

LA CaTS Center Pilot Grants Program

2023-2024 MULTI-INSTITUTIONAL GRANT APPLICATION INSTRUCTIONS (ROUND 12)

PURPOSE: The Louisiana Clinical and Translational Science (LA CaTS) Center is focused around the theme of "prevention, care and research of chronic diseases in the underserved populations of Louisiana". The LA CaTS Center will fund **two** new multidisciplinary, multi-institutional, multi-investigator awards in 2024. The goal is to develop collaborative research that results in highly significant preliminary data that can be used to compete for large multi-institutional or multi-PI federal grants, such as center planning grants, center grants, or program project grants. The projects should be focused on understanding the epidemiology, etiology and pathophysiology of chronic diseases that are relevant to the Louisiana population, and should help develop new approaches to disease prevention and/or treatment.

The total amount of the award for each project may vary depending on the scope of the project and the number of collaborating institutions. The LA CaTS Center will contribute up to \$75,000 to each award and each participating institution will contribute up to \$75,000 for each project that includes a PI at their respective institutions. For example, the support for a single project involving two institutions could be up to \$225,000 for one year (\$75,000 from LA CaTS +\$75,000 from each participating instititution). A second year of support may be offered, but will depend on availability of funds and scientific progress on the project.

We encourage collaborations in all areas of translational science related to our theme of chronic diseases and health disparities. In this round of applications we are prioritizing applications that include an obesity, cancer, diabetes, HIV/AIDS, or cardiovascular disease focus.

Eligibility Criteria

This special emphasis multi-institutional program is available to researchers that are faculty members of LA CaTS Center Member Institutions which are able to provide the required matching funds. The LA CaTS Center Member Institutions include Penningtion Biomedical Research Center, LSU Health New Orleans, Tulane University, LSU Health Sheveport, Xavier University of Lousiana, Ochsner Health System, Children's Hospital New Orleans, LSU A&M, University Medical Center (UMC), and Southeast LA Veterans Health Care System (New Orleans VA). Researchers who are <u>not</u> at Pennington Biomedical, LSU Health–New Orleans School of Medicine, or Tulane University School of Medicine are <u>required</u> to submit a letter of support from their school dean or

department chair, committing institutional funding to support the project to be eligible (see *Pre-Application Guidelines*).

Applicants must hold a PhD, M.D., or equivalent degree. Research teams with a collective track record of extramural research support and preliminary data and a strong premise to support the proposal. Engagement of early career faculty and/or post-doctoral fellows as co-investigators is encouraged. A pre-application is *required* prior to full applications to ensure eligibility and appropriateness of the research topic.

Criteria for Selection land Scoring Method

All applications are sent to a minimum of three reviewers assigned by the Review Committee, who score them based on the following review criteria:

- 1. Does the project meet the objectives of the LA CaTS Center to enhance clinical research and translation?
- 2. Does the project provide the opportunity of obtaining the necessary preliminary data to compete for a large federal grant, i.e. center planning grant, a center grant or a program project.
- 3. Is the project feasible within the time and budget constraints requested?
- 4. Is the project a collaboration between at least 2 investigators from participating partners?
- 5. If the project involves population research, does it follow the Community Based Participatory Research model and consider effective health communication strategies to recognize and address differences in culture, language and health literacy between investigators and community members?

The criteria will carry equal weight, and the overall scores will be based on the current NIH scale of scoring ranging from 1.0 (outstanding, few weaknesses) to 9.0.

TIMELINE:

Announcement Released: July 10, 2023

Pre-application Deadline: August 4, 2023 by 5:00pm CST; Pre-applications must be sent by email to info@LACaTS.org. Applicants will be notified directly if, based on their pre-application, they are selected to submit a full application for the competition. See Pre-application Guidelines below for requirements.

Announcement for Full Application Submission: August 25, 2023; Applicants will be notified directly if their preapplication is selected to move on to the full application stage of the competition. Notice of selected preapplications will also be sent to the Grants/Sponsored Projects Office or designee at each applicant's respective institution.

Full Application Deadline: November 1, 2023 by 5:00pm CST; Applications must be submitted online on the <u>LA CaTS Center SPARC Request System</u> (https://sparc.lacats.org). Applicants will need to create a profile and answer basic

information about the proposal before uploading the application. More detailed instructions will be sent to the selected applicants.

Please submit in <u>PDF format in color</u> on the LA CaTS website.

Earliest Anticipated Start Date: July 1, 2024; Projects selected for funding may begin after project and assurances (IRB/IACUC) are reviewed/approved by NIH.

Pre-application GUIDELINES:

preapplications accepted for review **MUST** include the following information:

- Project title, Principal Investigator, or Co-Principal Investigators and their interinstitutional or multi-disciplinary collaborations
- Specific Aims page, up to 2 pages of preliminary data, 1 page explaining the collaboration and the role of each institution/PI, and relevance to the LA CaTS mission.
- Statement that the applicant's Sponsored Projects/Grants Office (s) were notified of the preapplication submission.
- If applicable, list any current or pending funding from another NIH IDeA (Institutional Development Award) program (i.e. COBRE, INBRE, etc.) for the Principal Investigator. Include the funding period start and end dates.
- Researchers who are not at Pennington Biomedical Research Center, Tulane University School of Medicine, and LSU Health-New Orleans School of Medicine are required to submit a letter of support from their school dean or department chair, committing institutional funding to support the project to be eligible.

