Request for Applications (RFA): KL2 Multidisciplinary Scholars Program in Clinical & Translational Science

KEY DATES
RFA Release Date: January 2, 2019
Application Deadline: February 28, 2019
Anticipated Start Date: April 15, 2019

OVERVIEW
The goal of the SCTR KL2 program is to foster the discipline of clinical research and increase clinical research capacity through the training of junior faculty, bridging clinical and translational research training with research independence. The SCTR KL2 will provide mentored, protected research experiences to enhance the development and retention of early career investigators. The program includes the option to pursue a master’s degree in clinical or translational science, a supportive environment, start-up research funds, and access to program faculty who will provide expertise and guidance in research design, measurement and questionnaire design, study coordination, data management, biostatistical analysis, publishing and presenting research, and grant writing.

Key Personnel
• Marc I. Chimowitz, MBChB – KL2 Principal Investigator
• Carol Feghali-Bostwick, PhD – KL2 Associate Principal Investigator
• Diana Lee-Chavarria – SCTR Education & Workforce Program Manager

Please contact Diana Lee-Chavarria at leearchar@musc.edu as soon as you decide to proceed with an application. The Program will be holding a question and answer session in late January 2019 that you will be invited to.

SCTR KL2 Website: https://research.musc.edu/resources/sctr/funding-opportunities/multidisciplinary-scholars

KL2 BENEFITS
• Scholar Salary Support – up to $100,000 plus fringe at required 75% effort for two years
• Annual Research Budget – $25,000 to purchase research supplies and small equipment
• Travel Support – $1,000 to attend the Association for Clinical and Translational Science Annual Meeting in Washington, DC
• Individual Development Plan (IDP) guidance and mentorship with oversight by the KL2 Program Directors
• Facilitated externships and experiential training opportunities with collaborating CTSAs and Industry
• Support to develop an extramural grant application to fund research at the conclusion of the KL2 funding. Appointed scholars are required to apply for individual mentored K awards (e.g., K07, K08, K22, K23) or (preferably) independent R-series awards (R01, R03, R21) by the end of the second year of the KL2 program.
Note: if new funding is received during the KL2 appointment, the scholar’s appointment will be terminated upon the start of the new individual K or R award.
• **Access to SCTR consultation, services and staff** – includes SUCCESS Center research navigation, biostatistics, subject recruitment, REDCap data capture software, animal/human-subject regulatory consults, protocol development consults, NIH Public Access compliance (publications in PubMed Central), intellectual property consults and forms.

**ELIGIBILITY**

- **VA Appointment**: Special permission must be obtained for eligible faculty with Veterans Affairs (VA) appointments. Candidates must contact Diana Lee-Chavarria (leeachar@musc.edu) prior to applying.

- **Position and Degree Requirements**: Eligible candidates are junior faculty with doctoral-level professional degrees who are committed to a career in clinical translational research. Candidates must have:
  - A **full-time faculty appointment** (regardless of tenure or non-tenure track) at MUSC at the time of formal acceptance as a scholar
    - Senior fellows pending faculty appointment may apply.
  - A **health professional doctoral degree** or its equivalent – either Clinical (i.e. MD, DrPH, PharmD) or Non-Clinical Doctoral (i.e. PhD, ScD)
  - Junior faculty – anyone at the Instructor or Assistant Professor level who are within 10 years of having completed a postdoctoral specialty or subspecialty training (based on the definition for NIH Early Stage Investigators) who meets the other eligibility requirements for prior research experience, citizenship, education/degree, and clinical certification (if required).

- **Salary and Time Commitment**: Candidate must devote a **minimum of 75% full-time professional effort** in this program for the training and clinical research activities. The 75% effort is based on the entire amount of time worked in a typical week, and should be proportionate. The remaining 25% effort can be divided among other research, clinical and teaching activities if these activities are consistent with the proposed goals of the KL2 program.

- **Citizenship**: Candidates must be U.S. citizens or non-citizen nationals, or have been lawfully admitted for permanent residence and possess a Permanent Resident Card (I-151 or I-551) or some other verification of legal admission as a permanent resident. Individuals on temporary or student visas are not eligible for this program.

