SCTR College of Medicine Clinician Scientist K12 Program

<table>
<thead>
<tr>
<th>Key Dates</th>
<th>Key Personnel</th>
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<tr>
<td>Release Date: October 14th, 2015</td>
<td>Marc I. Chimowitz, MBChB Program Director</td>
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<tr>
<td>Application Deadline: November 16th, 2015 (noon)</td>
<td>Bonnie Martin-Harris, PhD Associate Program Director</td>
</tr>
<tr>
<td>Anticipated Start Date: (January 2016)</td>
<td>Diana M. Barrett, MS Workforce Development Program Manager</td>
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**Key Information**
- Number of Slots: 1-2 Slot for 2015-2016
- COM K12 Q & A Seminar for Applicants: TBD

SCTR COM K12 Website: [http://academicdepartments.musc.edu/sctr/education_training/K12](http://academicdepartments.musc.edu/sctr/education_training/K12)

The SCTR Institute and MUSC College of Medicine announce a funding opportunity for an institutionally - funded K12 Mentored Career Development Program in clinical and translational science. This K12 program supports the career development of scholars holding a research or health professional doctoral degree or its equivalent. The goal of the program is to transition scholars from a mentored training program to an independent research career.

The SCTR COM K12 program includes 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.

**K12 BENEFITS**
- Salary support at required 40% effort plus fringe related benefits for 2 years (subject to a cap of $199,700). Scholar’s department/division is responsible for paying over-the-salary-cap costs as well as the remaining 60% effort. A 3rd year may be awarded at the discretion of Program Leadership dependent upon satisfactory progress.
- Annual supply budget of $5,000.00 to purchase research supplies and small equipment with a department/division match of $15,000.00 is required (combined total of $20,000.00)
- Individual Development Plan (IDP) guidance and mentorship with oversight by the K12 Program Directors
- Facilitated externships and experiential training opportunities with collaborating CTSAs and Industry
- Support to develop an extramural grant application (preferably R-Series) to fund research at the conclusion of the K12 funding. Appointed scholars are required to apply for individual mentored K awards (e.g., K07, K08, K22, K23) or independent awards (R01, R03, R21) during the K12 program; if successful during the K12 program, the K12 appointment will be terminated upon funding received from the new individual K or R award.
- Access to SCTR consultation, services and staff including: 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 SCTR prior to applying.

• **Position and Degree Requirements:** Eligible candidates are junior faculty who are committed to a career in clinical translational research. Junior faculty includes 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). Candidates must have:
  - A full-time tenure-track faculty appointment at MUSC at the time of formal acceptance as a scholar;
  - A non-tenure track faculty may apply however, the Department/Division Chair Letter of Support must include a commitment to appoint faculty to tenure-track upon acceptance of K12 award.
  - An MD or DO degree.

• **Salary and Time Commitment:** Candidate must be able to commit 40% of full-time professional effort in this program for the training and clinical research activities. The 40% effort is based on the entire amount of time worked in a typical week, and should be proportionate. The remaining 60% effort can be divided among other research, clinical and teaching activities if these activities are consistent with the proposed goals of the K12 program. Candidates must provide a justification as to the barriers of participating in the regular SCTR K12 (K12) program, which requires 75% effort.

• **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:** Candidates may not simultaneously submit or have pending an application for any other PHS mentored career development award (e.g., K07, K08, K22, K23) that duplicates any of the provisions of the K component. Former or current PDs/PIs on any NIH research project grant (this does not include NIH Small Grants (R03), Exploratory/Developmental (R21) or SBIR, STTR (R43, R44 grants)) or equivalent non-PHS peer reviewed research grants that are over $100,000 direct costs per year, or project leaders on sub-projects of program project (P01) or center grants (P50) are NOT eligible to participate as scholars.
EXPECTATIONS

Candidate Department/Division Expectations (if awarded)

• Ensure that the protected time (40%) supported by this award is being met and used towards candidate’s research efforts, training, and scholarly pursuits.

• Department/Division is to pay any over-the-salary-cap costs as well as the remaining 60% effort (capped at $199,700).

• Department/Division is to contribute $15,000.00 to the candidate’s annual research supply budget (total research supply budget is $20,000.00).

K12 Candidate Expectations (if awarded)

• Ensure that the protected time (40%) supported by this award is being met and used towards candidate’s research efforts, training, and scholarly pursuits.

• Attend Joint K Orientation: Date TBD (full day required). Scholar Needs Assessment should be completed prior to orientation.

• Work with their 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 accomplish this and continued progress of research goals. Also meet regularly with your mentoring team as a whole.

• Establishment of a mentoring contract with all mentors is required.

• Meet quarterly with K Program Directors. These meetings will be used to discuss the research project, training advancements & monitor evidence of progress. Required reports, via Redcap survey, are due two weeks prior to these meetings (link will be emailed).

