SCTR TL1 (T32) Pre-doctoral Clinical & Translational Research Training Program
Request for Applications

KEY DATES
RFA Release Date: April 1, 2019
Application Deadline: July 3, 2019
Appointment Date: Sept 1, 2019

OVERVIEW
The NIH-funded pre-doctoral training program is designed to increase the number of well-trained translational researchers and is tailored for PhD and dual degree candidates with a strong interest in pursuing a career in clinical and/or translational research. The TL1 program aims to address pipeline issues by stimulating interest from doctoral students in health- and disease-related disciplines who will become future leaders in clinical and/or translational research. The program will provide early exposure to clinical and translational research methodology through experiential training opportunities, instructive coursework and the application of team science and cutting edge technology. Trainees will have rigorous research experiences and a complementary didactic curriculum.

TL1 trainees pursue research training on a full-time basis, defined by NIH as a minimum of 40 hours per week, devoting 100% time and effort. Appointments are for 12 months with an option for a second year. Trainees may not work outside of their research area.

KEY PERSONNEL
Principal Investigator: Perry V Halushka, PhD, MD
Associate Principal Investigator: Carol Feghali-Bostwick, PhD
TL1 Program Manager: Diana Lee-Chavarria
TL1 Program Coordinator: Carissa Hasseler

Please contact Carissa Hasseler (hasseler@musc.edu) as soon as you decide to proceed with an application. You will be invited to a question and answer session held by the Program on May 6.
Visit the TL1 Website

TL1 BENEFITS
- Mentored exposure to clinical and translational research methodology and team science
- Research Funding
  - Stipend support at the NRSA-established rate for pre-doctoral trainees. Mentors are required to supplement the trainee’s stipend up to the amount required by their respective colleges.
  - Tuition Support (Fall & Spring Only)
  - Up to $4,200 for research/training-related expenses
  - Up to $1,500 for travel to the Association for Clinical and Translational Science (ACTS) national meeting and a visit to Capitol Hill
- Access to SCTR/OCR research support and staff, including, but not limited to:
  - SUCCESS Center consults - research navigation, biostatistics, recruitment, REDCap, regulatory, grants forms and budgets, research opportunities and development
- Protocol development – regulatory review, Prospective Reimbursement Analysis construction, NIH Public Access compliance (publications in PubMed Central)
- Customized Individual Development Plan (IDP) to help guide your research career development
- Real-world clinical experience working alongside a physician-scientist seeing patients with the medical condition you are researching in your laboratory (Translational Sciences Clinic)
- Support with writing a competitive fellowship grant application
- Learn how discoveries are disseminated into improved health care
ELIGIBILITY

Degree Requirements: Students must have received a baccalaureate degree by the appointment start date and be enrolled in a program leading to a PhD or a combined degree program. The TL1 is designed for students with a strong interest in clinical and/or translational research, and who have prior research experience. The TL1 is not designed for individuals completing a professional clinical degree only (e.g., MD, DMD, DPT, PharmD, DNP). Individuals who have been previously awarded a doctoral degree are not eligible for this program. Individuals currently supported by other federal funds cannot be concurrently awarded a TL1 trainee appointment; however, they may be eligible to apply to the TL1 program if other federal funding is terminated by August 31, 2019.

Time Commitment: Trainees must commit 100% effort to the TL1 program and their dissertation research – no exceptions, per federal NRSA guidelines. Appointed TL1 Trainees are not allowed to simultaneously hold another appointment or position and must maintain the appointment during the entire award period. Vacation time follows the NIH guidelines. Trainees are not required to perform additional services for the graduate student fellowship stipend beyond normally required coursework and/or research activities.

Citizenship Status: At the time of appointment to the training program, selected individuals must be citizens or non-citizen nationals of the United States, or have been lawfully admitted to the United States for permanent residence and have in their possession a Permanent Resident Card (USCIS Form I-551) or other legal verification of such status. Non-citizen nationals are persons born in lands that are not states but are under U.S. sovereignty, jurisdiction, or administration (e.g., American Samoa). Individuals on temporary or student visas are not eligible for NRSA support.

Training Support: Appointment to the TL1 program is for a period of 1 year with the potential for a second year pending satisfactory progress. No individual trainee may receive more than 5 years of aggregate NRSA support at the pre-doctoral level.

Current TL1 trainees: Current trainees are eligible to compete for a second year of support as long as their anticipated graduation date is after June 30, 2020. However, they must submit a current TL1 progress report as part of their application as defined under “Application Documents”.

Trainees from all disciplines (pre-clinical, clinical and translational) are welcome to apply. Individuals from underrepresented groups, from disadvantaged backgrounds, and/or with disabilities are strongly encouraged to apply.