- **Prior Research Experience**: Per NIH regulations, applicants who have previously served as the PD/PI on a NIH R03 or R21 grant or non-PHS equivalent may apply for the KL2 program.
  - Applicants are **ineligible** to apply to the KL2 if:
    - they have a pending application for any other PHS mentored career development award (e.g. K07, K08, K23) that duplicates the provisions of the program, an NIH institute-specific K22, or a Pathway to Independence Award (K99/R00)
    - they have been or are currently a PD/PI on an independent NIH research grant (e.g. R01) or a subproject leader on a Program Project (P01) or Center Grant (P50), or a non-PHS equivalent to these grants.

**EXPECTATIONS**

**KL2 Candidate Expectations (if awarded)**

**Requirements**:

- Ensure that the **protected time (75%)** supported by this award is being met and used towards candidate’s research efforts, training, and scholarly pursuits.

- Attend **Joint K Orientation**: Date TBD. Scholar Needs Assessment should be completed prior to orientation.
• **Work with primary mentor** and others that are part of the mentoring team to develop skills needed to develop a successful career path.
  - **Meet regularly** with a primary mentor to discuss and assess continued progress of research goals; also meet regularly with your mentoring team as a whole.
  - **Establish a mentoring contract** with the primary mentor.
  - Work with mentor(s) to **perform a career development needs assessment and create an IDP** (available on the SCTR KL2 Program webpage). Agree upon a set of expectations and goals. Review this with your mentor quarterly.
  - **Set Annual Goals** and create a Program Timeline (see suggested timeline below). Include milestones and goals for career development progress, program requirements, training and research goals on a timetable to maintain throughout the K program.

• **Meet quarterly with K Program Directors.** These meetings will be used to discuss the research project, training advancements, and monitor evidence of progress. Required reports are due two weeks prior to these meetings.

• Participate in **Mock Study Sessions**. Prior to grant submission candidates will participate in a mock study session coordinated by the Office of Research Development. This will be scheduled to meet with the scholar’s goals and to allow for appropriate time to address issues identified during the process.


• **Attend monthly K to R Club meetings.** Meetings are scheduled for the 4th Tuesday of each month at 4pm in the Bioengineering Building Room 201. This is an opportunity to interact and learn from the experiences of all K Scholars on campus. Each candidate will present to this group annually and prior to an extramural grant submission.

• **Participate in Scientific Writing Seminars.** KL2 scholars will meet as a group to “workshop” manuscripts, grant proposals, and other scholarly writing that they are currently working on.

• **Attendance at the SCTR Annual Mentorship Training Symposium.**

• **Submission of an abstract and attendance at the Association of Clinical and Translational Science (ACTS) Annual Meeting** in Washington, DC.

• **Submit abstracts, journal articles and publications** yearly to maintain evidence of scholarly productivity.
  - Publications must cite grant funding and adhere to the NIH Public Access Policy. Candidates will coordinate the review of manuscripts that will be submitted for publication with their mentor(s) prior to submission. **All papers published during this appointment should cite the SCTR KL2 grant number (NIH/NCATS KL2 TR001452).**

• **Awardees must apply for an extramural grant** (preferably R-Series) no later than by the end of Year 2.

**Encouraged:**
- **Attendance at Tools for Mentors & Mentees** monthly workshops.
- **Attendance at the Mentor Training Course.**
- **Attendance at the Society of Clinical Research and Translational Early Scientist (SOCRATES) meetings.**
  SOCRATES (combined with B&B) meetings are held the first & third Wednesday of each month at 4:00 pm in the Bioengineering Building Room 201. These provide a forum for faculty to present their research projects in front of their peers and senior researchers. This will provide constructive feedback for improving and enhancing research studies and grant proposals.

