



Request for Applications 2024 Translational Bridge Award \$450,000 over 2 years

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BACKGROUND

The Lupus Research Alliance (LRA) is the largest private funder of lupus research worldwide. The organization aims to transform lupus treatment while advancing towards a cure by funding cutting-edge, innovative research.

At present, therapy for lupus is mostly empiric and involves largely non-specific anti-inflammatory and immunosuppressive agents. While these treatments are frequently beneficial, many patients do not respond adequately or suffer significant side effects. Importantly, even patients with low disease activity accrue organ damage over time. Thus, new conceptual and therapeutic approaches are urgently needed. However, many scientific discoveries that have the potential for clinical translation and commercialization are stunted due to lack of specific funding and guidance to proceed to the next step. The LRA established the Translational Bridge Award (TBA) to provide a dedicated funding mechanism to bridge the gap between post-discovery and pre-commercial development and to accelerate the pace at which promising LRA-funded foundational research discoveries are translated into clinical evaluation and transitioned to a viable product that impacts patients directly.

PROGRAM DESCRIPTION

The Translational Bridge Award provides up to \$450,000 over two years for milestone-driven projects with strong, relatively near-term commercialization potential or with an immediate opportunity for clinical evaluation. All projects should advance the discovery of potential commercial entities or clinical products with a **clear and direct relevance to**

people with lupus and offer the potential to improve diagnosis or standard of care for the disease or usher in a cure. These can include a range of technologies, therapies, interventions, and diagnostics. Proposals should be centered around a well-defined bridge plan of translating the discovery and/or advancing the entity or product to the next development stage. This bridge plan should consider the scientific, clinical, business and/or commercialization objectives outlined below.

PROJECT OBJECTIVES

Proposals should include milestone-driven projects with clear objectives, well-defined on the translational, clinical or drug/diagnostic development path, with relatively near-term commercialization potential.

Two main types of projects will be considered:

1. Projects that aim to establish a robust data validation package, including pre-clinical or pilot clinical studies, to advance the discovery of a potential entity or product by enabling translational inflection points such as securing/bolstering of intellectual property, securing additional venture capital for a start-up company, obtaining clinical proof-of-concept, etc.
2. Ancillary projects to ongoing or recently completed clinical trials for further analysis on a potential entity or product, or other defined study components (such as associated biomarkers).

Scientific project objectives should be aimed at:

1. Late-stage evaluation or validation (no foundational discovery research) of the proposed entity or product, including, but not limited to, clinical proof of concept, projects that aim to scale up previous results, move to a more relevant testing system or population, compound screening, chemical fine-tuning, pharmacological evaluations, and/or sensitivity/specificity testing.
2. Clinical trial ancillary projects can also include experimentation aimed at further understanding the mechanism of action or pharmacodynamics of the entity or product, molecular effects and/or companion biomarkers.

Proposals can include multiple scientific and/or clinical objectives. Other objectives not mentioned here may be appropriate, and we recommend you contact LRA scientific staff to consult on this topic.

The proposal should also include a description of the legal, regulatory, business and/or commercialization objective(s) of the project, such as, but not limited to, generating data that would support:

1. Creating or strengthening an intellectual property position.
2. Launching a commercial enterprise, such as a start-up company, around the entity or product.
3. Raising industry interest around the entity or product, including initiating a clinical investigation.
4. Forging a commercial partnership

5. Securing additional rounds of financial backing or funding.

ELIGIBILITY

Applicants must have previously received LRA funding or were affiliated with a previously funded LRA award and have **completed or will complete the** award term, inclusive of any no-cost extensions, between January 1, 2019, and December 31, 2024. Current LRA funded investigators whose awards will be completed after December 31, 2024, are not eligible to apply.

Applicants must have 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. US federal government research laboratories are not eligible for this award. There are no citizenship requirements for investigators applying to this program.

Applicants must also be up to date with all progress and financial reports and other Terms and Conditions of the original LRA award(s) at the time of application.

The same research project may not be submitted for consideration to multiple LRA grant mechanisms in the same year. Such submissions will be triaged without review.

APPLICATION PROCESS AND INSTRUCTIONS

A two-stage application process will be employed. A Letter of Intent (LOI) will be used to judge the strength, commercialization potential, clinical relevance, and alignment of the proposed project with the TBA funding mechanism objectives. Please consult and adhere to the comprehensive LOI instructions provided. Applicants whose LOIs successfully pass this first review stage will be invited to submit a full application in the second stage of the application process. Applicants are encouraged to consult with LRA scientific staff to discuss the responsiveness of their proposal to this program. **LRA will host a webinar on March 22, 2024, at 1pm ET** for interested applicants to provide further context to this RFA and to answer any questions. A recording of the presentation will be made available.

KEY DATES

RFA Release:	February 26, 2024
Letters of Intent Due:	April 29, 2024
Letter of Intent Decision:	June 2024
Full Applications Due*:	July 2024
Full Application Decision:	September 2024
Expected Start Date:	January 2025

*By invitation only with an approved LOI. The date is approximate and will be communicated at the time of LOI decision.

