



Funding Opportunity: Request for Applications Mentored Translational Research Scholars Program Award (KL2) June 4, 2018

Overview

The Miami Clinical Translational Science Institute (CTSI) is sponsoring up to four Mentored Translational Research Scholars Program Awards (KL2) for the fiscal year FY19. This program will support the research career development of early stage investigators (Assistant Professor level), by providing two years of support, pending on the availability of funds and the satisfactory review performance of the project.

The support will include yearly (1) 75% salary support up to the NIH Salary Cap; (2) \$2,500 for travel and training-related activities; and (3) \$30,000 for research expenses. Awardees will be required to devote 75% of their time to research.

Objective

The objective of the KL2 program is to develop outstanding independent researchers by providing a structured research training program under the guidance of individualized mentorship.

The mentored research program provides a structure that includes: (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 epidemiology, research design, regulatory support, ethics, community engagement, and biostatistics; and (5) modest funds to cover research costs and/or expenses associated with tuition, training opportunities, and travel support for preceptorship in expert labs or to attend relevant scientific meetings.

The program will provide mentorship and support to promote the research and the advancement of KL2 scholars throughout the University. Mentoring is a required component of the program and will include the applicant's scientific mentor(s) and a mentor assigned by the CTSI to ensure oversight and efficient progress through the training program.

Criteria for eligibility follow published NIH guidelines. Candidates must demonstrate exceptional promise for future independence as scientists. Junior minority faculty and women are encouraged to apply.

Applicant Eligibility

All eligibility criteria must be met at the time of submission of the proposal (August 13, 2018).

Candidates for Miami CTSI KL2 awards must:

- Be a U.S. citizen, a non-citizen national, or a legal permanent resident of the U.S.
- Have a doctoral degree¹
- Be, at the time of submission, a full-time UM Assistant Professor (tenure or non-tenure-track) within 6 years of the first faculty appointment. Jackson Health System and the Miami VA full-time faculty may apply, with a UM faculty primary mentor. Residents, post-doctoral and clinical fellows are not eligible.
- Commit a minimum of 75% time to research and research training over the award period. The remainder of time may be spent in clinical or teaching pursuits and/or research-related activities consistent with the objectives of the award.
- Obtain the primary department commitment for 75% research protected time and necessary resources.
- Demonstrate a commitment to a career in clinical and/or translational research.
- Identify a faculty mentor who is an experienced investigator, with ongoing peer-reviewed, extramural

research support.

- Commit to apply for a K or R grant during the award period.

Not eligible for the KL2 award are:

- Individuals on temporary or student visas.
- Individuals who have received funding as a Principal Investigator (PI) on any major federal, VA, state, or foundation award: for example, individual-mentored career development award (e.g., K01, K08, K22, K23), research projects (R01), First Award (R29), sub-projects of a program project (P01), or center grants (P50); or
- Individuals who have a current pending application as a PI to any of the awards described above.

Notes:

- Having received a small NIH grant, such as an R03 or R21, does not disqualify an applicant.
- KL2 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 KL2 award.
- Candidates for the KL2 awards are encouraged to participate in one of UM's formal clinical research training programs, such as the Master of Science in Clinical & Translational Investigation (MSCTI). Requests for tuition waiver for the master's program will be reviewed on an individual basis.

Proposal Eligibility

The KL2 award will provide support for qualified junior faculty (Assistant Professor level) in any health-related discipline, including, but not limited to medicine, surgery, pediatrics, obstetrics/gynecology, nursing, dentistry, epidemiology, behavioral sciences, psychology, rehabilitation, and physical therapy.

The proposed research must be translational in nature: pre-clinical research (T1), clinical research (T2), clinical implementation (T3), or public health (T4). Basic research projects (T0) are not eligible. The NCATS Translational Science Spectrum is described [here](#).

As per NCATS Guidelines, the Miami CTSI does support clinical trial activity beyond phase IIA².

KL2 Selection Criteria

KL2 program Scholars will be selected based on the following criteria:

- Compliance with all eligibility requirements.
- Commitment and potential for a career in clinical and/or translational research.
- Commitment of the necessary resources and protected time from the primary department.
- Scholarship, as assessed from biosketch, letters of reference, and past academic performance.
- Evaluation of the proposed research project (scientific merit, potential clinical importance, scholar's ability to execute the research plan, available resources, likeliness of successful completion).
- Evaluation of the proposed mentored development plan, appropriateness and commitment of mentoring team and collaborators.
- Likelihood that the KL2 support will contribute to a successful K or R Award application (or equivalent).
- The impact of the research on improving the health of minority and underserved population.