**PROGRAM TIMELINE**

Since our goal is for Scholars to become independently funded by the end of their KL2 award period (or earlier), we set out these general guidelines on when to complete core requirements:
Year 1

- Obtain IRB approval
- If human subjects research – submit study to the Office of Clinical Research for a Prospective Reimbursement Analysis (PRA)
- Take required courses:
  - Responsible Conduct of Research (RCR)
  - K Scholars Grant Writing
  - Clinical Biostatistics (exempt if equivalent course taken)
  - Team Science

Year 2

- Take required courses: Budget Management Workshop and Leadership Training Workshop
- Submit proposal for review to a K Scholar Mock Study Section
- Submit an extramural grant (typically R01, K23, or other federal, state, foundation or industry grant)

Year 1 and Year 2

- Present at least annually at the K to R Club
- Participate in Mock Study Sections
- Participate in Science Writing Seminars
- Complete one or more high quality publications that may form the basis of a grant application
- Attend annual meetings (ACTS, MUSC Research Day, Mentorship Training Symposium)

KL2 MENTOR EXPECTATIONS

- Help develop the skills needed to promote the career of the mentee. Mentor will set aside protected time to meet with mentee to accomplish this.
- Ensure that the protected time supported by the award for the KL2 scholar is being met.
- Ensure that a mutually agreed-upon set of expectations and goals are in place at the outset of the mentoring period; will work with the mentee to create an IDP and mentoring plan.
- Maintain a relationship with the mentee that is based on trust and mutual respect. Open communication and periodic formal performance reviews with the KL2 team will help ensure that the expectations of both parties are met.
- Promote all ethical standards for conducting research including compliance with all institutional and federal regulations as they relate to responsible conduct in research, privacy and human subjects research, animal care and use, laboratory safety, and use of radioisotopes.
- Ensure that the mentee has sufficient opportunities to acquire the skills necessary to become an expert in an agreed upon area of investigation.
- Mentor will provide the mentee with the required guidance and mentoring, and will seek the assistance of other faculty and departmental/institutional resources when necessary. Mentor must provide access to formal opportunities/programs in complementary areas necessary for a successful career.
- Mentor will encourage the interaction of the mentee with fellow scientists both intra- and extramurally and encourage the mentee’s attendance at professional meetings to network and present research findings.
- Mentor will ensure that the research performed by a mentee is submitted for publication in a timely manner and that she/he receive appropriate credit for the work she/he performs. Mentor will acknowledge her/his contribution to the development of any intellectual property and will clearly define future access to tangible research materials according to institutional policy.
- Mentor will make available to the mentee, as appropriate, data from previous or ongoing projects that are related to the mentee’s area(s) of interest, and will encourage the mentee to submit manuscripts for
publication during the award period and after the award period is over. Mentor will ensure that mentee receives appropriate credit for the work she/he performs.

- Mentor will commit to being a supportive colleague to mentees as they transition into the next stage of their career and to the extent possible, throughout their professional life.
- Mentor will play a fully involved role in the SCTR KL2 Program by participating in quarterly SCTR KL2 progress report meetings, K to R Club Meetings (required when mentee is presenting), and fulfilling the role of a reviewer for K Program Mock Study Section.
- Mentor training and development opportunities will be taken to enhance one’s own skills. Suggested opportunities include SCTR’s Annual Mentorship Training Symposium, the in-person Mentor Training Course and the online mentor training program *Optimizing the Practice of Mentoring* through the University of Minnesota’s CTSA (free).
- Mentor will have read the potential scholar’s KL2 application package and provided constructive feedback, both for the career/training components and the research plan.

**SELECTION CRITERIA**

Two senior researchers on campus who are familiar with the area of study, the KL2/K12 Program Directors, and the TL1 Program Directors will review each application. Each reviewer will provide a priority score using the NIH 9-point scale and a written critique based on the NIH K23 review criteria and form ([Link to template](#)). All applicants will receive reviewer comments on their applications.

The applications with the highest priority score will present their proposals to the KL2/K12 Executive Committee (the KL2/K12 Program Directors, SCTR PI, SCTR Associate PIs, and the TL1 Program Directors), addressing any issues raised in the written critiques. Following the presentations, the KL2/K12 Executive Committee will select the scholar.

KL2 scholars will be selected based on a competitive application process in which the following primary components will be assessed:

- The track record and potential of the candidate
- Scientific merit of the proposed research.
- The transdisciplinary/translational science of the research project
- The experience of the mentorship team
- The quality of the training plan

*Individuals from underrepresented ethnic minority groups are encouraged to apply, and special consideration will be given to individuals in departments and disciplines that have traditionally been under-represented in clinical research.*

**KL2 APPLICATION INSTRUCTIONS**

The MUSC SCTR KL2 Program supports the career development of investigators who have made the commitment to a career in clinical and translational patient-oriented research. This KL2 Award is available for a period of two years pending satisfactory progress. A 3rd year is possible if the scholar has made satisfactory progress in the program and has submitted an extramural grant that was not funded but is considered to be promising by the reviewers.

