



LA CaTS Center Short Experiences in Clinical Trials Funding Opportunity 2024-2025 APPLICATION INSTRUCTIONS

I. PURPOSE:

The Louisiana Clinical and Translational Science (LA CaTS) Center is seeking applications to support training opportunities for junior investigators in clinical and translational research. Short Experiences in Clinical Trials Awards will be targeted to New Investigators or Early-Stage Investigators, as defined by the NIH; for details, see <https://grants.nih.gov/policy/early-stage/index.htm>. Support of these investigators is central to the aim of the LA CaTS Center to increase the critical mass of investigators performing clinical and translational research. This is a competitive application to identify and select Clinical Trial Scholar candidates. The overall objective of the program is to provide support so that junior faculty can extend and enhance their skill set related to clinical trials by learning the complexities of proposing, obtaining approval, and implementing a novel investigator-initiated trial. Awards can be used to visit an experienced clinical trial mentor and their collaborating biostatistical and data management coordinating centers at their respective institutions or to attend specific short-term training programs in clinical research.

Each award may be **up to \$5,000** in total costs.

II. GOALS AND OBJECTIVES:

A goal of the LA CaTS Center is to provide support to develop researchers who have a high likelihood of subsequently competing successfully for independent funding from the NIH or a comparable agency in clinical or translational research. The objective of this RFA is to support junior investigators in clinical or translational research, and to link them with clinical trial mentors to assist their development in the field. It is specifically intended for investigators to learn about initiating and managing clinical trials and to acquire different skills and expertise by interacting with experts in the field outside of the LA CaTS Center institutions.

III. ELIGIBILITY REQUIREMENTS:

The Short Experiences in Clinical Trials program emphasizes mentoring in clinical science. It will be available to **New and Early-Stage Investigators** as described at <https://grants.nih.gov/policy/early-stage/index.htm> in any discipline who can demonstrate a path towards clinical or translational research. Applicants must hold a PhD, M.D., or equivalent degree. Eligible candidates can be faculty or a LA CaTS Roadmap Scholar at any of the LA CaTS Center member institutions, with interest in health-related research, but lack sufficient training, experience, or guidance in clinical trials to compete successfully for NIH funding as an independent investigator. Individuals who have had LA CaTS pilot funding but need additional training to learn other skills to enhance clinical trials development of an ongoing project are also encouraged to apply. Institutional commitment to support the Short Experiences in Clinical Trials Scholar's time during program activities is required.

There is no citizenship requirement for award 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.

IV. SUPPORTED ACTIVITIES:

The Short Experiences in Clinical Trials Program will be coordinated through the Pilot Grants Program and the Administrative Core. The Professional Development Core will assist, when needed, with coordinating successful applicants with experienced researchers/mentors. Funds will be awarded to

support travel to a mentor's research center that provide benefits to LA CaTS institutions. The Short Experiences in Clinical Trials Program **does not include salary support** for the LA CaTS awardee at the host institution. Funds should be budgeted for the awardee to attend a specified LA CaTS Center meeting in Baton Rouge or New Orleans, LA.

V. FORMAT OF THE APPLICATION

Applications **must** be submitted online under the applicant investigator's account on the LA CaTS Center's Service Request Page, SPARC at: <https://sparc.lacats.org>.

All materials submitted must follow the font and margin guidance for NIH applications available at: <http://grants.nih.gov/grants/funding/phs398/phs398.pdf>.

Applications must include the following:

1. **NIH Form Page 1:** Face Page (signed by authorized institutional representative)
2. **Research Plan:** The Research Plan will consist of two pages (maximum) including:
 - A. Background and goals towards developing a clinical or translational research career,
 - B. Activities to achieve these goals,
 - C. Research topic that fits the LA CaTS Center theme to "address health disparities and improve health outcomes in our underserved population with chronic diseases", and
 - D. Identification of appropriate clinical trial mentors/training program.
 - E. Timeline for the proposed Short Experiences in Clinical Trials activity.
3. **NIH Biosketches** of the applicant and mentor(s), 5 page limit.
4. **IRB approval documentation** if applicant is involved in human subjects research.
5. **Letters of support** from the mentor(s), 2 page limit.
6. **Budget & Budget Justification** (on NIH Form pages 4 and 5)

Expenditures Allowed:

- Registration costs
- Research supplies directly related to the training experience
- Domestic Travel

Expenditures NOT Allowed:

- Salary support for the awardee or mentor
- Foreign Travel
- Office equipment and office supplies
- Computers
- Dues and membership fees in scientific societies

**** Other expenditures not listed, please contact info@LACaTS.org.**

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 anticipated for an award of this type, your institution will consider these costs as matching funds to your project.