Resubmissions

Only one resubmission to the CTSI KL2 Awards Program is allowed.

If this application is a resubmission to any internal or external grant mechanism, applicants will be required to provide the proposal reviews (Summary Statement, or equivalent), and highlight steps taken to improve the previous application (enhanced training, mentors, changes in research plan, etc.).

NCATS Delayed Onset Prior Approval (DOPA)

All Miami CTSI Pilots and KL2 projects involving human subjects and/or live vertebrate animals must receive approval from NCATS prior to the involvement of human subjects and/or live vertebrate animals.

Why this new requirement? The Miami CTSA grant was submitted to NIH/NCATS with the knowledge that human subjects and/or live vertebrate animals projects may be supported by the grant, but definite plans for these projects could not be described in the application. Pilot and KL2 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. This process is called NCATS Delayed Onset Prior Approval (DOPA). For more information on NCATS DOPA, click [here](#). To check if your project involving human subjects is exempt from NCATS DOPA, go to [Decision Tree Exemption 4](#).

Applicants invited to submit their full application will be asked to immediately initiate the NCATS DOPA process (IRB approval, IACUC approval, gathering of required documentation, etc.). Awarded KL2 scholars must submit the request for NCATS approval at least 30 days before the involvement of human subjects and/or live vertebrate animals. NCATS prior approval will not be obtained without valid IRB/IACUC approval documentation. Funding will not be released and human subject and/or live vertebrate animals research will not start until NCATS approval is obtained. The Miami CTSI will provide guidance through this process.

Progress Reporting

To allow tracking of the progress and success of the CTSI KL2 scholars, the funded investigators will be required to submit

- (1) an interim progress report every 6 months during the funding period and
- (2) a 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)	June 4, 2018
Orientation meetings for KL2 applicants	June 8 and June 14, 2018 (5-6 PM CTSI 710B)
Letters of Intent due	July 2, 2018
Full Application (by invitation only) due	August 13, 2018
Notification of awards	October 1 st 2018
Beginning of the award period	October 2018 (contingent upon CTSI period award start and NCATS approval)

Application Process

The application process for the Miami CTSI KL2 awards is done in two steps: (1) a required Letter of Intent (LOI) and (2) a Full Application (by invitation only). Both are submitted on-line.

The structured LOI will be used to verify the applicants eligibility, and to assess the potential feasibility and scientific merit of the proposed research. To access the LOI submission form, go to the [CTSI website](#), or to the [UM Funding Opportunities website](#).

Within a week from the LOI submission, selected candidates will receive an invitation to submit their full application.

For complete details on the contents of the LOI and full application, refer to the [instructions document](#).

Orientation Meeting & Information

Two orientation meetings for KL2 applicants will be held on June 8 and June 14, from 5 to 6 p.m., at the CTSI Research Commons, Suite 710. Dr. Gwendolyn Scott, Director of the KL2 Program, will provide an introduction to the KL2 Award, and answer any question you may have.

Questions regarding the KL2 Program should be emailed ahead of time to [Gwendolyn B. Scott](#), M.D., Director, Miami CTSI KL2 Program, and/or [Alessia Fornoni](#), M.D., Ph.D., Co-Director, with a copy to [Patricia Avissar](#).

Questions related to the on-line application process should be directed to [Patricia Avissar](#), or at 305-243-5085 during office hours, and before the deadline.

¹ Doctoral degree: a Ph.D., M.D., or comparable doctoral degree from an accredited domestic or foreign institution. For a complete list, go to <http://grants.nih.gov/grants/guide/pa-files/PAR-06-470.html#SectionIII>. (subsection1B)

² Definition of Phase IIA Clinical Trial: A Phase IIA clinical trial is a pilot study to evaluate the effectiveness and safety of an intervention in patients with the disease or condition to be treated, diagnosed or prevented. These studies may focus on participant population characteristics, dose response, dose frequency or other characteristics related to safety or efficacy. Phase IIA trials are not considered pivotal trials showing the effectiveness of an intervention. (Source: <http://www.ncats.nih.gov/research/cts/ctsa/about/about.html>)