Please read these instructions carefully before beginning your application. The entire application package must be successfully submitted by **February 28th at 11:59 pm** via the InfoReady submission portal. Applications received after this time will be executively withdrawn.

**INCOMPLETE AND/OR LATE APPLICATIONS WILL NOT BE ACCEPTED FOR ANY REASON!**
All candidates MUST submit a SPARC Request to get a Research Master ID before submitting an application.

1) Go to sparc.musc.edu
2) Select “South Carolina Clinical and Translational Research Institute” from the menu on the left
3) Select “Funding Opportunities” from the drop-down menu
4) Select “SCTR KL2 Multidisciplinary Scholars Program” from the opportunities listed
5) Select “Add” to submit SPARC Request
6) Click on “Show Details” for a link to the application portal

Additional Information:
- Link to MUSC’s funded proposal library: https://research.musc.edu/resources/ord/faculty-toolkit/proposal-library
- SCTR KL2 website, RFA, KL2 Needs Assessment Form, Individual Development Plan, and other information: https://research.musc.edu/resources/sctr/funding-opportunities/multidisciplinary-scholars

Questions? Contact Diana Lee-Chavarria, SCTR Education & Workforce Development Program Manager, at leeachar@musc.edu or 792-8205. We’d like to know if you plan to submit a grant in advance so please let Diana know as soon as you decide to proceed with the application. The Program will be holding a question and answer session in late January 2019 that you can attend.

APPLICATION DOCUMENT REQUIREMENTS
Candidate must submit an application including: candidate’s background, career goals and objectives, proposed career development/training activities during award period, research plan, human subjects section, and detailed budget for initial 12-month budget period.

- Format: All application materials must be submitted online in PDF format.
- Font: Arial – no smaller than 11-point
- Margins: half-inch (1/2”) on all sides

The following elements must be uploaded into the InfoReady application portal as PDFs:

1) NIH BIOSKETCHES
   - NIH-formatted biosketches are required for:
     1) Applicant – please list all prior funding/awards
     2) Primary Mentor – Other Support must be included
     3) Others on the Mentor Team – Other Support must be included
     4) Consultant (optional)
   - Please use the most updated format: https://grants.nih.gov/grants/forms/biosketch.htm

2) APPLICANT CV
   This should include:
   - Previous institution
   - Degree and year earned
   - Doctoral thesis title
   - Residency training institution
   - Title of specific training
   - Previous/current funding
3) CANDIDATE’S STATEMENT (3-Page Limit)
This section should address all of the following:

- **Track Record** – *Creativity of the candidate and potential to lead excellent research judging by track record in some or all of the following: areas of expertise and prior training; publications; previous research experience and funded grants.*
  - Describe any previous training in clinical and translational research (e.g., MSCR degree, MSTP program, previous mentor program, etc.).
  - Give examples of opportunities you’ve had to engage in research (basic or clinical); describe your role in these projects.
  - Highlight examples of your productivity (e.g., pursuing an original research question, analyzing data, pursuing extramural funding, and presenting or publishing your findings).

- **Research Plan Overview** – *Scientific value, potential clinical importance, and feasibility of the written research plan*
  - State your long-term clinical and translational research career goal(s), including the type of research you plan to conduct, the clinical problem(s) your research will address, and the potential impact your research will have on human health.
  - Explain how conducting the research project proposed in this application will prepare you to compete successfully for an NIH grant, such as an R03, R21, or R01 and provide some scenarios for what that project would be.
  - Note: A SCTR Biostatistics Consultation is required for all applicants. Schedule your consultation via SPARC as soon as possible. This will provide you valuable statistical and study design information that you will likely want to incorporate into your research plan.

