NOTICE OF FUNDING OPPORTUNITY (NOFO) STRATEGIC, INNOVATIVE AND MEANINGFUL SCIENCE (SIMS)

FROM THE OFFICE OF THE VICE PRESIDENT FOR RESEARCH AFFAIRS 2025

Purpose: To provide an Inter-Institutional funding opportunity to engage in research collaborations between Loma Linda University faculty and faculty from externally designated R1 Institutions. This funding award is designed to fund pilot studies of high impact, cutting edge research that will allow a continuum of relational growth between institutions and investigators, which will lead to collaborative external grant funding.

Description:

Maximum award: \$75,000
 Term of award: 24 months
 Start date: January 2025
 Number of awards: up to 2

New Applications:

Letters of Intent must be submitted no later than Monday, July 8, 2024
Application due date Monday, August 12, 2024
Application pre-review date Monday, August 19, 2024

Anticipated date of award announcement December 2024

- Letters of Intent and Application Process: Intent to submit a SIMS application must be indicated by completing the Letter of Intent form, including the signatures from the LLU Principal Investigator (PI), and the external research collaborator. Please include the biosketch of the external collaborator. Submit documents to Research Affairs via email rapreaward@llu.edu. Your LOI will be used to create your LLeRA record for uploading your application documents. Questions should be directed to the Pre-Award team https://researchaffairs.llu.edu/pre-post-award/contacts.
- II. Eligibility (determine your eligibility before applying):
 - The project must be directed by an eligible LLU PI from any LLU school.
 - The research collaborator must be from an R1 research institution (https://carnegieclassifications.acenet.edu/institutions/?basic2021 du%5B%5D=15) and have expertise in the discipline relevant to the application. He or she must also have a primary appointment corresponding to this expertise.
 - The research collaborator must agree to a fee-for-service contractual relationship; research collaboration agreement.
 - The LLU PI must have an appointment that meets the institution's <u>PI Eligibility</u> policy. An investigator's primary appointment will be used to determine eligibility.
 - The external collaborator must have prior research funding and a history of publishing his or her work.
 - Only studies conducted primarily at facilities on the Loma Linda campus will be considered.
 - At least one manuscript in one peer-reviewed journal during the past year must have been published by each member of the team. This manuscript is to be included in the biosketch.
 - See III. Individuals who have received prior SIMS awards may reapply for SIMS support provided that for each prior SIMS award: the LLU PI must have 1) published one or more peer-reviewed manuscripts, and 2) submitted one or more applications for extramural funding from an R series NIH grant (or Foundation equivalent) on which they are listed as PI or co-investigator with the data of their SIMS work included. The grant application must have occurred after receiving the prior SIMS award.

- Applicants that submitted unsuccessful SIMS applications may resubmit a revised application by invitation
 only. The revised application must include an "Introduction to the Revised Application," of up to one page
 that describes the changes made to the proposal.
- Only one application per LLU PI is allowed.
- III. Eligibility for previous SIMS recipients: For LLU PIs who are previous SIMS recipients, provide the following:
 - Peer-reviewed and published papers:
 - Citations for one or more articles that were published or accepted subsequent to the SIMS award and that acknowledge SIMS funding support.
 - PDF of or hyperlink to the article(s).
 - Information regarding extramural grant applications:
 - LLeRA number
 - Principal Investigator
 - Title
 - Sponsor name
 - Date of submission
 - Amount
 - Current status (i.e., funded, pending, scored, not discussed, etc.)
- IV. Application pre-review: To ensure a quality application has been submitted, an administrative/scientific merit review will be conducted by Research Affairs and the Charles and Nancy Sims Institute for Genetics and Translational Genomics. Administrators will decide which application(s) should move forward for reviewer assignment and consideration for funding.
 - Review will include an evaluation of the scientific merit and format to determine if NIH standards are met.
 - Administrators will decide and communicate directly with PIs if edits will be allowed or if the application will be withdrawn. Pre-Award will communicate with applicants that are accepted for reviewer assignment.
- V. Criteria for Full Application Evaluation: Awards will be based primarily on scientific merit, including significance, innovation, approach and investigator, as well as alignment with the purpose of this award. The quality of interinstitutional collaboration, justification of the budget, and potential for future funding will also be considered. Inclusion of preliminary data supporting the proposed study is highly recommended. In the absence of preliminary data, strong literature support for the planned study is required. The focus will be on funding high-impact, paradigm-shifting, innovative projects. Consequently, the application must clearly describe the potential impact of the project on the field and highlight its innovative elements. Applications are expected to appropriately address issues of rigor and reproducibility. Proposals will be reviewed by a panel of investigators selected including those with extramural funding and a preference for those who have served on federal grant review panels. To the extent possible, applications will be kept confidential, but the abstracts of funded projects will be published.
- VI. Application Format: Text must be 11 point or larger with six lines per inch and margins of at least one-half inch. The sections identified below may not exceed their indicated page limits. Headers, footers, and appendices are not allowed. The following sections are expected:

Title Page (one page): Include the title of the project, names of the LLU PI and external research collaborator, their contact information (including institutional e-mail, phone numbers, WhatsApp Id, Skype Id, Zoom Id, name of department or center), a list of all key personnel (other significant contributors), and total dollars requested.

