**MIAMI CTSI FY25 PILOT FUNDING OPPORTUNITY ANNOUNCEMENT**
**April 17, 2024**

## 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 of improving the health of our South Florida 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 that generates scientific and operational innovations that overcome longstanding challenges along the translational research pipeline. These include innovations that transform the way research is done, making it faster, more efficient, and more impactful.

## Intention of CTSI Pilot Awards

In alignment with the Miami CTSI mission, pilot funds will support innovative, interdisciplinary, clinical translational science proposals that are well-aligned with the CTSI's overarching goals. Pilot projects will be led by talented junior investigators under the mentorship of established investigators.  Projects will generate data and information to support subsequent external funding.  **All projects are expected to result in at least one peer-review first authored publication by the awardee.**

Funding is prioritized for projects that are consistent with the national mandate to achieve health equity, and address health disparities and challenges in health-related areas that disproportionately affect [minority health]() and/or [underserved populations]() as defined by the National Institutes of Health.  Community and external stakeholder engagement is also expected to be included as a crucial piece of the project.

## Budgetary Information

The CTSI Pilot Program will award meritorious projects for **up to $40,000 each**. Funds can be used for a variety of scientific needs (e.g. staff salaries, supplies, participant payments). The award period is 12 months, with an estimated project period of <u>February 2025 – January 2026</u> (*subject to NCATS prior approval*). Pilot awards are contingent upon funding from NIH/NCATS for the overall Miami CTSI. Per 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 <u>not</u> 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 short, structured electronic questionnaire: [CTSI Pilot Awards-FY25-LOI]()

Applicants will be invited to submit full applications based on eligibility criteria, relevance to CTSI's overarching goals and potential impact on clinical and translational science (CTS).  Submissions that are incomplete or otherwise do not follow instructions will not be considered for review. Late applications will not be accepted. **We strongly encourage attending the information session** to gain a clear understanding of the goals of this call for applications.

## Deadlines & Award Timeline

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| RFA Issued | Wednesday, April 17, 2024 |
| Information Session (*optional*) | Wednesday, May 1, 2024 @5pm - *registration required* [Pilot Application Information Session](#) |
| Letter of Intent (LOI) Due | Tuesday, May 14, 2024 by 11:59 PM |
| Invitation to Submit Full Application | Friday, May 24, 2024 |
| Full Applications Due (*invited applicants only*) | Thursday, July 18, 2024 by 11:59 PM |
| Funding Decisions Announced | October 2024 |
| Obtain Regulatory Approval <u>and</u> NCATS Prior Approval | October - January 2025 |
| Estimated Award Period (*requires NCATS Prior Approval*) | February 2025 - January 2026 |

## Applicant Eligibility

All eligibility criteria must be met **as of application due date** (July 18, 2024).

- Only full-time faculty at the ranks of Assistant and non-tenured Associate Professor are eligible to apply as Principal Investigator (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 <u>not</u> eligible to apply as PI.
- Proposals submitted by females, individuals from [disadvantaged backgrounds](#), and/or individuals from groups underrepresented in sciences and medicine are encouraged. For more information, visit [NIH Chief Officer for Scientific Workforce Diversity (COSWD) Strategic Plan.](#)

## Project Eligibility

- Translational research projects aligned with our overarching goals, but projects must also clearly articulate a [clinical translational science (CTS)](#) component. For detailed information, visit [NCATS Translational Spectrum](#) and/or request consultation with CTSI to ensure your project meets criteria.
- Projects must involve improving community health, promoting health equity, and/or addressing health disparities.
- Discovery science applications are welcomed but such applications must also articulate how their projects will contribute toward the CTSI's overarching goals.