REQUIREMENTS

A. Trainee Requirements

TL1 trainees will fulfill the didactic and career development requirements, as well as programmatic requirements outlined in the tables below, in addition to requirements of their respective colleges/programs. The use of a trainee’s specific college requirements to satisfy TL1 programmatic requirements will be determined on an individual basis. TL1 Trainees must remain in good academic standing (minimum cumulative grade point average of 3.00) while making reasonable progress toward the graduate degree.

<table>
<thead>
<tr>
<th>Didactic &amp; Career Development Requirements</th>
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<tbody>
<tr>
<td>Essentials of Scientific Practice III (CGS 712)</td>
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<td>Translational Medicine Seminars (CGS 716)</td>
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<td>Designing Rigorous Research (CGS 727)</td>
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<td>Principals, Practices, and Professionalism (CGS 770)</td>
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<td>Present Research at Translational Research Day</td>
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<td>Present Research at Perry V. Halushka Student Research Day</td>
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<td>Annual Mentorship Training Symposium</td>
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<td>Online Team Science Course (MCR 752)</td>
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<td>Translational Research Journal Club (CGS 805)</td>
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<td>Translational Science Clinic (CGS 871)</td>
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<td>Month in the Research Nexus (CGS 832)</td>
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<td>Present Research at SCTR All Staff Meeting</td>
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<td>Career Development Conference (1)</td>
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Programmatic Requirements

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<tr>
<th>Attend TL1 Orientation &amp; Complete its Requirements</th>
<th>Cite TL1 Grant on all TL1 Funded Projects (2)</th>
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<tr>
<td>Attend Quarterly Program Meetings</td>
<td>Complete Individual Development Plan</td>
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<tr>
<td>Complete Appointment &amp; Closeout Documents</td>
<td>Complete Annual NIH Progress Report Documents</td>
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</table>

1. First year TL1 trainees will be required to attend the ACTS (Association for Clinical and Translational Science) national meeting in Washington, DC. Second year trainees may identify a national meeting at which to present their work. The abstract must be approved by the mentor and TL1 leadership prior to submission and TL1 funds will only cover the expenses of the meeting if the abstract is accepted.

2. Any publications that are produced during the award year or future publications related to the TL1 funded project must cite the grant support of the TL1 award and follow the NIH public access policy. Trainees are expected to have at least one first author publication upon completion of the requirements for their PhD degree.

3. As part of NIH reporting requirements, recipients of the TL1 must comply with yearly information requests for 15 years upon completion of their award (even after departure from MUSC). This request consists of a brief annual survey and current curriculum vitae/biosketch.

B. Mentor Requirements

It is expected that the applicant will identify a mentor in their area of research interest who is likely to be a member of the faculty in the applicant’s unit. Under guidance and editing from the mentor, the applicant will further develop their proposal that describes the research project to be undertaken. Mentors and Trainees will read and sign the AAMC *Compact between Biomedical Graduate Students and Their Research Advisors*, paying special attention to the Commitments of Graduate Students and Commitments of Research Advisors. **The mentor must have independent funding for the duration of the applicant's TL1 appointment and for future years to cover the anticipated time for completion of the PhD degree.**

The mentor (or each co-mentor) is responsible for:

- Guiding and encouraging the design and execution of an original, high quality, dissertation research project.

- Guidance for the following activities and documents, including but not limited to:
  1. Initial TL1 application
  2. Individual Development Plan (IDP)
  3. Progress reports
  4. Manuscripts
  5. Abstracts/Posters
  6. Presentations
  7. TL1 Journal Club

- Providing career development and counseling by assisting trainee to apply for post-TL1 funding.

- Including the TL1 trainee as an author and cite the SCTR TL1 grant and UL1 on all relevant publications, posters, and presentations:
  “The project described was supported by the NIH National Center for Advancing Translational Sciences (NCATS) through Grant Numbers TL1 TR001451 and UL1 TR001450.”

   This includes ensuring that the research performed by a mentee is submitted for publication in a timely manner and that she/he receives 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.

- Meeting with trainee regularly (weekly at minimum) and attend required meetings/activities organized by SCTR Institute.
Quality mentorship is fundamental to the future success of junior faculty, influencing trainees’ productivity in research, career satisfaction, informed career decision-making, networking within the profession, and career trajectory. In addition to the responsibilities listed above, mentors agree to the following:

- Ensure that the projected time supported by the award is being met.
- Promote all ethical standards for conducting research including compliance with all institutional and federal regulations as they relate to responsible conduct in research, training in rigor, reproducibility and transparency, privacy and human subjects research, animal care and use, laboratory safety, and use of radioisotopes. Mentor will clearly define expectations for conduct of research and be available to discuss ethical concerns as they arise.
- Ensure that the mentee has sufficient opportunities to acquire the skills necessary to become an expert in an agreed upon area of investigation.
- Seek the assistance of other faculty and departmental / institutional resources when necessary.
- 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.
- Commit to being a supportive colleague to trainees as they transition into the next stage of their career and to the extent possible, throughout their professional life.
- Take training and development opportunities to enhance one’s own skills. Attend SCTR’s Annual Mentorship Training Symposium. Additional opportunities include SOCRATES/B&BS (held twice monthly) and the online Mentor Training Program: Optimizing the Practice of Mentoring through the University of Minnesota's CTSA (free) [UM CTSI Professional Development Course](#).

