

## Request for Applications (RFA)

### Mentored Research Career Development Program Award in Clinical and Translational Science (K12)

February 18, 2025

#### Overview

The Miami Clinical Translational Science Institute (CTSI) is sponsoring up to four (4) Mentored Research Career Development Program Awards in Clinical and Translational Science (K12) for fiscal years FY2026-2027. The K12 program will support the research career development of Early-Stage Investigators (ESI) by providing two years (24 months) of funding, contingent on the availability of funding/scholar slots and proposal review.

The support will include annually: (1) 75% salary support up to NCATS Scholar Salary Cap (\$120K); (2) \$20K for research expenses. Awardees will be required to devote 75% of their time to research (protected time) or no less than 50% if from surgical disciplines.

**The earliest anticipated start date of the K12 Scholar awards is September 1st, 2025, contingent on the CTSI K12 grant award and availability of scholar slots.**

#### What is Translational Science?

Translation is the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public - from diagnostics and therapeutics to medical procedures and behavioral changes. Translational Science (TS) is the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process. For detailed information on the Translational Science (TS) spectrum, visit the National Center for Advancing Translational Sciences (NCATS) [TS Spectrum](#) and additional [NCATS TS resources](#).

To summarize the NCATS position on the critical importance of Translational Science:

Several thousand diseases affect humans, and only about 500 have any treatment. A novel drug can take 10 to 15 years and more than \$2 billion to develop, and about 95 percent of human studies fail. Numerous scientific and operational roadblocks limit the speed of progress. Solving this problem is NCATS' mission. The Center is improving the translational process by:

- Understanding what is similar across diseases to help develop multiple treatments at a time.
- Developing models that better predict a person's reaction to a treatment.
- Enhancing the design and conduct of clinical trials so the results more accurately reflect the patient population.

#### Objective

The objective of the K12 program is to develop outstanding independent researchers by providing a structured research training program under the guidance of individualized mentorship.

The structured mentored research program provides: (1) an individualized research and career development plan; (2) educational programs suited to the mentee, including enrollment in and completion of an advanced degree in clinical research, should it be needed; (3) experiential training with established faculty researchers as mentors; (4) supportive resources that include access to CTSI experts in research design, regulatory support, community engagement, and biostatistics; and (5) modest funds to support research costs and/or expenses associated with training opportunities, and travel support for preceptorship in expert labs or to attend relevant scientific meetings up to the maximum thresholds stipulated for applicable expenses.

The program will provide mentorship and support to promote the research and the advancement of K12 scholars throughout the University. Mentoring is a required component of the program and will include the applicant's scientific mentor(s) approved by the CTSI to ensure oversight and efficient progress through the training program.

Eligibility criteria for K12 scholars follow published NIH guidelines. Candidates must demonstrate exceptional promise for future independence as scientists.

## Type of Submission

- First submission to Miami CTSI K12 program
- First re-submission to previous CTSI KL2/K12 program

Note: Candidates who have previously applied to any internal (e.g., CFAR, CHARM, SCCC, etc.) or external grant mechanism are required to disclose this information in their K12 application. If the application was not awarded, applicants are required to provide the proposal reviews (Summary Statement or equivalent), and highlight steps taken to improve the previous application (training, mentors, changes in research plan, etc.).

## Applicant Eligibility

All eligibility criteria must be met at the **time of appointment (September 2025)**

### **Candidates for Miami CTSI K12 awards must:**

- Be a U.S. citizen, a [non-citizen national](#), or a legal permanent resident of the U.S.
- Have a research or health-professional doctoral degree or its equivalent.
- Meet the [NIH Early-Stage Investigator \(ESI\) criteria](#): ESI is a Program Director/Principal Investigator who has completed their terminal research degree or end of post-graduate clinical training, whichever is later, within the past 10 years and who has not previously competed successfully as a PD/PI for a substantial NIH independent research award.
- Have a **full-time UM faculty appointment**. JHS or VA investigators are eligible if their primary mentor is a UM faculty.  
Voluntary faculty, Adjunct faculty, Lecturers, Residents, post-doctoral and clinical fellows are not eligible.
- **Commit a minimum of 75% time to research** and research training over the award period (50% if from surgical disciplines). The remainder of time may be spent in clinical or teaching pursuits and/or research-related activities consistent with the objectives of the award. Candidates must obtain the primary department commitment for 75% (or 50%) research protected time and necessary resources (department letter of support required at submission).
- Demonstrate a commitment to a **career in clinical translational science**.
- **Mentoring requirements:**
  - Candidates are strongly encouraged to have a primary mentor already identified at the time of the LOI submission (March 20, 2025). If a mentor(s) is not identified, the K12 program directors will assist the candidates to select appropriate mentors aligned with the proposed research and career goals.
  - At least one mentor on the mentoring team should have a clinical background.
  - Mentors should hold faculty positions, be supported by NIH or other competitively awarded grants, and be acknowledged experts in clinical and translational science.
  - Applicants are encouraged to reach out to the program directors for advice on the selection of their mentoring team.
- Must **commit to apply for individual mentored K awards** (e.g., K07, K08, K22, K23) and/or independent awards (e.g., R01, R03, R15, R21, R34, or equivalent applications from other federal agencies) during the K12 award period; if successful, scholars may be required to reduce or terminate their effort depending on program requirements.
- Awardees will be selected based on their anticipated ability to complete the entire two-year (24 month) proposed program. The selection committee will consider whether individuals who have pending NIH research grant applications with fundable scores that would require early K12 termination are appropriate for this award.
- Candidates for the K12 awards are strongly encouraged to participate fully or partially in the **Master of Science in Clinical Translational Investigation (MSCTI)**. Tuition remission for MSCTI courses will follow UM policy on Graduate Tuition Remission Taxation.