- **Mentor Training Plan** – *Quality, appropriateness, and multidisciplinary complementarity of the proposed mentors, and plan for additional didactic and other training at MUSC or elsewhere*
  - Explain what additional training you need to achieve your research career development goals. Using the KL2 Needs Assessment form (available on the SCTR KL2 Program webpage), identify specific areas where you have deficiencies and describe how you will obtain additional training in each area.
  - Describe the roles each of your mentors will play. Be specific; cite examples from your proposed training or research plan whenever possible.

- **Resources** – *Tangible commitment and resources provided by the home department/division, and suitability of the available clinical and laboratory infrastructure and multidisciplinary team*
  - Comment on the resources (space, staff, clinical materials, funds, etc.) provided by your department and mentors, and their adequacy to your career development. Be specific as to amounts that will be available to you for doing research.

- **Career Potential** – *Global assessment of the likelihood that you will develop a career as an outstanding investigator who will lead multidisciplinary teams and have an important impact on health*
  - Explain how you will benefit from the KL2 program and how it will contribute to your career in multidisciplinary clinical and translational research.
  - Comment on the leadership role you expect to play in your department in 5-10 years.

4) RESEARCH PLAN (7-Page Limit: 1 page for Specific Aims; 6 pages for Background & Significance, Preliminary Studies, and Research Design & Methods)
The research plan should be described along the lines of instructions contained in PHS 398. Ideally, the research plan should be completed within two years so that an extramural grant application that includes these results can be submitted by the end of year two.

Combine the following into a single PDF to upload:
• Specific Aims (1 page limit)
• Background & Significance* (*combined 6-page limit)
• Preliminary Studies*
• Research Designs and Methods* – should include a summary of your future research plan
• PHS Human Subjects and Clinical Trials Information (not included in page limit)
• Literature Cited (not included in page limit)
• Detailed Budget for initial 12-month period – use the PHS 398 budget form (not included in page limit)
• Individual Development Plan – use the IDP found on the first page in the application portal (not included in page limit)

5) LETTERS OF SUPPORT (1-Page Limit/Each)
Three letters of support are required, one each from:
   1) your Primary Mentor (include 1 paragraph on the mentor’s research focus)
   2) your Department/Division Chair affirming 75% protected research time
   3) an individual familiar with your potential to develop an independent research career

Considerations for the Primary Mentor and Department/Division Chair letters:
• Describe the goals and how you will foster an environment conducive to a successful clinical and translational career path
• Describe additional resources/experiences you might bring to bear during the candidate’s appointment to enhance their training and research agenda

The letters should be addressed to:
Marc I. Chimowitz, MBChB
Carol Feghali-Bostwick, PhD
Medical University of South Carolina
125 Doughty Street, Suite 100
MSC 195
Charleston, SC 29425-0195

6) MENTOR’S TRAINING TABLE(S)
• Include all current and pending mentors
• Use the format found on the first page of the application portal
• Upload training table(s) for consultant(s) if applicable

7) SIGNED SIGNATURE PAGE
• Page 9 of RFA
• Signed by mentor, department chair, and applicant
In addition to the candidate’s letters of support, three additional signatures are required (the Primary Mentor, Department Chair, and Candidate) signifying an understanding and commitment to the SCTR KL2 program if the candidate is awarded.

Primary Mentor
As the Primary Mentor, I have read the potential scholar’s KL2 application package and provided constructive feedback, both for the career/training components and the research plan. I have read and agree to abide by the KL2 Mentor Expectations on page 4 of this application. To the maximum extent possible I will meet regularly with the scholar. I understand that myself or another member of the mentorship team will be required to attend SCTR sponsored events, including the Annual Mentorship Training Symposium and the Joint K Orientation, as well as others stated in the Mentor Expectations.

________________________
Signature of Primary Mentor

Date

Department Chair
This individual is qualified for this program and will receive immediate priority for clinical coverage (if applicable), all requirements for protected time, and all financial needs according to the RFA.

As Chair of ______________________ (department name), I agree to grant this individual the required 75% protected time. I understand that this is a two-year award.

________________________
Signature of Department Chair

Date

Applicant/Candidate
I certify that the statements herein are true and complete to the best of my knowledge and that I will comply with all applicable SCTR KL2 terms and conditions governing my potential appointment. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

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Signature of Applicant/Candidate

Date