• Work with mentor(s) to create an Individual Development Plan (IDP). Agree upon a set of expectations and goals. Review this with your mentor annually, at a minimum.

• Set Annual Goals & Create a Program Time Line. Include milestones and goals for career development progress, program requirements, training and research goals on a time line to maintain throughout the K program.

• Attendance at the K Scholars Grant Writing Course Course is required.

• Mock Study Sessions participation is required. 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 (required). Meetings are scheduled for the 4th Tuesday of each month at 5pm 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 twice a year

- Attend Translational Research Journal Club (required).
- Attendance is encouraged at Tools for Mentors & Mentees monthly workshops.
- Candidates are required to obtain training in clinical and translational research as a K12 Clinician Scientist, whether a MSCR is pursued or personally developed training is sought.
- Scholars holding an MSCR or other formalized clinical and/or translational degree must include an outline for additional training in their Training Plan in the application.
- Candidates are encouraged to complete a NEXUS rotation by the end of their second program year.
- Attendance is encouraged at the Society of Clinical Research and Translational Early Scientist (SOCRATES) meetings. SOCRATES (combined with B&BS) meetings are held the first & third Wednesday of each month at 5pm 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.
- 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 K12 grant number (appropriate number will be provided).
- Attendance at the SCTR Annual Mentorship Training Symposium is required.
- Submission of an abstract and attendance at the Annual Translational Science Meeting in Washington, DC (April) is strongly encouraged. We recommend that a minimum of $1,000.00 is budgeted to fund the awardees attendance at the annual conference.
- Submit abstracts, journal articles and publications yearly to maintain evidence of scholarly productivity.
- Candidates must apply for an extramural grant (preferably R-Series) no later than by the end of Year 2.

**K12 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 K12 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 and will work with the mentee to create an Individual Career Development plan (IDP).
• Maintain a relationship with the mentee that is based on trust and mutual respect. Open communication and periodic formal performance reviews with the K12 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.

• Mentor will 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 K12 Program by participating in quarterly SCTR K12 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 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 K12 application package and provided constructive feedback, both for the career/training components and the research plan.
CANDIDATE MILESTONES

Since our shared goal is for Scholars to become independently funded by the end of their K12 award period (or earlier), we set out these general guidelines for scholars to consider:

1st year:
- Complete approved plan of research and timeline
- Have obtained IRB approval
- Complete Fall Grantsmanship Course and present twice at the K to R Club
- If applicable, completion of the Core Clinical Research Training Course
- One or more high quality publications that may form the basis of a grant application.

2nd year:
- Complete one or more high quality publications that may form the basis of a grant application.
- 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)
- Present twice to the K to R Club

Possible 3rd Year:
- A third year of funding will only be considered if circumstances are justified, all program requirements had been met in previous years and there is high probability of extramural funding in the near future.
- Example: A grant submission was reviewed and scored, but not funded and development of a resubmission would be benefitted by the additional support.
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). 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.

* A SCTR Biostatistics Consultation is required for all applicants. Schedule your consultation 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. Requests must be submitted via SPARC.

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.

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<th>Overall Impact or Criterion Strength</th>
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KL2 APPLICATION INSTRUCTIONS

The MUSC SCTR COM K12 Program supports the career development of investigators who have made the commitment to a career in clinical and translational patient-oriented research. This K12 Award is available for a period of 2 years. Pending satisfactory progress, a 3rd year is at the discretion of the Program Director’s and Associate Director’s discretion.

Please read these instructions carefully before beginning your application. The ENTIRE application package must be successfully submitted by November 16, 2015@ 12:00 Noon EST via the SCTR AppSite portal. Applications received after this time will be/executively withdrawn.

Incomplete applications WILL NOT be accepted for any reason!

SCTR COM K12 website, RFA, and application forms:
http://academicdepartments.musc.edu/sctr/education_training

Direct link to SCTR COM K12 application form in the SCTR AppSite portal:
https://sctrweb2.musc.edu/apps/kl_institutional_applications/new

QUESTIONS?
Contact Diana Barrett, SCTR Workforce Development Program Manager at (843) 792-1497 or barretd@musc.edu.

ADDITIONAL INFORMATION
K12 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

All applicants will receive reviewer comments on their applications. Incomplete applications WILL NOT be accepted for any reason!

Link to MUSC’s funded proposal library:
http://academicdepartments.musc.edu/research/ord/proposal-library/

APPLICATION DOCUMENT REQUIREMENTS
- Format: All docs must be submitted as PDF files
- Font: Arial – no smaller than 11-point
- Margins: half-inch (1/2") on all sides
- Address letters of support to: Marc Chimowitz, MBChB (KL2/K12 Principal Investigator) and Bonnie Martin-Harris, PhD (KL2/K12 Associate PI) – upload these docs to the SCTR AppSite portal as part of your complete application package – DO NOT send via email, hand delivery or interoffice mail
- All application materials must be submitted online in PDF format.
Application Documents
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. Further critical elements to be included are indicated below.