Abstract & Key Words (up to 30 lines of text): The project summary/abstract is a succinct and accurate description of the proposed work and should be able to stand on its own (separate from the application). This section should be informative to other persons working in the same or related fields and understandable to a

scientifically literate reader. Please be concise. State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project. Describe the research design and methods for achieving the stated goals. Be sure that the project summary reflects the key focus of the proposed project. Four to six key words are required to identify the general area of research and the principal elements of the study.

Biographical Sketches (up to five pages per investigator): Provide NIH style biosketches for both the LLU and external PI, external research collaborator(s) (if any) and key personnel (Other Significant Contributors) in the format provided in the following link http://grants.nih.gov/grants/forms/biosketch.htm).

Budget: Design a complete budget for up to 24 months of support. The LLU PI will be the named recipient of all awarded funds for budgetary purposes and serve as the point of contact for budget-related issues, with the external collaborator the recipient of a Research Collaboration Agreement. Identify expenditures for salaries, supplies, and miscellaneous costs. SIMS awards may not be used for equipment costing \$5,000 or more, travel expenses, or indirect costs. The total budget may not exceed \$75,000. **Only non-faculty salaries and wages** are permitted; however, LLU PIs are expected to commit a minimum of 10% effort to the project. All other Key-Personnel should be listed as "*Other Significant Contributors*" (OSC), no internal consultants or co-investigators should be listed on the application. OSCs are individuals who have committed to contribute to the scientific development or execution of the project but are not committing any specified measurable effort (i.e., person months) to the project and will not receive a salary. LLU core facilities must be utilized whenever possible – In the event that LLU does not have the resource on campus, contact your Pre-Award team member (<a href="majorated-number-representation-representation-representation-member-representation-representation-member-represen

Budget Justification (one to two pages): Provide detailed information on all items included in your budget. For personnel, provide a description of the role and effort in calendar months. Also include the purpose of supplies, equipment, and other costs, etc. For the external research collaborator, please provide a scope of work and explanation of deliverables with timetable and separate budget. If funded, these documents will be used to execute a research collaboration agreement.

Resources and Environment: Describe facilities and other resources available to complete your project, both that LLU and at the partner institution. Also state how the scientific environment in which the research will be done contributes to the probability of success. Note major items of equipment already available for your project, including those available in core facilities.

Both LLU and the research partner may have assets that are uniquely advantageous to the successful completion of the proposed project. For example, investigators may wish to utilize the Adventist Health Study 2 Database, a particular piece of equipment in a core facility run by either institution, or a unique population cohort. Should this be the case, indicate this in the "Resources and Environment" section, and provide a signed letter of support from the Individual authorized to approve the use of this asset.

Research Plan (6 Pages): Much of the text below is taken from NIH instructions (https://grants.nih.gov/grants/funding/r21.htm) to facilitate conversion to a R03, R21, etc. application.

Specific Aims (one page): State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved. List succinctly the specific objectives of the research proposed.

Research Strategy (limited to 6 pages): Six pages in total are allowed for the subsections of Significance, Innovation, and Approach. Suggested allocations of this space for those three subsections are noted below.

- **Significance** (suggested length, ½ page): Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
- Innovation (suggested length, ½ page): Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?
- Approach (suggested length, 5 pages): Are the overall strategy, methodology and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?

Future Directions (one page): Briefly describe the future directions to be taken with this project, assuming that this initial phase is successful. For example, describe grants or industry funding to be applied for and how the preliminary data obtained in this first phase will enhance those applications. Also, if this pilot data will allow design of a larger study, describe briefly the anticipated study design for this larger study.

References: Include references that demonstrate the need for this research, establish feasibility for hypotheses and procedures, and provide support for the approach. Include titles and authors.

- VII. Letters of Support: You must provide a letter of commitment from the external research collaborator. This letter must contain an understanding of the scope of work, deliverables and budget allocated for the work to be performed. Other Letters of support from key personnel and consultants are encouraged.
- VIII. Compliance: When the proposal involves human embryonic stem cells, ionizing radiation, laboratory animals, human subjects, or other elements that requires approval by an oversight committee, integrate the descriptions into the Research Strategy section. If the proposal is awarded, separate applications must be made to the appropriate oversight committee before the work can begin, e.g., Institutional Animal Care and Use Committee (IACUC), Institutional Review Board (IRB), Institutional Biosafety Committee (IBC), Stem Cell Research Oversight Committee (SCRO).
- IX: Final Report: Extensions of the project period may be requested and if granted, will follow NIH guidance. A progress report is due at the end of year one. Within 60 days of the end of the project period, a final report is due. It should include accomplishments, significant results, manuscripts prepared for publication and plans for extramural grant applications. Contact Post Award for information, ext. 44589.

X. Resubmission Applications: By invitation only.

• All resubmission applications must include: Introduction to Revised Application (one page, required only for revised applications): Summarize the substantial additions, deletions and changes to your application. In addition, concisely address each of the concerns raised by the previous reviewers.

Contacts:

General Information, Technical, and Application Guidance: https://researchaffairs.llu.edu/pre-post-award/pre-award/grants-for-research-and-school-partnerships-grasp

Pre-Award: rapreaward@llu.edu

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