

LUPUS RESEARCH ALLIANCE POLICY STATEMENT FOR RESEARCH GRANTS

Research Awards

All LRA research grants (“Grants”) funded by the Lupus Research Alliance (“LRA”) are subject to the terms and conditions outlined in this policy (the “Policy Statement”) and the accompanying grant funding letter (the “Funding Letter”). Deviations from the policies outlined in these documents are valid only if made in writing and approved by an official of the LRA. Research performed under a Grant 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 Activation and Payments

Grants are typically activated on the date listed in the Funding Letter. Alternate activation dates are strongly discouraged. All acceptance materials must be submitted via the Award Management System, proposalCENTRAL, by the date indicated in the 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. Progress and financial reports must be received and approved before any payments can be made beyond the first year of the grant.

Sponsoring Institutions located outside of the United States should be aware that all LRA Grants 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 Grant to its original value.

Research Plan

The Principal Investigator shall commence the research described in the Research Plan within four weeks of when 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 Plan and may not be used for any other purpose without the express written consent of the LRA. Any Grant funds that are unexpended or uncommitted when the Grant is terminated shall be remitted to LRA within ninety (90) days of such termination.

Progress and Financial Reports

Progress Reports

Annual progress reports are due to LRA no later than sixty (60) days after the anniversary of the date on which the Grant was awarded and will be required if a no-cost extension is requested. Final progress reports must be submitted to the LRA no later than sixty (60) days after the termination

date of the Grant. The Final Progress Report should delineate the objectives and significant findings of the research, provide future directions suggested by the research, and include a list of publications resulting from the research that are being prepared for submission, or have been submitted, for publication. All progress report submissions must be made electronically using the LRA's progress report template, available in the deliverables section in proposalCENTRAL.

Financial Reports

Annual financial reports are due to LRA no later than sixty (60) days after the anniversary of the date on which the Grant was awarded and will be required if a no-cost extension is requested. Final financial reports must be submitted to the LRA no later than sixty (60) days after the final termination date of the Grant. A Final Financial Report signed by the responsible administrative official ("Responsible Official") at the Sponsoring Institution should accompany the Final Progress Report along with a refund of any unexpended balance in excess of \$500 USD. All financial report submissions must be made in the Award Management System, proposalCENTRAL. A copy of the template is available in the deliverables section in proposalCENTRAL.

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) the 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. Unless another amount is required by the Sponsoring Institution, approval is only required to carry-over funds that are greater than twenty percent (20%) of the yearly budget. Please note that, unless there are exceptional circumstances (such as a change of Sponsoring Institution), Grant awards will not be extended beyond one year.

Budget Modifications

The Funding Letter for all Grants stipulates a 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 five percent (5%) of the total amount approved for the Grant. If the Principal Investigator wishes to reallocate funds from one category to another in an amount that exceeds five percent (5%) of the total Grant amount, LRA approval must be requested in writing. Up to 10% of the annual budget for the Grant may be allocated to salary of the Principal Investigator. Please note that under no circumstances may indirect costs exceed ten percent (10%) of direct costs excluding equipment. In addition, Grant funds may not be reallocated to the travel budget without prior LRA approval. In the second and third years of a Grant award, Grant funds may not be reallocated to the equipment budget without prior LRA approval.

Grant 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

Grant recipients are required to attend LRA's Annual Scientific Conference (the "Annual Conference"), Forum for Discovery, where they may be asked to present the progress of their work. Grant recipients will be notified of the meeting logistics in advance of the Annual Conference.

Travel funds provided under this Grant must be used to pay for all travel expenses related to attending the Annual Conference. 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 Grant funded by the LRA shall acknowledge funding support by the LRA. As soon as a manuscript is accepted for publication (either 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 Department at publications@lupusresearch.org. As soon as reprints of a publication are available, an electronic copy should be uploaded in proposalCENTRAL.

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 and Grant recipients 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 to treat lupus.

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 the 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, and 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 and Grant recipient and Sponsoring Institution agree to comply with all relevant HIPAA provisions as they relate to patient data. 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 databases (e.g. dbGaP, ImmPort) are now being made available to expedite the sharing of data. Where possible, subject to HIPAA regulations, data from LRA funded studies should be submitted to these publicly available databases.

Sharing of Research Resources

Investigators conducting biomedical research frequently develop unique research resources (“Research Resources”). Research 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 of unique Research Resources 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 an important means to enhance the value of LRA sponsored research. Restricting the availability of unique Research Resources can impede the advancement of further research. Therefore, LRA requires that Research Resources developed with Grant funds be made available for research purposes to the scientific community.

Investigators submitting Grant proposals that are expected to result in the development of a Research Resource must include a plan for sharing these Research Resources or clearly explain why sharing of the Research Resource is not possible.

Termination of the Grant

LRA may terminate a Grant upon written notice to the Principal Investigator and Responsible Official at the Sponsoring Institution if in the sole discretion of the LRA: (a) upon review of the progress of the project for which the Grant was awarded, the LRA determines that the scientific progress made to date does not meet the expectations at the time the Grant was awarded, (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 Policy Statement or the Funding Letter, (d) the LRA no longer has the available funds necessary to continue supporting this Grant, (e) the LRA concludes that the Principal Investigator has received overlap funding for the Grant or that the funds are not being used for the purposes originally outlined in the Research Plan, (f) the Principal Investigator is unable to carry out the research for any reason, or (g) 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.

Overlap Funding

The Principal Investigator and the Sponsoring Institution are responsible for ensuring that the research described in the Research Plan 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.

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 ninety (90) days of such termination. Grants may not be transferred to another individual and/or Principal Investigator working at the Sponsoring Institution unless there is an exceptional circumstance without the express written consent and approval of LRA.

If the Principal Investigator transfers institutions, he/she must submit a formal request to transfer their Grant to a new institution (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 and the project; 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 Sponsoring 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 Grant and for a period not to exceed sixty (60) 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 plan is reviewed and approved in writing by an Institutional Review Board (IRB) constituted in

accordance with current regulations promulgated by the United States Department of Health and Human Services (“HHS”) and approved by HHS. 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 Grant 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 IRB indicating that final approval for the project has been provided. All consent form submissions must be made electronically in proposalCENTRAL. Approval forms from the Sponsoring Institution’s IRB must be submitted prior to Grant activation and prior to the disbursement of any LRA funds.

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.

Laboratory Visits

As a condition of support, the Principal Investigator agrees that the LRA may, upon at least two (2) days’ prior notification, visit and inspect the laboratory or other venue where the Grant is being funded.

Travel

Travel funds provided as part of this Grant must be used to pay for all travel expenses related to attending the Annual Conference. Appropriate travel expenditures are permitted on 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 choose not to stay at the selected hotel, moderately priced hotel accommodations must be utilized. The travel budget category should not exceed \$2,000 per year.

Indirect Costs

Indirect costs for all Grants are limited to a maximum of ten percent (10%) of direct costs excluding equipment.

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 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 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 ("IRC"), 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 IRC. 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 IRC.

*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.
September 2020*