

MIAMI CTSI FY24 PILOT FUNDING OPPORTUNITY ANNOUNCEMENT May 1, 2023

Miami CTSI Focus

The primary focus of the Miami Clinical & Translational Science Institute (CTSI) is to advance Clinical and Translational Science (CTS), with the overarching goals improving the **health of our community, addressing health disparities, and promoting health equity**. Translational Science, as defined by the National Center for Advancing Translational Sciences (NCATS) of the National Institutes of Health (NIH), is the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process.

Intention of CTSI Pilot Awards

Pilot projects are expected to generate publications and data for external funding for talented junior investigators. In alignment with the Miami CTSI mission, pilot funds will support innovative, interdisciplinary, clinical translational science proposals that clearly align with the goals listed above. Funding is prioritized for projects that directly relate to health disparities, or address challenges in health areas that disproportionately affect minority health and/or underserved populations.

Budgetary Information

The CTSI Pilot Program will award up to **four (4)** meritorious projects for **up to \$40,000 each**. Funds can be used for a variety of scientific needs. The award period is 12 months, with an estimated project period of January 2024 – December 2024 (start date subject to NIH/NCATS prior approval). Pilot awards are contingent upon funding from NIH/NCATS for the overall Miami CTSI. Per NIH/NCATS guidelines, pilot projects must be completed within the 12-month project period. No Cost Extensions will not be available.

Awards are for direct costs only (NIH allowable direct costs). Indirect (overhead) costs will not be awarded under the CTSI Pilot Program. All efforts must be made to utilize UM facilities and resources. Unallowable costs include: faculty salary; subawards/consulting/services outside UM; equipment; foreign involvement. Funds may not directly support any clinical trials beyond Phase IIB with the exception of Phase III clinical trials for treatment of rare diseases.

Letter of Intent & Full Application

Proposal submission is a two-step process that requires both a Letter of Intent (LOI) and a Full Application. The LOI is a structured electronic questionnaire: [CTSI Pilot Awards-FY24-LOI](#). Submissions that are incomplete or otherwise do not follow instructions will not be considered for review.

Applicants will be **invited** to submit their full application based on eligibility criteria and the potential scientific merit of the project described in the LOI. We strongly encourage attending the information session to gain a clear understanding of this call for applications focused on clinical and translational science.

Deadlines & Award Timeline

RFA Issued	Monday, May 1, 2023
Information Session (optional)	Monday, May 15, 2023 @5pm – <i>registration required in advance</i> Pilot Application Information Session
Letter of Intent (LOI) Due	Tuesday, May 30, 2023 by 11:59 PM

Invitation to Submit Full Application	Monday, June 5, 2023
Full Applications Due (<i>invited applicants only</i>)	Monday, July 24, 2023 by 11:59 PM
Funding Decisions	November 2023
NCATS Prior Approval Process (<i>requires all regulatory approvals</i>)	November 1, 2023 – December 1, 2023
Estimated Award Period (<i>requires NCATS Prior Approval</i>)	January 2024 – December 2024

Applicant Eligibility

All eligibility criteria must be met **as of application due date** (July 24, 2023).

- Only full-time faculty at the ranks of Assistant or Associate Professors are eligible to apply as Principal Investigators (PI). Full Professors may serve only as co-investigators or mentors.
- Jackson Health System and Miami VA full-time early stage faculty may apply as PI, with at least one full-time UM faculty co-investigator.
- Residents, instructors, staff, post-doctoral and clinical fellows are not eligible to apply as Principal Investigator.
- Proposals submitted by women, individuals from [disadvantaged backgrounds](#), and/or individuals from racial/ethnic groups underrepresented in sciences and medicine are encouraged. For more information, visit [NIH guidance on underrepresented groups in the extramural scientific workforce](#).

Project Eligibility

- Pilot projects must be focused on clinical translational science (CTS) – understanding a scientific or operational principle underlying a step of the translational process with the goal of developing generalizable principles to accelerate translational research. Translational research projects, i.e., projects focused on crossing a particular step of the translational process for a particular target or disease, are not allowed.
- Projects are intended to: (1) explore innovative new leads or new directions in an area of CTS; (2) stimulate investigators from other areas to lend their expertise in research in CTS; and (3) provide initial support to establish proof of concept. For detailed information, visit [NCATS Translational Spectrum](#).
- Examples of activities that may be supported: (1) Development of new research methodology and/or new technologies/tools/resources that will advance CTS, increasing the efficiency and effectiveness of translation; (2) Early-stage development of new therapy/technology with generalizable application to an identified translational roadblock; (3) Demonstration in a particular use case(s) that the new methodology or technology advances translational science by successfully making one or more translational process steps more effective or efficient; (4) Dissemination of effective tools, methods, processes, and training paradigms; (5) Feasibility/proof of concept studies to support future clinical translational science projects; (6) Secondary analysis of existing data (e.g., projects using the National COVID Cohort Collaborative (N3C) Data Enclave <https://ncats.nih.gov/n3c>).
- Projects conducted outside of the U.S. to any extent will not be considered responsive to this RFA.
- Only new applications and first resubmissions to any UM internal award mechanism are allowed.

Evaluation Criteria, Review & Selection Process

The scientific and technical merit of the proposals will be evaluated using the [NIH Peer Review Criteria](#). Miami CTSI projects including team science, community engagement, those leveraging tools of dissemination and implementation science, and those promoting diversity, equity, inclusion and accessibility (DEIA), will be carefully considered. All reviewed applications will receive reviewer feedback. The CTSI Pilot award review is a two-tier process:

(1) Applications will undergo:

- Scientific and technical merit review by the CTSI Pilot Program Review Committee.

- Community review by non-scientists selected from various CTSI external stakeholders and community collaborators.
 - Biostatistics, Ethics, and/or Regulatory review at the discretion of CTSI Pilot Director and/or reviewers.
 - Budget and Administrative review by CTSI fiscal and administrative teams.
- (2) Applications within the funding range will undergo a programmatic review by the CTSI Pilot Management Committee and/or Executive Committee.

Note: If needed due to internal conflicts of interest, external reviewers may be involved.

General Information

- **Biostatistics Consultations are MANDATORY.** Applicants are required to meet with the [Biostatistics Collaboration and Consulting Core](#) (BCCC) for a free initial consultation before applications are submitted. These consultations are tracked. Free biostatistical support is provided to awarded pilots.
- **Fiscal/Administrative Consultations are MANDATORY.** Contact [Melanie Couch](#) to coordinate your review prior to submitting your application. These consultations are tracked.
- **CTS Consultations may be required upon invitation to submit the full application.** These consultations will be conducted by the CTSI Pilot Program Director and/or CTSI Executive leadership and will ensure projects are responsive to the CTS focus areas.
- **Regulatory, participant recruitment, and community engagement consultations** by the CTSI team are encouraged and available upon request.
- For additional details about the Pilot Program, visit the [Miami CTSI website](#).

NIH Prior Approval Process

The Miami CTSI is funded by the National Center for Advancing Translational Sciences of the National Institutes of Health. Awarded pilot projects involving human subjects and/or live vertebrate animals **must receive approval from NCATS prior to starting project** (drawing down funds) and can only be obtained with valid IRB/IACUC/IBC required regulatory approval documentation and numerous other documents. The preparation for prior approval typically takes 15 to 30 days to submit to NCATS. NCATS approval typically takes a minimum of 30 days. The CTSI Team will work with awardees to ensure prior approval requirements are met and documentation is submitted. Failure to obtain NCATS Prior Approval could result in revocation of award.

CTSI Pilot Awards Program Contact Information

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