



**LA CaTS Center Pilot Grants Program
2017 PILOT GRANT APPLICATION INSTRUCTIONS (ROUND 6)**

PURPOSE:

The LA CaTS Center is seeking research applications to support highly innovative projects aimed at preparing major publications and grant applications to compete for extramural funding (e.g. NIH, DOD, or Foundations). The 2017 round will favor applications from junior investigators, and applications must include a mentoring component. These projects should address biological, epidemiological or clinical issues related to specific diseases that have a high prevalence among the population of Louisiana, including, but not limited to, obesity, diabetes, cancer, cardiovascular disease, and HIV/AIDS. The program will support research activities and will also provide eligible pilot projects with access to scientific, statistical and regulatory cores to facilitate their development.

Each award may be up to \$50,000/year in total costs for one year. A second year of support may be offered, but is not guaranteed and will depend on availability of funds and scientific productivity of the pilot project team.

Areas of research may be related but not limited to:

1. Early phase clinical trials, including early phase I studies to test or evaluate tolerability in humans, stemming from investigator-initiated research that are ready to start (trials supported by pharmaceutical companies are excluded from these grants).
2. Animal studies required to support the development of early stage clinical trials and the testing of novel compounds in the clinic.
3. Research using patient materials (biological samples, questionnaires, surveys, etc) that are important for the development of new diagnostic tools, prognostic or pathophysiological information.
4. Population research projects that aim to develop interventions that improve health outcomes of the residents of Louisiana by using the Community Based Participatory Research (CBPR), health literacy methodologies (i.e. use of health literacy as a variable, impact of health literacy on outcomes, use of questionnaires and education that is usable and actionable) and behavior modification studies related to managing risk factors.
5. Cost effectiveness of prevention or treatment modalities

As outlined, priority will be given to projects that are very close to initiation, so projects for which the relevant human subjects' and/or animal care and use reviews are in process or approved will be given priority.

Eligibility Criteria

Applicants will be faculty members of the participating institutions that are part of the LA CaTS Center. Applicants must hold a Ph.D., M.D., or equivalent degree. All junior faculty (i.e. assistant professors), house officers, instructors, and senior post-doctoral fellows, will require a letter of support that must indicate a commitment to recruitment or retention of the faculty at a participating institution and also a letter of support from the primary mentor.

A pre-application is required prior to full applications to ensure eligibility and appropriateness of the research topic. Only investigators who submitted and received an approval of the pre-application will be eligible to submit a full application.

There is no citizenship requirement for pilot funding recipients, but visiting scientists with whom the LA CaTS Center's institutions do not have a long-term collaborative relationship will not be considered for support.

Prior and current pilot grant awardees and scholars are eligible to submit a pre-application for this round. Applications that seek to extend a current pilot project must demonstrate suitable progress on the current award to be considered for additional funding.

Mentoring Component

Applicants must identify two senior mentors (Primary and Secondary Mentors) in their application. A short description of the mentoring plan must be provided in the application, including the role of the mentors on the project and the nature and frequency of communication between the Principal Investigator and the mentors.

Criteria for Selection and Scoring Method

All applications will be sent to three reviewers who are assigned by the Pilot Grants Program Review Committee. Reviewers will score proposals based on the five NIH criteria: 1) significance, 2) investigator(s), 3) innovation, 4) approach and 5) environment; with special consideration of the following questions:

1. Does the project meet the published objectives of the LA CaTS Center to enhance clinical and translational research?
2. Is the project at an advanced stage, i.e. ready to initiate protocol and/or has regulatory (i.e., IRB) approval.?
3. Will the proposed project obtain sufficient data to compete for extramural funding during the period of funding? If successful, will the project likely lead to new research or therapeutic avenues?

4. Does the project involve novel methodologies to enhance translational research and/or does it meet a need identified in represented populations?
5. Is the project a collaboration between investigators at one or more of LA CaTS Center institutions (e.g., LSUHSC-NO, LSUHSC-S, Tulane, Pennington Biomedical, Xavier, LSU, Children's Hospital, Ochsner Health System, Southeast Louisiana Veterans Healthcare System, LSU-NO School of Dentistry)?
6. Is the project a collaborative project between investigators (e.g., junior/senior, mentee/mentor, MD/PhD, spans across disciplines)?
7. If the project involves community-based 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 review 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 (major weaknesses). Reviewers will be asked to provide scores and an overall impact paragraph to include comments on the significance and potential impact of the proposed work, relevance to the LA CaTS Center mission and overall project strengths and weaknesses.