LETTER OF INTENT

LOIs must be submitted electronically, via [ProposalCentral](#), **by 11:59pm US ET on the stated deadline**. LOIs will not be accepted via any other means.

The following information is required to submit a complete LOI. Numbers correspond to the application sections found on the left side of the ProposalCentral website.

1. **Title Page:** Enter the title of the proposed project. Indicate whether the applicant is currently funded by the LRA. Indicate whether the proposed project involves the use of human samples and/or data.
2. **Download Templates & Instructions:** The Request for Applications, Letter of Intent Instructions, and Letter of Intent template can be downloaded from this page.
3. **Enable Other Users to Access this Proposal:** Enter the information for any other users who will need to work on the LOI.
4. **Applicant/PI:** The applicant's information is pre-loaded with the contact information from their ProposalCentral profile. Click the Edit Professional Profile button if any changes need to be made. Upload a standard [NIH Biosketch and Other Support Format Page](#), which should detail all other financial support (current as of the date of application submission) available to the applicant for their research endeavors. Applicants who are not based in the United States may submit a copy of their curriculum vitae, which must be limited to five pages in length.
5. **Institution:** The institution will be pre-loaded with the applicant's institution. Enter the requested information for the Signing Official.
6. **Letter of Intent & Other Attachments:** Upload the Letter of Intent and biosketches/CVs for all key personnel as PDFs.
 - A. **Letter of Intent (LOI):** The Letter of Intent template provided on ProposalCentral must be used. Margins must not be less than 0.5 inches on each side and 12-point Times New Roman or the equivalent should be used for the text. **The LOI text, responsive to the specific instructions and template available on ProposalCentral, should not exceed three pages and cannot include any figures, tables, or legends.** However, up to two pages of figures, tables, and legends can be added to the LOI text.
 - B. **Biosketch(es):** Submit a standard NIH-style biosketch for all key personnel working on the project. A curriculum vitae may be submitted for key personnel not based in the United States.
7. **Validate:** Click the "Validate" button to check for any missing required information or attachments.
8. **Sign:** Click the "Sign" button to electronically sign the LOI. By signing, the applicant certifies that the information contained in the LOI is true, complete, and accurate to the best of their knowledge.

9. **Submit:** After successfully passing the validate check, click the “Submit” button. An e-mail will be sent confirming submission.

LOI Restrictions

Only one LOI will be accepted per applicant in a grant cycle.

FULL APPLICATION

Full applications may be submitted only by applicants whose LOIs have been approved to advance to the next stage of the review process. Applications must be submitted electronically, via [ProposalCentral](#), **by 11:59pm US ET on the stated deadline**. Detailed instructions for the full application will be available on ProposalCentral. The full application site will only be accessible to applicants with approved LOIs.

REVIEW CRITERIA

The LOI review will be based on the strength of the initial status of the proposed entity or product, its commercialization potential, and the comprehensiveness of its project plan (including objectives, experimental design, and appropriate decision points [go/no-go]).

Should your LOI be recommended for full application, you will receive detailed feedback on how to improve and expand your application. The full application review will be based on the above-mentioned criteria, as well as its responsiveness to the reviewer feedback.

Applications that are not aligned with the goals and the mission of the LRA will not be peer-reviewed.

Review Process

All eligible grant applications will be peer-reviewed by a unique panel of external reviewers, including drug developers, venture capitalists, and clinical/translational scientists, the results from which will be considered by the LRA Scientific Advisory Board (SAB) in the context of the LRA grant portfolio and LRA's strategic research priorities. The SAB will make funding recommendations to the LRA Board of Directors, which will, in turn, consider all previous recommendations and provide a lay perspective including patients' concerns and expectations, as well as deliberations on the business aspects of funding the recommended grants. The LRA Board of Directors will make all final funding decisions.

Review Feedback

For applicants invited to submit full applications, a summary statement containing the reviewers' critiques will be provided. The LRA does not provide scores or application rankings to applicants.

AWARD TERMS AND CONDITIONS

The TBA provides up to US\$450,000 over two years. Partial funds will be distributed upon execution of the award, and subsequent payments are dependent on the budgeted amount for each milestone and their timely and satisfactory completion, as determined by the Program Officer monitoring the progress with input from external experts where

necessary. Indirect costs must not exceed 10% of the total budget and must be included within the \$450,000 annual budget cap.

Grant recipients must attend and present at Forum for Discovery, the LRA annual scientific conference, each year. Travel funds (up to \$2,000 per year) provided by the grant must be used to pay for travel expenses related to attending Forum for Discovery meetings.

The LRA is committed to the publication and dissemination of data/information and materials developed using the organization's resources. LRA staff will work with the awardees of this funding mechanism to enable this key LRA principle while ensuring commercialization potential.

INQUIRIES

Scientific:

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ProposalCentral:

For assistance with the electronic grant application process, please contact ProposalCentral at pcsupport@altum.com or 800-875-2562, extension 227.