



Request for Applications LRA-Celgene Accelerator Awards

Release Date: September 11, 2019

Letter of Intent Due Date: October 25, 2019

Earliest Start Date: July 2020

Background

The Lupus Research Alliance (LRA) is the world's leading private funder of lupus research. The organization's mission is to improve treatments for lupus while advancing towards a cure through the support for research. At present, therapy for lupus is empiric and involves a variety of mostly nonspecific anti-inflammatory and immunosuppressive agents. While these treatments are frequently beneficial, many patients do not respond adequately and suffer significant side effects, including organ damage. Importantly, many unanswered questions regarding the pathogenesis of lupus remain, and new conceptual and therapeutic approaches are urgently needed.

Celgene—a global biopharmaceutical company—focuses on the discovery, development, and commercialization of products for the treatment of cancer and other severe, immune, inflammatory conditions. More than 300 clinical trials are underway at major medical centers using compounds from Celgene.

The LRA-Celgene Partnership brings together two leaders in harnessing the power of science to improve lives. This initiative aims to identify and enable the early testing of highly innovative approaches to some of the key challenges in lupus research and translation.

Program Goals and Scope

The overarching objective of the LRA-Celgene Accelerator Awards is to fund cutting-edge research projects that focus on understanding the underlying mechanisms of disease, addressing lupus heterogeneity, and identifying novel biomarkers.

The initiative aims to stimulate lupus research innovation, accelerate investigation on **human** lupus rather than relevant model organisms, and realize synergies between academia and industry. Accordingly, studies using human lupus samples will be prioritized over animal model-based projects.

Examples of pertinent topics include, but are **not** limited to:

- *Mechanisms of disease*: Mining of bulk and single-cell transcriptomic and proteomic datasets derived from lupus patient blood and target tissues (e.g., skin, joint, kidney);
- *Target discovery and validation*: Characterization of genetic drivers of lupus, such as but not limited to understanding gain-of-function or loss-of-function risk alleles, eQTLs, or mRNA splicing;
- *Biomarker identification*: Identify or validate early biomarkers of clinical flares, remission or response to therapy;
- *Patient selection*: Novel methods of identifying SLE patient subsets based on immunological and clinical heterogeneity;
- *Clinical endpoint derivation and harmonization*: addressing the need for outcome measures for skin disease, lupus-specific arthritis measures, and other endpoints that would facilitate and accelerate the conduct of clinical trials in lupus and its complications.

Eligibility

Individuals with a doctoral degree (MD, PhD, DO, or equivalent), holding a faculty, or equivalent, position and leading an independent research team at an academic, nonprofit, or government research institution are eligible to apply. The Lupus Research Alliance does not impose geographic restriction on its applicants, and researchers working outside of the United States are encouraged to apply.

Application Guidelines

Applications must be submitted electronically, via [proposalCENTRAL](#) by 11:59 pm ET on the stated deadline. Paper applications are not accepted.

A two-stage application process will be employed. A 2-page Letter of Intent (LOI) will be used to judge the significance, novelty, and alignment of the proposed project concept with the LRA-Celgene Accelerator Award. Only applicants whose LOIs have successfully passed this first review stage will be invited to submit full applications.

I. Letter of Intent

A Letter of Intent is required and must be submitted electronically, via [proposalCENTRAL](#), by 11:59 pm ET on the stated deadline. It should contain the following information:

(Items 1–4 should not exceed **2 pages**. Figures, tables and legends are included within the page limit. However, citations are not counted towards the page limit.)

1. *Brief background*: Provide a succinct contextual framework for the proposed project. This section may be particularly valuable to applicants new to lupus and applying knowledge from other scientific areas—that need to be introduced—to bear on lupus.
2. *Overall objective and preliminary Specific Aims*: State the overall objective and outline the preliminary specific aims.
3. *Project plan*: Describe the *significance*, *innovation*, and *approach* for the proposed project.
4. *Resource assessment*: Assess your ability to carry out this project and outline resources you may need to accomplish it, such as access to patient samples, proprietary reagents or technologies and key collaborators. If the applicant’s primary scientific expertise is outside of lupus, please describe how you intend to apply your unique knowledge to address a

critical issue in the pathogenesis and/or treatment of lupus.

5. *Biosketch*: A standard NIH-style 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.