TIMELINE:

Announcement Released: Tuesday, September 5, 2017

Pre-Application Deadline: Monday, October 2, 2017

Announcement for Full Application Submission: by Monday, October 16, 2017; Applicants will be notified directly if, based on their pre-application, they are selected to submit a full application for the competition. Notice of applicants selected to submit full applications will also be sent to the Grants/Sponsored Projects Office or designee at each applicant's respective institution.

Full Application Deadline: Monday, November 13, 2017; Applications **must** be submitted online under the applicant investigator's account on the LA CaTS Center Website, under Research Funding at: <http://www.lacats.org/members/researchfunding/>.

Announcement of Results of Review: Friday, December 22, 2017

Anticipated Start Date: Projects selected for funding may begin after project and written assurances (e.g., IRB/IACUC) and subcontracts are reviewed/approved by the LA CaTS Center Executive Committee and/or NIH.

PRE-APPLICATION GUIDELINES:

The Pre-Application **MUST** include the following information:

- Project title, Principal Investigator, names of primary and secondary mentors, and any inter-institutional or multi-disciplinary collaborations
- Abstract of intended work including a clinical research component or potential for a clinical component utilizing human subjects.
- The Specific Aims of the project (limited to 1 page)
- Biosketch of the Principal Investigator and Primary Mentor
- Statement that the applicant's Sponsored Projects/Grants Office was notified of the Pre-Application 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.

FORMAT OF FULL APPLICATION:

Please submit in **PDF format in color** on the LA CaTS website.

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

- Submission Checklist (*found on website, at the bottom of RFA instructions*)
- NIH Form Page 1: Face Page (signed by authorized institutional representative)
- NIH Form Page 2: Project Summary
- 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 and Primary and Secondary Mentors
- 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*)
- Research plan (**Proposals should range 5 to 10 pages (maximum) excluding references and abstract; Arial 11, single-spaced**).
 - A. Abstract of proposed work (150 words or less), not included in 10 page max, for dissemination purposes if awarded (i.e. LA CaTS Center website, LA CaTS Center governing & advisory boards, LA CaTS Center meetings, etc.).
 - B. Specific Aims
 - C. Research Strategy
 1. **Significance** (address translational relevance and transition to external funding), including how project relates to obesity, diabetes or health disparities in the population of Louisiana 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 LA CaTS Center resources as well as the investigator's 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](http://LACaTS.org) website (sparc.lacats.org). Search the SPARC service catalog for the necessary services. *Please provide acknowledgement of this requirement in the proposal.*

D. Future funding plans: Explain how the completion of the study and data obtained will be used for future funding applications.

E. Timeline for project completion: Outline major milestones for project completion over the one year timeframe and include regulatory approvals.

- For **previously awarded LA CaTS Pilot Investigators** applying for second year of funding for the same project, also include a progress report (not part of the 10 page Research Plan max):
 1. Specific progress made on project in the first year (1 page maximum) including data collection, specific findings to date, presentations and publications resulting from the LA CaTS work, and outline clearly how this award differs from the prior award.
 2. For NIH-defined clinical research, include a completed NIH Inclusion Enrollment Report (NIH PHS 398 form).
- When **Human Subjects** are involved, please include a Human Subjects Protection section that includes the following:
 - A. Protection of Human Subjects plan
 - B. Inclusion of Women and Minorities
 - C. NIH Inclusion Enrollment Report (NIH PHS 398 form)
 - D. Inclusion of Children
- When **Vertebrate Animals** are included, please also provide a Vertebrate Animals Section that addresses the following:
 - A. Detailed description of proposed use of animals. Identify species, strains, ages, sex and numbers of animals to be used.

- B. Justify use of animals, chose of species and numbers to be used.
- C. Information on veterinary care to be provided.
- D. 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).
- E. Describe any method of euthanasia to be used and reason(s) for selection. State whether method is consistent with AVMA recommendations.

- 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.

- Resource Facilities Usage and Required Approvals Forms
- Copy of IRB or IACUC approval letter (if approval is pending, provide submission date and #) if project involves human or animal subjects.
- Letter(s) of Support: If a junior faculty serves as PI, a letter of support from the applicant's mentor must accompany the application. The letter must confirm that the mentor and the institution support an overall plan to establish an independent research career for the applicant.
- 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.

Allocation and Expenditure of Funds

Please provide a detailed budget and budget justification using NIH PHS 398 Form Page 4 and Form Page 5. These forms can be found:

<http://grants.nih.gov/grants/funding/phs398/phs398.html>

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 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 and Resources 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 and Resources 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 & RESOURCES

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 and Resources 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](http://sparc.lacats.org) (sparc.lacats.org) and search the service catalog for the necessary services.

Additional Information: Please check the LA CaTS Center website or email questions to info@LACaTS.org.