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<tr>
<th>Document</th>
<th>Page Limit</th>
<th>SCTR AppSite Upload</th>
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<tr>
<td>Candidate Biosketch (New NIH Format)</td>
<td>5-Pages</td>
<td>Combined Single PDF to PI Biosketch Box</td>
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<td>Candidate Other Support</td>
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<td>Candidate CV*</td>
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<tr>
<td>Biosketch for all current and pending mentors (New NIH Format)</td>
<td>5-Pages (each)</td>
<td>Combined Single PDF to Mentor Biosketch Box</td>
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<td>Other Support for all current and pending mentors</td>
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<tr>
<td>Mentor’s Statement (if there are additional letters, please include them in this PDF)</td>
<td>1-Page</td>
<td>PDF to Mentor’s Statement Box</td>
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<tr>
<td>Mentor’s Training Table(s) for all current and pending mentors</td>
<td>No-Limit</td>
<td>PDF to Mentor’s Training Table Box</td>
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<td>Dept/Division Chair Statement confirming commitment of 40% protected time</td>
<td>1-Page</td>
<td>PDF to Department/Division Chair Statement Box</td>
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<td>Candidate’s Statement and Training &amp; Career Development Plan (should include track record, research plan overview, mentor training plan, resources, and career potential)</td>
<td>3-Pages</td>
<td>PDF to Candidate’s Statement Box</td>
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<td>Abstract</td>
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<td>Specific Aims</td>
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<td>Background &amp; Significance, Preliminary Studies, and Research Design and Methods (to include summary of future research plan)</td>
<td>6-Pages</td>
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<td>Human Subjects</td>
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<td>Literature Cited</td>
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<tr>
<td>Detailed Budget for initial 12-month period</td>
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<td>Individual Development Plan (use provided template)</td>
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<tr>
<td>Evidence of candidate’s potential to become independent investigator</td>
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Do NOT use PHS 398 PDF "fillable" forms. You must complete in Word or Excel and then convert to PDF.

*Candidate CV should include:
- Previous institution
- Degree and year earned
- Doctoral thesis title (if applicable)
- Residency training institution and title of specific training
- Personal e-mail address
- Indicate previous/current funding
CANDIDATE’S STATEMENT (3-Page Limit)
This section should address all 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.
  o Describe any previous training in clinical and translational research (e.g., MSCR degree, MSTP program, previous mentor program, etc.).
  o Give examples of opportunities you’ve had to engage in research (basic or clinical); describe your role in these projects.
  o 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
  o 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.
  o 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.

• **Training Plan** - Quality, appropriateness, and multidisciplinary complementarity of the proposed mentors, and plan for additional didactic and other training at MUSC or elsewhere
  o Explain what additional training you need to achieve your research career development goals. Identify specific areas where you have deficiencies and describe how you will obtain additional training in each area.
  o 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
  o 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
  o Explain how you will benefit from the K12 program and how it will contribute to your career in multidisciplinary clinical and translational research.
  o Comment on the leadership role you expect to play in your department in 5-10 years.
**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 2.

**NIH BIOSKETCHES** (New NIH Format)

You must upload NIH formatted biosketches of yourself, your primary mentor, and everyone else who is on your Mentor Team. Please note this should be the new biosketch (5 pages).

Biosketch instructions and sample can be found here: [http://grants.nih.gov/grants/funding/424/SF424R-R_biosketchsample_VerC.docx](http://grants.nih.gov/grants/funding/424/SF424R-R_biosketchsample_VerC.docx)

Biosketch format page can be found here: [http://grants.nih.gov/grants/funding/424/SF424R-R_biosketch_VerC.docx](http://grants.nih.gov/grants/funding/424/SF424R-R_biosketch_VerC.docx)

**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 protected research time, and 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
Bonnie Martin-Harris, PhD
Medical University of South Carolina
125 Doughty Street, Suite 140
MSC 195
Charleston, SC 29425-0195

Please see table above for uploading into AppSite.
In addition to the candidate’s letters of support, three additional signatures are required (including the Primary Mentor, Department Chair, and Candidate) signifying an understanding and commitment to the SCTR K12 program if the candidate is awarded.

**Signature: Primary Mentor**

As the Primary Mentor, I have read the potential scholar’s K12 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 K12 Mentor Expectations on pages 4-5 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 listed previously.

___________________________________  __________________
Signature of Primary Mentor  Date

**Signature: Department Chair Committing Protected Time**

This individual is qualified for this program and will receive immediate priority for clinic 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 40% protected time. I understand that this is a two year award with a possible third contingent upon satisfactory progress.

___________________________________  __________________
Signature of Department Chair  Date

**Signature: 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 K12 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.

___________________________________  __________________
Signature of Applicant/Candidate  Date