



# Funding Opportunity Announcement

## Pilots & Collaborative

### Translational & Clinical Studies Awards FY2020

November 30, 2018

The mission of the **Miami Clinical and Translational Science Institute (CTSI)** is to improve the quality and efficacy of clinical and translational research, advance team science, and culturalize health sciences.

The Miami CTSI is now offering funding opportunities to support up to four scientifically-meritorious pilot projects that will advance translational, innovative and interdisciplinary research, and/or promote research oriented toward community and health disparities.

#### Purpose of the Pilot Awards

The Pilot funds are meant to support highly innovative, translational ([T1 to T4](#)), interdisciplinary, and/or health disparities-oriented research proposals.

In alignment with its mission, the Miami CTSI strongly encourages translational, scientifically-meritorious projects that are:

- (1) **directly** related to health disparities and racial/ethnic minority health, or addressing challenges in health areas that disproportionately affect racial/ethnic minorities, and/or
- (2) **multi-disciplinary projects**, where the Principal Investigator and at least one co-investigator are from different fields of expertise, and/or
- (3) submitted by women and/or individuals from racial and ethnic groups underrepresented in sciences and in medicine.

In accordance with the CTSA-mandated [NCATS Common Metrics Initiative](#), it is expected that Pilot projects will generate publications and data for external funding.

#### Number & Type of Awards

The CTSI Pilot Program will award up to four (4) meritorious projects. The Pilot funds are intended to be flexible and can be used to fit a variety of scientific needs. Examples of allowable research costs include salaries for technical personnel, laboratory supplies, animals used to conduct the proposed research. Faculty salary is not allowable.

The Miami CTSI encourages faculty to submit proposals that deal with:

- (1) **Health Disparities**: directly related to health disparities and racial/ethnic minority health, or addressing challenges in health areas that disproportionately affect racial/ethnic minorities.
- (2) **Informatics, Data & Diagnostics**: novel informatics, diagnostics, data capture tools, analytics, work on Data Trusts, patient-reported data methods.
- (3) **Special Populations Novel Methods**: novel methods to engage and recruit underserved populations of all ages, research dissemination strategies.
- (4) **Translation to Care**: studies on barriers to translating research knowledge to care/policy; obstacles to team-based research.

#### Award Period & Funding Amount

The award period is for one year, from June 1<sup>st</sup>, 2019 to May 31<sup>st</sup>, 2020. The research project must be completed within the award period.

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Funding for pilot projects will be **up to \$40K** for each project (direct research costs only.) A no-cost extension (NCE) of support will NOT be available.

### Applicant Eligibility

Eligibility criteria must be met as of date of submission (February 20, 2019).

All **UM junior and mid-career full-time faculty** are eligible to apply to these awards (ranks of Assistant and Associate professors only). Study teams of Full Professors may apply, only if the Principal Investigator is junior faculty.

Jackson Health System and the Miami VA full-time faculty may apply, with at least one full-time UM faculty collaborator.

Residents, instructors, staff, post-doctoral and clinical fellows are not eligible.

### Project Eligibility

- (1) Research projects conducted outside of the U.S. are not eligible.
- (2) Only new applications and first resubmissions to any UM internal award mechanism are allowed.
- (3) The research supported by this program must be [translational in nature \(T1 to T4\)](#). Basic research projects are *not* eligible. Examples of translational projects are listed below:
  - Preclinical studies that are directly relevant to human health and use human cells or other human biological materials, with the endpoint of identifying new therapies or biomarkers.
  - Early bench to bedside research leading up to and including first-in-human and/or clinical proof of concept trials evaluating new drug treatments, medical devices and diagnostics.
  - Community-based clinical research studies using human subjects, families, and/or communities for testing new treatments or interventions, assessing new health outcomes, etc.
  - Studies of effectiveness and/or implementation and/or dissemination of clinical research findings in practice.
  - Studies on the science of translational research, i.e., on methods and approaches that improve the process of conducting translational research.
  - Studies that promote team science and address researchable health issues from the perspectives of multiple disciplines.