7. **Institutional Letter of Support:** Since longitudinal support of New and Early Career Investigators is essential to their ultimate success, applications must include a letter of support

from an appropriate official at the applicant's institution. Institutional Letters of Commitment should describe:

- A. faculty release time,
- B. leveraging of additional resources, and
- C. cost sharing.

VI. TIMELINE:

Full Application Deadline: This annual RFA has an open application period through June 30, 2025 or until the maximum number of awards allowable are issued for this current fiscal year, whichever comes first. This is a competitive application process. Awards will be based on merit and on a first come, first served basis. We encourage you to apply early in each fiscal year (July 1 – June 30).

Applications **must** be submitted online under the applicant investigator's account on the LA CaTS Center's Service Request Page, SPARC at: <https://sparc.lacats.org>.

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

Award Notification Date: **Approximately 1 month after submission.**

VII. REVIEW AND SELECTION PROCESS:

The LA CaTS Center Administrative Core will coordinate the application process for the Short Experiences in Clinical Trials Program and the Pilot Grants Program will undertake the reviews. Final decisions on the awardees resides with the LA CaTS Center Executive Council.

Applications that are complete and responsive to the RFA will be evaluated for scientific merit. Each of the criteria below will be addressed and considered in the review. Note that an application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to developing the awardee's career in clinical and translational research.

Significance: Does the proposal address an important gap in the applicant's progression towards developing a clinical and translational research career that would be filled by visiting the mentor's institution? If the aims of the application are achieved, how will the applicant's career be advanced? What will be the potential effect and impact of the proposed activities on the clinical and translational career of the applicant? What are the unique technologies, services, or resources provided by the mentor(s) that will significantly impact the career development of the applicant?

Approach: Is the conceptual framework for the time that the applicant will spend at the mentor's institution adequately developed, well-integrated, well-reasoned, and appropriate to the aims of the proposed program? Does the applicant acknowledge potential problem areas and consider alternative tactics? Is the likelihood of successful completion high given the described environment at the mentor's institution and the applicant's abilities? Are the proposed timeline and interim milestones appropriate, feasible, and technically sound?

Investigators: Are the proposed Short Experiences in Clinical Trials applicant and mentor(s) appropriately trained and matched to carry out this work? Is the work proposed appropriate to the experience level of the Clinical Trial Scholar and other researchers? Does the mentee-mentor relationship bring complementary and integrated expertise to the project (if applicable)?

Milestones and Product Development Plan: Are the defined objectives/milestones and future career development plans appropriate and feasible? Feasibility should address the requirement that work be completed before the end of the funding period.

Additional Review Criteria:

In addition to the above criteria, the following items will be considered in the determination of scientific merit and the priority score:

Institutional Commitment: Evidence of longitudinal institutional commitment will be evaluated, as this will be central to the awardee's ultimate success in competing for independent funding in clinical or translational research.

Protection of Human Subjects from Research Risk: Is the appropriate IRB approval with reference to the risks to the subjects included in the application?

Biohazards: If materials or procedures are proposed that are potentially hazardous to research personnel and/or the environment, reviewers will determine if the proposed protection is adequate.

Budget: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research. The priority score will not be affected by the evaluation of the budget but the programmatic objectives of the LA CaTS Center to support a variety of investigators across the region will be considered in the Executive Council's recommendations for funding.

VIII. REPORTING

Awardees will be required to submit a Progress Report using a format provided by the LA CaTS Center no later than 30 days after the end of the award. Standard financial reports will be required per NIH guidelines. Awardees may be required to present their progress at LA CaTS Center retreats, External Advisory Committee meetings, or another specified LA CaTS Center event. Awardees will also be required to submit a specified progress report at 6 and 12 months following the award start date, to provide updates, such as manuscripts, publications or presentations since the Short Experiences in Clinical Trials Program opportunity.

Awardees will be required to sign the LA CaTS Center Memorandum of Understanding (MOU), agreeing to cite the LA CaTS Center IDeA-CTR grant (U54 GM104940) on future publications and presentations that are associated with this funding opportunity.

IX. AWARD ADMINISTRATION INFORMATION

Award Notices

The applicant will be notified of the decision approximately one month from the time of the submission. With the exception of applications from Pennington Biomedical Research Center, awards will be made by LSU Health New Orleans, School of Medicine, under the parent grant #U54 GM104940 from the National Institute of General Medical Sciences (NIGMS).

Human Subjects Protection

If the awardee is involved in Human Research, the application must describe training or experiences involving human subjects as well as inclusion of appropriate IRB approval.

If applicable, IRB approval must be obtained at both the applicant and host institutions before an award can be issued.

Additional Questions

Please contact info@LACaTS.org for any additional questions on this opportunity.