA. In the event that an indemnified party receives a claim subject to this indemnification provision then the party shall tender his, her or its defense to the Sponsoring Institution. In the event that the same counsel cannot due to a conflict or potential conflict represent the indemnified party, then the indemnified party shall select counsel of its own choosing and the Sponsoring Institution shall promptly pay for all reasonable legal fees and expenses as those fees and expenses are incurred.

Human Subjects

For research involving human subjects, the Sponsoring Institution shall ensure that the research protocol is reviewed and approved in writing by an Institutional Review Board constituted in accordance with current regulations promulgated by the United States Department of Health and

Human Services and approved by the Department. Legally acceptable informed consent must be secured for all human subjects taking part in any research funded in whole or in part by LRA. Prior to award activation and the disbursement of funds, all consent forms used in the project must be submitted to the LRA office along with a letter from the appropriate individual representing the Institutional Review Board indicating that final approval for the project has been provided. All consent form submissions must be made electronically in proposalCENTRAL.

Use of Experimental Animals

For research involving animals, the Sponsoring Institution shall ensure compliance with applicable chapters of the Public Health Service Animal Welfare Policy, the NIH Manual for Grants and Contracts, and any and all requirements of the Sponsoring Institution concerning animal welfare. Approval forms from the Sponsoring Institution's Animal Care and Use Committee (IACUC) must be submitted prior to award activation and prior to the disbursement of any LRA funds.

Overlap Funding

The Principal Investigator and the Sponsoring Institution are responsible for ensuring that the research described in the Research Protocol is not sponsored or funded by any other entity or organization. If support for the project is obtained elsewhere, the Principal Investigator agrees to notify LRA as soon as he/she becomes aware of the overlap.

Laboratory Visits

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

Travel

Travel funds provided as part of this grant must be used to pay for all travel expenses related to attending the LRA Annual Scientific Conference. Appropriate travel expenditures are permitted on LRA grants up to the amount indicated in the funding letter. All travel must be coach class or less expensive. The LRA will make the hotel selection for the annual conference. If you chose not to stay at the selected hotel, moderately priced hotel accommodations must be utilized.

Indirect Costs

Indirect costs for Target Identification in Lupus grants are limited to a maximum of 8 percent of direct costs excluding equipment.

Indirect costs are not allowed for the William J. Paul Distinguished Innovator Awards and for the Novel Research Grants.

Complete Agreement

This Policy Statement and the accompanying Funding letter represent the complete agreement between the Sponsoring Institution and the LRA. Any and all amendments to this Policy Statement or the accompanying Funding Letter must be memorialized in writing and signed by representatives of the LRA. The provisions of this Policy Statement and the accompanying Funding letter supersede all prior agreements, promises and arrangements whether written or oral.

Other Terms and Conditions

By signing the institutional agreement form, the signer certifies that the Sponsoring Institution named in this application is in compliance with all statutes, executive orders, and regulations restricting or prohibiting U.S. persons from engaging in transactions and dealings with countries, entities, or individuals subject to economic sanctions administered by the U.S. Department of the Treasury's Office of Foreign Assets Control. The Sponsoring Institution is aware that a list of countries subject to such sanctions, a list of Specially Designated Nationals and Blocked Persons subject to such sanctions, and overviews and guidelines for each such sanctions program can be found at <https://sanctionssearch.ofac.treas.gov/>. Should any change in circumstances pertaining to this certification occur at any time, the Sponsoring Institution is required to notify the LRA immediately.

If any terms or provisions of this Policy Statement and the accompanying Funding Letter, or the application thereof to any person or any circumstances, shall to any extent, be invalid or unenforceable, the remainder of the terms and provisions of this Policy Statement and accompanying Funding Letter shall not be affected.

If the Sponsoring Institution is domiciled in the United States, the Sponsoring Institution represents and warrants that it is a corporation duly organized, validly existing and in good standing under the laws of the state of its incorporation and its domicile. Throughout the term of the grant, the Sponsoring Institution is and shall continue to be, an organization which is exempt from federal income tax under Section 501(c)(3) of the Internal Revenue Code (or any corresponding provision then in effect) and to which contributions are deductible for federal income, gift and estate tax purposes under the Internal Revenue Code as amended from time to time. The Sponsoring Institution shall inform the LRA immediately if any alterations in its structures or activities may adversely affect its status as an organization exempt from income tax under the Internal Revenue Code. Notwithstanding any other provision of this Policy Statement or the accompanying Funding Letter, the LRA shall not be obligated to make any further payments under this grant if the Sponsoring Institution is no longer exempt from federal income tax under the provisions of the Internal Revenue Code.

*This Policy Statement is effective as of the date listed below and supersedes all prior editions.
All policies and procedures enumerated in this Policy Statement are subject to change without notice.
November 2017*