For more information, visit [NCATS Translational Spectrum page](#)

### Budgetary Limitations

**Funds Available and Budgetary Limitations:** Awards will be **\$40K** each (direct research costs only). No indirect costs or overhead will be awarded under the CTSI Pilot Program.

Only [allowable direct costs](#) may be charged.

Awarded projects will be required to adhere to the applicable OMB Uniform Guidelines, NIH Grants Policy Statement and University of Miami policies. Award funds may cover research support costs such as technical/laboratory assistants, clinical research coordinators, undergraduate and/or graduate student support, technical supplies, publication costs, U.S. based domestic travel to professional/scientific meetings, vertebrate animals/care/housing, and participant payments for IRB-approved protocols. Applicable non-federal fringe benefits for employees and health insurance coverage for students should be included.

In addition, proposed budgets must adhere to the following budgetary limitations:

- Faculty salary is not an allowable expense within the budget.
- Patient care is not an allowable expense within the budget.
- Publication costs are limited to \$2K.
- Travel: **U.S. domestic travel** only. Travel is limited to attending professional meetings to present research findings or for training needed for the project (not to exceed \$2,5K).

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- Equipment and software purchases are strongly discouraged\* (see note below). If necessary, these purchases must not exceed \$5K.
- The project must be conducted at UM. The use of outside-UM services is strongly discouraged\* (see note below).

**\*IMPORTANT NOTE:** Proposed budgets requesting support for equipment and/or outside UM services will require a **robust and comprehensive budget justification at proposal phase** as well as subsequent review and approval by CTSI Leadership prior to award issuance. All efforts must be made to use UM equipment and services when available.

The [CTSI Fiscal Team](#) will be available for one pre-application budget consultation to ensure that the proposed costs are allowable and reflective of the proposed project needs.

### Deadlines and Award Timeline

Proposal submission is a two-step process requiring both a **Letter of Intent (LOI)** and a **full application**. Based on eligibility criteria and on the potential scientific merit of the proposed research presented in the LOI, applicants will be **invited** to submit their full application.

- **LOI due: January 15, 2019 at 11:59 PM (Extended deadline)**
- Invitation to submit full application: January 23, 2019.
- Full application (**for those invited**) due: **February 20, 2019**.
- Funding decisions will be announced in April 2019.
- Start of the Award: June 3rd, 2019.

For the link to the Letter of Intent application form, and for additional details about this program and the submission, please refer to the Information & Instructions for Application guide available on the [Miami CTSI website](#).

### Translational Science Spectrum (<https://ncats.nih.gov/translation/spectrum>)

**T1: Pre-Clinical Research** connects the basic science of disease with human medicine. During this stage, scientists develop model interventions to further understand the basis of a disease or disorder and find ways to treat it. Testing is carried out using cell or animal models of disease; samples of human or animal tissues; or computer-assisted simulations of drug, device or diagnostic interactions within living systems.

**T2: Clinical Research** includes studies to better understand a disease in humans and relate this knowledge to findings in cell or animal models; testing and refinement of new technologies in people; testing of interventions for safety and effectiveness in those with or without disease; behavioral and observational studies; and outcomes and health services research. The goal of many clinical trials is to obtain data to support regulatory approval for an intervention.

**T3: Clinical Implementation** involves the adoption of interventions that have been demonstrated to be useful in a research environment into routine clinical care for the general population. This stage also includes implementation research to evaluate the results of clinical trials and to identify new clinical questions and gaps in care.

**T4: Public Health:** In this stage of translation, researchers study health outcomes at the population level to determine the effects of diseases and efforts to prevent, diagnose and treat them. Findings help guide scientists working to assess the effects of current interventions and to develop new ones.

**NOTE: Basic research projects (T0) defined below are not eligible for this Pilot award program.**

**T0: Basic Research Basic** involves scientific exploration that can reveal fundamental mechanisms of biology, disease or behavior. Every stage of the translational research spectrum builds upon and informs basic research. NCATS scientists typically do not conduct basic research; however, insights gained from the Center's studies along the translational spectrum can inform basic research.