### **The following are NOT eligible for the K12 award:**

- Individuals who are not U.S. citizen, [non-citizen national](#), or a legal permanent resident of the U.S.
- Individuals on temporary or student visas.
- Voluntary faculty, Adjunct faculty, Lecturers, Residents, post-doctoral and clinical fellows.
- Individuals who have received funding as a Principal Investigator (PI) on any individual-mentored career development award (e.g., K07, K08, K22, K23).
- Individuals who have previously received funding as PI or MPI on any major federal, VA, state, or foundation award: for example, research projects (R01), First Award (R29), sub-projects of a program project (P01), center grants (P50), or equivalents.

### **Concurrent Funding**

- Small (<\$100K/year) non-career-development awards, such as an R03 or R21, or equivalent, are allowed. To verify if your award qualifies as a small award, consult with the K12 Administrator, [Patricia Avissar](#)
- K12 scholars may not receive any other salary support from a government sponsored grant (e.g., NIH grant) including training grants, during the term of the K12 award.

### **Proposal Eligibility**

- The K12 award will provide support for a scientifically meritorious research project in any **health-related discipline**, including, but not limited to medicine, surgery, pediatrics, obstetrics/gynecology, nursing, epidemiology, behavioral sciences, psychology, rehabilitation, physical therapy, and other disciplines.
- The proposed project must be **translational in nature**: pre-clinical research, clinical research, clinical implementation, or public health. Refer to the description of the [NCATS Translational Science Spectrum](#). To ascertain that the proposed research meet the criteria of Translational Science, please contact the [K12 Program Administrator](#).
- The proposed research project must address **community engagement**, generalizability of results, and applicability of project to the population groups that comprise South Florida.
- As per NCATS guidelines, the Miami CTSI will not support clinical trial activity beyond Phase IIA
- Only one proposal per person may be submitted.

### **K12 Awardee Selection Criteria**

K12 Scholars will be selected based on the following criteria:

- Commitment to and potential for a career in clinical translational science.
- Compliance with all applicant and project eligibility requirements at the time of submission.
- Timely compliance with all three mandatory consultations requirements (due by May 1<sup>st</sup>, 2025)
  - Biostatistics consultation
  - Community consultation
  - Budget/administrative consultation
- Commitment of the necessary resources and protected time as corroborated by the primary department.
- Scholarship, as assessed from biosketches, letters of reference, and past academic performance.
- Evaluation of the proposed research project (scientific merit, potential clinical-translational importance, scholar's ability to execute the research plan, available resources, likelihood of successful completion).
- Evaluation of the proposed mentored individual development plan (IDP); appropriateness and commitment of mentoring team and collaborators.
- Likelihood that the K12 support will lead to a successful individual K or R award application (or equivalent).

### **NCATS Prior Approval**

All Miami CTSI K12 projects involving human subjects and/or live vertebrate animals must receive prior approval from NCATS. As required by NCATS, all K12 projects must be reviewed and approved by NCATS to ensure protection of human subjects and/or live vertebrate animals, appropriate data and safety monitoring, and scientific integrity. NCATS prior approval will be obtained only with valid IRB/IACUC approval documentation, and other requirements. The Miami CTSI will provide guidance and support through this process.

K12 awardees must diligently submit and receive IRB and/or other regulatory approvals and NCATS approval. Failure to do so could result in the pro-rating of the award budget up to rescinding of award.

## Progress Reporting

To allow tracking of research progress, K12 Scholars will be required to submit:

- Progress Reports every 6 months during the funding period.
- Ad hoc reports required by NCATS and related to the annual Research Performance Progress Report.
- Final Report at the end of the funding period, no later than 60 days after the award start date.

## Application Timeline

Request for Applications (RFA)	TU 2/18/2025
Applicant Q&A session (via Zoom)	TH 2/27/2025
Letter of Intent (LOI) deadline	TH 3/20/2025
Invitation to full application	TH 3/27/2025
Full application deadline	TH 5/8/2025
Award notification	TH 7/31/2025
Program start date	MO 9/1/2025

## Application Process

Application to the Miami CTSI K12 awards is a two-step process: (1) a required Letter of Intent (LOI) and (2) a Full Application by invitation only. Both are submitted online.

The structured LOI will be used to verify applicants' eligibility and to assess the potential feasibility and scientific merit of the proposed research. Eligible candidates will receive an invitation to submit their full application.

For complete details on the LOI and the full application, refer to the instructions document located the CTSI website <https://miamictsi.org/k12>.

## Q&A Session

A virtual Q&A session via Zoom will be held on February 27, 2025, at 5 PM (Zoom invite to follow).

Questions regarding the K12 Program can be emailed ahead of time to K12 MPIs [Dr. Tatjana Rundek](#) and [Dr. Alessia Fornoni](#) (with K12 Administrator, [Patricia Avissar](#) copied). Questions will be answered at the orientation meeting.

Technical questions related to the online application should be directed before the deadline to [Patricia Avissar](#).