FORMAT OF FULL APPLICATION:

The application packet must include the following (applicants are required to use the NIH PHS 398 forms):

- NIH Form Page 1: Face Page (signed by authorized institutional representative of each institution)
- NIH Form Page 2: Summary, Project/Performance Sites, Key Personnel, etc.
- NIH Form Page 4: Detailed Budget for Initial Budget Period
- NIH Form Page 5: Budget for Entire Proposed Project Period and Detailed Budget Justification
- NIH Biosketch of PI (or Co-PIs) and Co-investigators (including personal statement and other support)
- LA CaTS Project Data Form (found on website, at the bottom of RFA instructions)
- LA CaTS Core Service Planned Usage Form (found on website, at the bottom of RFA instructions)
- Abstract of purposed work (150 words or less) for dissemination purposes if awarded (i.e. LA CaTS website, LA CaTS governing & advisory boards, LA CaTS Center meetings, etc.).
- Research plan (8-page maximum excluding references, Arial 11, single-spaced).
 - A. Specific Aims

B. Research Strategy

- 1. **Significance** (address translational relevance and transition to external funding), including how project fits with LA CaTS Center theme and how it has potential to be applied to clinical practice.
- 2. **Innovation** (Describe any novel theoretical concepts, approaches or methodologies, instrumentation or intervention[s] to be developed or used, and any advantage over existing methodologies, instrumentation or intervention[s]).
 - Provide brief description of any background intellectual property associated with the proposed research. Please contact your institution's Office of Intellectual Property for assistance.
- 3. **Research Approach** (Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project; please include anticipated use of Center resources and institutional environment).
- 4. Statistical Analysis: Applicants are required to consult with the LA CaTS Biostatistics & Epidemiology Core regarding their statistical plan, and provide a plan for approval to the Core OR work with the Core to develop a statistical plan. If the applicant has a statistician, the statistical plan proposed must be sent to the LA CaTS Biostatistics & Epidemiology Core (Biostatistics@LACaTS.org) for review prior to submission of the full application. [This is a requirement for submission.] Requests for a biostatistical consultation are made online on the LA CaTS Center SPARC Request website (https://sparc.lacats.org). Please provide acknowledgement of this requirement in the proposal.
- 5. **Future funding plans:** Explain how the completion of the study and data obtained will be used for future funding applications.
- 6. **Timeline for project completion:** Outline major milestones for project completion over the one year timeframe and include regulatory approvals.
- When human subjects are involved, include a Human Subjects Protection Plan
 in accordance with NIH (Link: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#3.1). The NIH PHS Human Subjects and Clinical Trials
 Information Form (SF424 R&R-Version E) is not required in the application
 review stage, however this form will be required prior to funding if awarded.
 Applicants should include a description of each section below following NIH
 guidelines.
 - A. Protection of Human Subjects plan
 - **B.** Inclusion of Women and Minorities
 - C. Inclusion of Individuals Across the Lifespan
 - **D.** NIH Inclusion Enrollment Report https://grants.nih.gov/grants/forms/inclusion-enrollment-report.pdf

- When vertebrate animals are included, please also provide a Vertebrate Animals Section in accordance with NIH (https://olaw.nih.gov/guidance/vertebrate-animal-section.htm):
 - A. **Description of Procedures**: Detailed description of proposed use of
 - A. **Description of Procedures**: Detailed description of proposed use of animals. Identify species, strains, ages, sex and numbers of animals to be used.
 - B. **Justifications**: Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).
 - C. Minimization of Pain and Distress: Describe procedures for ensuring discomfort, distress, pain and injury will be limited to that which is unavoidable in the conduct of scientifically sounds research (describe analgesic, anesthetic and tranquilizing drugs, and/or comfortable restraining devices).
 - **Method of Euthanasia**: State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.
- NIH 398 forms can be found at: http://grants.nih.gov/grants/funding/phs398/phs398.html

If necessary, additional materials, such as reprints (2 maximum) or letters can be submitted as an appendix, such as:

- Copy of submission to IRB or IACUC if project involves human or animal subjects.
 - The submission to the IRB/IACUC will be requested as per the NIH practice of Just-In-Time (JIT) mechanism.
- If project requires a sponsor, consultant or collaborator, this individual must write a letter of support for the application and clarify any potential overlap between their support and the subject of the proposal. This letter should accompany the application.
- NIH Biosketch including personal statement from the mentor and "Other Support" if currently independently funded.

Allocation and Expenditure of Funds

For assistance in creating the budget, please contact info@lacats.org

Expenditures Allowed:

- Technical and clinical staff salary support
- Subject stipends
- Special fees (pathology, photography, etc.)
- Research supplies and animal maintenance costs directly related to the project
- Consulting costs directly related to the project
- Publication costs, including reprints

Subawards (follow NIH policy)

Expenditures NOT Allowed:

- Principal Investigator or Co-investigator salary support
- Secretarial/administrative personnel salary support
- Office equipment and office supplies
- Computers
- Tuition
- Domestic or Foreign Travel
- Dues and membership fees in scientific societies
- Honoraria and travel expenses for visiting lecturers
- Equipment costing more than \$5,000
- Alterations and Renovations

The LA CaTS Center Cores offer many no-cost or discounted services for pilot grants. Applicants are strongly encouraged not to budget for services (i.e. biostatistics, community engagement, clinical sites, etc.), which the LA CaTS Center Cores can provide.

Although facilities and administrative costs are allowed under the terms of the prime award, it is our belief that these funds should be used in the spirit intended (i.e. direct costs) in support of this project. It is suggested for an award of this type, institutions forego the facilities and administrative costs and consider these costs as matching funds for the project.

Consultations with LA CaTS Center Cores

In addition to the required consultation with the LA CaTS Biostatistics & Epidemiology Core for the proposal, applicants are encouraged to consult with other LA CaTS Cores during proposal development and the pilot grants application process. To request a consultation or to review all available services, please go to LA CaTS Center SPARC Request (https://sparc.lacats.org) and search the service catalog for the necessary services.

<u>Additional Information:</u> Please check the LA CaTS website or email questions to <u>info@LACATS.org</u>.