The LOI will include a check box for each applicant's institution to agree to the 10% indirect cost rate, as well as to Celgene having first option to negotiate—following the conclusion of the project—for any intellectual property arising from the funded research. Please refer to the “Terms of Award” section below for further details.

II. Full Application

Full applications may be submitted only by applicants whose LOIs have been approved and who have been invited by the LRA to advance to the next stage of the review process. Applications should contain the information outlined below and should be submitted via proposalCENTRAL (please log into this site for detailed description). The full application site will only be accessible to applicants with approved LOIs.

It is projected that about half of the investigators invited to submit full applications will be funded.

It is further anticipated that this funding opportunity will be re-released within a year.

Review Criteria

The scientific review committee will consider the following criteria in assigning the application's overall score, weighting them as appropriate for each application.

- *Relevance* of the proposed project to the objectives and research emphasis areas defined in this RFA.
- *Novelty* of the proposed research: 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?
- *Potential impact* of the project to lead to lupus cure, prevention, or a highly effective therapy; new mechanistic understandings in lupus; new methods to stratify lupus patients; or new clinical endpoints for clinical trials in lupus.
- *Scientific merit* of the research proposal: 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?
- *Feasibility* to accomplish the proposed work within a 2-year time frame with defined milestones at 6-month intervals.
- *Investigator*: Does the investigator have a demonstrated track record of innovation, of shifting scientific paradigms and breaking open new areas of research?
- *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?

Budget

The LRA-Celgene Accelerator Awards will be supported for up to US \$150,000 per year for up to 2 years (up to \$300,000 total). Grant payments will be contingent on achieving the pre-agreed upon scientific milestones as determined by the LRA-Celgene Joint Steering Committee described below. Major pieces of laboratory equipment cannot be included in the budget. The award cannot be used for a graduate student's tuition and/or stipend. It is anticipated that up to nine LRA-Celgene Accelerator Awards will be funded during this partnership.

This grant mechanism is made possible by a generous gift from Celgene to the LRA. Thus, all indirect costs may not exceed LRA's cap of 10% of the total award budget.

Terms of Award

The progress of the LRA-Celgene Accelerator Awards will be reviewed by a Joint Steering Committee (JSC) consisting of three scientific experts appointed by the LRA and three Celgene scientists. Every 6 months, grant recipients will be required to participate in a conference call with the LRA-Celgene JSC to review the progress towards the pre-agreed upon research milestones. Grantees will make 30-minute presentations to the JSC, which will provide constructive feedback and recommendations. Funding for Year 2 of the award will be contingent on satisfactory progress in Year 1, as judged by the JSC. Towards the end of the award period, grant recipients will be required to participate in and present their findings at the LRA annual scientific meeting, Forum for Discovery. Travel funds provided by the grant award should be used to attend this event.

Celgene will not hold intellectual property rights on any of the grant awards. Following the completion of each project, Celgene may choose to exercise its first option to negotiate with the grantee's institution for licenses under any arising intellectual property. This exclusive negotiation period is limited to 120 days. If Celgene and the grantee's institution, acting in good faith, are unable to reach an agreement in this period, the grantee's institution will be free to enter negotiations with a third party.

The LRA is committed to the publication and dissemination of all information and materials developed using the organization's resources. All recipients of LRA awards must agree to this principle and must take steps to facilitate availability of data and materials.

Review Process

LOIs will be reviewed by the LRA-Celgene JSC. Invited full applications will be reviewed by a specially empaneled study section comprising experts in areas relevant to the applications under consideration, including a biostatistician. The JSC will participate in the review of the full applications and will make funding recommendations, based on the study section rankings, to the LRA Board of Directors which will have the ultimate approval power.

Review Feedback

For applicants invited to submit full proposals, a summary statement, containing the reviewers' critiques and a synopsis of the review discussions, will be provided within three months of the

review date. LOIs not recommended to advance to the full proposal stage will not receive written critiques. The LRA does not provide scores or applications' rankings to applicants.

Key Dates

RFA Release:	September 11, 2019
Letter of Intent Due:	October 25, 2019
Letter of Intent Decision:	November 22, 2019
Full Application* Due:	January 24, 2020
Scientific and Board Reviews:	March 2020
Award Notification^:	April 2020
Earliest Anticipated Start:	July 2020

*By invitation only with an approved LOI

^For full applications only

Inquiries

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proposalCENTRAL:

For help with the electronic grant application process, please contact the help desk of proposalCENTRAL pcsupport@altum.com
+1-800-875-2562, extension 227