

MIAMI CTSI FY26 PILOT FUNDING OPPORTUNITY ANNOUNCEMENT

April 1, 2025

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 addressing and improving the health of our South Florida communities**. [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.**

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 February 2026 – January 2027 (*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 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 short, structured electronic questionnaire: [CTSI Pilot Awards-FY26-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	
RFA Issued	Tuesday, April 1, 2025
Information Session (optional)	Monday, April 14, 2025 @5pm - <i>registration required</i> Pilot Application Information Session
Letter of Intent (LOI) Due	Tuesday, April 29, 2025 by 11:59 PM
Invitation to Submit Full Application	Wednesday, May 14, 2025
Full Applications Due (invited applicants only)	Wednesday, July 9, 2025 by 11:59 PM
Funding Decisions Announced	October 2025
Obtain Regulatory Approval <u>and</u> NCATS Prior Approval	October - January 2026
Estimated Award Period (requires NCATS Prior Approval)	February 2026 - January 2027

Applicant Eligibility

All eligibility criteria must be met **as of application due date** (July 9, 2025).

- 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.
- Residents, instructors, staff, post-doctoral and clinical fellows are not eligible to apply as PI.

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 address community engagement, generalizability of results, and applicability of project to the population groups that comprise South Florida. Discovery science/early translation/basic science applications are welcomed but such applications must also articulate how their projects will contribute toward the CTSI's overarching goals.

Projects that are not considered responsive 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 without a solid community engagement plan.
- Projects with foreign involvement to any extent (examples include any foreign involvement related to human subjects recruitment/study enrollment, or if a large portion of the scope and/or budget will be attributed to a foreign company). If you are unsure whether your proposed project includes foreign involvement, please discuss with us in advance of submission.
- More than two resubmissions to the CTSI Pilot Program.

Evaluation Criteria, Review & Selection Process

The CTSI Pilot Award review includes several steps:

(1) Phase 1 of Review:

- Scientific and technical merit review by scientific reviewers utilizing the NIH 9-point rating scale (1=exceptional; 9=poor). Clinical translational science relevance and community and stakeholder engagement are score-driving criteria. All reviewed applications will receive de-identified reviewer feedback.
- Community review by CTSI external stakeholders and community collaborators. Community reviewers will provide scores based on their review of the non-scientific sections of the application, including but not limited to the lay summary and community/stakeholder engagement plan.

- Budget and Administrative review by CTSI Fiscal and Administrative teams.
- Additional Biostatistics, Ethics, and/or Regulatory review at the discretion of CTSI Pilot Director and/or reviewers.

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

(2) Phase 2 of Review:

- Proposals with discrepant scores in Phase 1 will be further discussed by the assigned reviewers.

(3) PMC Review:

- Once scores are finalized in Phase 2 of Review, applications within the funding range that meet all requirements will undergo a review by the CTSI Pilot Management Committee (PMC) and funding decisions will be determined.

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.

MANDATORY Prior to Letter of Intent (LOI) Due April 29, 2025:

- Applicants are **required** to watch **1) recorded Training on CTS and 2) download guide sheet**. Instructions can be found within the REDCap LOI form [CTSI Pilot Awards-FY26-LOI](#).

MANDATORY Upon Invitation to Submit Full Application Due July 9, 2025:

- 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.
- Applicants are **required** to have a **Fiscal / Administrative Consultation**.
- Applicants are **required** to attend live zoom session or watch recording of **Community Engagement (CE) Training**.

Additional Consultations (e.g. regulatory, participant recruitment, Jackson Health System involvement, CTS, CE) with the CTSI team are encouraged and available upon request to [Melanie Couch](#). **Such consultations may be made mandatory for certain applications that need to strengthen specific aspects of their applications.**

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 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, approvals may be delayed - it is imperative that the process begin as soon as possible. The CTSI Team will work with awardees to ensure prior approval requirements are met and documentation is submitted. **Failure of the pilot PI to obtain regulatory approval and submit the internal prior approval documentation in a timely manner could result in revocation of award.**

CTSI Pilot Awards Program Contact Information

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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 may be beneficial to your pilot project?

- [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
- [Research Compass](#): This dynamic tool, organized around the stages of the research lifecycle, will guide you to the critical resources needed to make research and scholarship happen at the University of Miami.
- [Epic SlicerDicer](#): UChart's self-service reporting tool for exploratory data analysis and identification of patient cohorts for research
- [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