Projects that are <u>not considered responsive</u> to this RFA include:

- Projects without a CTS component, i.e., projects only focused on crossing a specific step of the translational process for a particular target or disease.
- Projects conducted outside of the U.S. to any extent.
- More than 2 resubmissions to the CTSI Pilot Program

## Evaluation Criteria, Review & Selection Process

The CTSI Pilot award review is a two-tier process:

(1) <u>Stage 1 Review</u>:

- Scientific and technical merit review by the CTSI Pilot Program Review Committee utilizing the NIH 9-point rating scale (1=exceptional; 9=poor). Clinical translational science relevance, community and stakeholder engagement, and health equity/disparities focus are all score-driving criteria. All reviewed applications will receive reviewer feedback.
- Community review by various CTSI external stakeholders and community collaborators. Community reviewers will provide scores based on their review of the non-scientific sections of the application such

as lay summary, health disparities, health equity, community health, and community/stakeholder engagement.
- Additional Biostatistics, Ethics, and/or Regulatory review at the discretion of CTSI Pilot Director and/or reviewers.

(2) <u>Stage 2 Review</u>:
- Applications within the funding range that meet all requirements will undergo a programmatic review by CTSI Executive Leadership.
- Budget and Administrative review by CTSI Fiscal and Administrative teams.

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

## Required Trainings and Consultations Prior to Submission

Required consultations and trainings are tracked, and applications will not be accepted if these requirements are not met prior to submission.

**<u>Required prior to application submission on July 18, 2024:</u>**

- **Biostatistics Consultations are MANDATORY** upon invitation to submit the full application**.** Applicants are required to meet with the [Biostatistics Collaboration and Consulting Core](#) (BCCC) for a free initial consultation before applications are submitted. Free biostatistical support is provided for awarded pilots.
- **Fiscal / Administrative Consultations are MANDATORY** upon invitation to submit the full application. A calendar link will be provided upon invitation to submit the full application.
- **Community Engagement and CTS Session attendance is MANDATORY** upon invitation to submit the full application. This session (live zoom and recording will be available) will ensure projects include a thoughtful community engagement plan and are responsive to the CTS focus.

<u>Additional Considerations</u>

- **Regulatory, participant recruitment, CTS and community engagement consultations** with the CTSI team are encouraged and available upon request to [Melanie Couch](#).

## 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 <u>prior to</u> starting project** (drawing down funds) and can only be obtained with valid IRB / IACUC / IBC regulatory approval documentation and numerous other documents. Once regulatory approval is received, the preparation for prior approval typically takes 10-15 days. Once submitted to NCATS, approval typically takes 30 days. The CTSI Team will work with awardees to ensure prior approval requirements are met and documentation is submitted. **Failure to obtain regulatory approval and NCATS Prior Approval in a timely manner could result in revocation of award.**

## CTSI Pilot Awards Program Contact Information

- **W. Dalton Dietrich, PhD,** Director, Miami CTSI Pilot Program [ddietrich@med.miami.edu](mailto:ddietrich@med.miami.edu)
- **Melanie Couch, MHA**, Director, Research Operations, Miami CTSI [mweiss2@med.miami.edu](mailto:mweiss2@med.miami.edu)

For additional details about the Pilot Program, visit the [Miami CTSI website](#).

**Did you know there are multiple resources available from CTSI and throughout UM that you could tap into for your pilot project?**

- [Epic SlicerDicer:](#) UChart's self-service reporting tool for exploratory data analysis and identification of patient cohorts for research

- [ONENESS Research Solution (ORS):](#) Query de-duplicated and de-identified data of UM and JHS patients for preparatory-for-research activities, cohort discovery, and other clinical research activities

- [Consent-to-Contact:](#) Resource for recruitment of UHealth patients into clinical studies

- [MyChart Research Recruitment:](#) Tool available through Epic allowing study teams to send recruitment messages to patients who have an active MyUHealthChart account AND are part of the Consent to Contact Registry

- [REDCap:](#) Software for data collection where users can build and manage online surveys and databases

- [IT Resources for Researchers:](#) Variety of technological resources to assist researchers, consultations also available

- [UMiamiHealthResearch.org:](#) A searchable web-based community facing tool for UM study teams to feature their health research studies and connect with potential volunteers

- [CTSI Consultation Services:](#) The Miami CTSI advises researchers on available resources and helps them navigate research-related processes