

School of Medicine Clinical Investigator Kickstart (CIK) Pilot Program

Due date: Monday, April 3, 2017 by 11:59p.m. CST. Applications must be submitted via the InfoReady platform at uthscsa.infoready4.com

Please refer questions to Courtney Peebles, MPH, Senior Research Coordinator in the SOM Dean's Office, at 210-562-6869 or peeblesc@uthscsa.edu

Mission: To foster patient-centered outcomes and/or comparative effectiveness research within the School of Medicine, UTHSCSA, and our collaborating institutions.

Strategy: The SOM Office of the Dean has allocated funds to support development activities and pilot projects that strengthen our ability to submit competitive applications for extramural funding for health services and patient-centered research. In addition, separate funding is available for projects related to children's health. This funding opportunity supports the SOM Strategic Plan.

Description: While formal pilot projects are appropriate for this mechanism, *planning activities necessary for team development and building infrastructure are also appropriate.* Examples of scope of work may include:

- Assembling grant and investigator teams in preparation for program project grants and other collaborative extramural funding opportunities
- Standing up a patient engagement panel or community advisory board
- Regulatory support for preparation of IRB submission
- Statistical support for manuscript preparation and preliminary data leading to PCOR publications
- Preliminary/secondary data collection
- Analytic support
- Utilization of institutional community engagement cores, e.g., the IIMS Community Engagement Team or other similar entities

While all types of research are eligible, areas of high interest include:

Children's Health

- Clinical research trial development in pediatrics
- Psychosocial issues pertaining to the well-being of children
- Issues specific to children and families in our catchment area including disparities in care
- Issues related to the transition of medical care from pediatrics to adulthood

Patient-Centered Outcomes Research

- Stakeholder engagement activities (patient and caregivers, community, providers) including engaging consultants and other organization to create advisory boards and other mechanisms to support collaborative research and grant planning and conduct
- Pragmatic trials development
- Improving healthcare systems
- Health disparities research

Treatment and Health Systems Research

- Screening, assessment, prevention, diagnosis, and treatment options
- Dissemination/implementation research
- Utilization of EHR technology for clinical research
- Health services research
- Clinical trial pilots, etc.

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Eligibility: Applications must be submitted by investigators whose primary faculty appointment is the School of Medicine. Faculty are encouraged to collaborate with individuals from IIMS partner organizations which include University of Texas Health Science Center at San Antonio (UTHSCSA), San Antonio Metropolitan Health District, San Antonio Military Health System, South Texas Veterans Health Care System, Texas Biomedical Research Institute, University Health System, University of Texas San Antonio, University of Texas Rio Grande Valley, University of Texas School of Public Health–San Antonio and Brownsville Regional Campuses, University of Texas College of Pharmacy, and UT Medicine.

Amount and Term: Requests for funds of \leq \$50,000 will be considered for project periods of up to 1 year. Funds are available to fund up to 3 projects, contingent upon the submission of a sufficient number of scientifically meritorious applications. In collaboration with the Department of Pediatrics, up to three additional projects specifically addressing clinical/patient oriented issues in children's health may be funded.

Application Submission: Applications should be submitted via the InfoReady platform. Documents should be uploaded as Portable Document Format (PDF), use Arial 11 point font, single spacing, and .75-inch margins in all directions. Failure to follow these or the following guidelines may result in the application being administratively withdrawn.

The application should include the following:

- Project Summary/Abstract (NIH form page)
- Budget (NIH form page)
- Budget justification - no faculty salaries (NIH form page)
- Specific Aims (1 page maximum)
- Overall project narrative (4 page maximum)
- Literature citations (1 page maximum)
- Target funding mechanism and description of plans for obtaining external funding (1 page maximum)
- NIH Biosketch for all investigators (new NIH format, limit to 5 pages/investigator)
- Program announcement (if applicable)
- Summary Statement(s) (if applicable)
- Letters of support, not required (if applicable)

Budget and financial policies: Awards will be made for a project period of up to one year, starting on or about June 1, 2017. The maximum budget for these one-year awards is \$50,000, although proposals with smaller budgets will be considered and reviewed under the same criteria. Facilities and Administrative (F&A, indirect cost) expenses will not be reimbursed. Funds may not be used to support the salary of the PI(s), faculty-level collaborators, or graduate students. Although the PI(s) should be listed in the personnel section of the summary page, there is no minimum effort requirement. Salary (plus associated fringe benefits) may be requested for non-faculty support staff, including postdoctoral fellows. Other allowable expenses include: equipment essential for the project (maximum \$10,000, including computer hardware); PI or Co-PI travel to relevant scientific meetings (maximum \$1,500); consumable laboratory supplies; animal purchase and per diem; IIMS, CTRC, GCCRI, UTSA, or other core facility fees; consultation fees (maximum \$5,000); computer time; software; publication / presentation expenses; costs related to human subject enrollment and management (listed as "Patient Care Costs" on budget page); research related to children's health, regardless of academic home of principle investigator, is encouraged to utilize resources in the Department of Pediatric research core. Other expenditures will be allowed that can be justified as essential for the completion of the project. Account management will be centralized within the SOM.

For projects involving the use of human subjects or vertebrate animals, expenditures will only be permitted upon Dean's Office receipt of a copy of the official letter of approval by the appropriate Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC). This

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announcement is specifically intended for highly innovative pilot projects with a high likelihood of submission for external funding within 12-18 months from the time of award. **The expectation is that institutional approvals (INCLUDING IRB and/or IACUC) will be promptly obtained and projects initiated/funds disbursed within 60 days of award. If a different timeline is anticipated, address this in the application.**

Applicants must also be in compliance with institutional conflict of interest disclosure policies. UTHSCSA Certificate of Proposal (COP) is required upon award.

Review process and criteria: Applications will be peer-reviewed via an NIH-like study section. Merit will be scored based on the following criteria:

- Significance
- Novelty / innovation
- Strength of the study protocol, including:
 - Design
 - Feasibility
 - Preliminary data (to the extent available)
 - Integration with ongoing research
 - Quality of the investigative team
- Contribution to career development of clinical/translational scientists, if applicable
- Investigative team, including extent of meaningful interdisciplinary collaboration and/or community engagement
- Likelihood of submission for/securing extramural funding within 24 months of award
- Likelihood of leading to publishable research findings
- Protection of human subjects and experimental animals

Other criteria for review include:

- Fit with priorities identified in the SOM Research Strategic Plan including aging, cancer, diabetes, infectious disease, neuroscience, and population health
- Responsiveness to children's health

Funding decisions will be based on scientific merit, as well as programmatic considerations, such as breadth and depth of the overall pilot study portfolio, interactions among partners, community involvement, and balance among program areas and disciplines.

Administrative management: Progress reports will be requested six, 12, and 24 months after the initiation of funding. One progress report presentation will also be required during the initial 12 month funding period.

Recipients of grants in the area of children's health will be requested to present findings at Pediatric Research Day in 2018.

Continuation of the pilot program is contingent upon evaluation of return on investment (i.e., extramural funding) of the funded pilots and the availability of funds.