TL1 APPLICATION INSTRUCTIONS

Please read these instructions carefully before beginning your application. The entire application package must be successfully submitted by July 3, 2019 @ 5:00PM via the SCTR InfoReady portal.

Questions? Please contact Carissa Hasseler, TL1 Program Coordinator, at hasseler@musc.edu.

INCOMPLETE AND/OR LATE APPLICATIONS WILL NOT BE ACCEPTED FOR ANY REASON.

A. Selection Criteria

TL1 trainees will be selected based on a competitive application process in which the applicant’s qualifications and potential to pursue a successful translational research career will be reviewed. Scientists who are familiar with the area of study, the TL1 Program Directors, and members of the TL1 steering committee will review each application. Reviewers provide a score using the NIH 9-point scale and a written critique. All applicants will receive the reviewers’ comments for their applications.

The TL1 Executive Committee will review the applications with the highest priority scores to select the trainees. If necessary, applicants with competitive applications may be interviewed before a final decision is given.

B. Important Information

Stipends: Trainees receive stipends related to their academic programs. They do not render services for pay, and therefore are not considered employees and are not eligible to pay into the state retirement system, nor will they accrue vacation, or service credits for the length of the award period. Monthly stipends for fellowships may be subject to federal, state and local taxes. Depending on a fellow’s residency status, their taxes may or may not be withheld from their stipend. Questions regarding taxes on stipends should be directed to Redell Sherrill, SCTR Business Office, 843-792-8250, or sherrillr@musc.edu.

All candidates MUST submit a SPARC Request to get a Study 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 TL1 Predoctoral Research Training Program” from the opportunities listed
5) Select “Add” to submit SPARC Request
6) Click on “Show Details” for a link to the application portal

C. Application Document Requirements

- **Format**: All documents must be submitted as PDF files
- **Font**: Arial, no smaller than 11-point
- **Margins**: one inch (1”) on all sides

<table>
<thead>
<tr>
<th>Application Documents</th>
<th>Page Limit</th>
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<tbody>
<tr>
<td>Applicant NIH Biosketch</td>
<td>5 pages</td>
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<tr>
<td>Fellowship Biosketch</td>
<td></td>
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<tr>
<td>Applicant CV</td>
<td>No Limit</td>
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<tr>
<td>Include:</td>
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<tr>
<td>• Personal home address &amp; email address</td>
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<tr>
<td>• Undergraduate and graduate academic degree(s), including institution(s), major(s), degree(s) and year(s) awarded</td>
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<td>• Current MUSC academic degree program(s), month/year of program entry, courses taken, current GPA, and anticipated graduation date</td>
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<td>• Date/score of PhD qualifying exam – if you have not taken the exam, please include the month/year you expect to take it</td>
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<td>• Comprehensive list of publications to date in APA format</td>
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<td>• Indication of previous federal funding (eg. NIH, NRSA, CDC, etc.)</td>
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<tr>
<td>Primary Mentor NIH Biosketch &amp; Training Table</td>
<td>5 pages &amp; No Limit</td>
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<tr>
<td>Undergraduate/Graduate Research Experience</td>
<td>No Limit</td>
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<tr>
<td>• Description of undergraduate and graduate research experiences.</td>
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<tr>
<td>Career Development Plan</td>
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<tr>
<td>The TL1 Required Career Development Activities are defined in the table above under trainee requirements. Use this list, and other training opportunities to describe:</td>
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<td>• Areas/skills in which further development is needed for the applicant</td>
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<td>• How the applicant will gain skills, knowledge, and experience in clinical and translational research through the TL1 program</td>
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<td>As appropriate to the applicant’s background and experience, describe:</td>
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<td>• Learning expectations from mentored research experience, and structured activities such as coursework or workshops</td>
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<td>• It is important to discuss anticipated training and research enhancement from the TL1 program compared to training without the award.</td>
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<tr>
<td>Research Plan</td>
<td>3 pages</td>
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<td>• Title of the proposed project</td>
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<td>• <strong>Statement of the Research Problem</strong>: This should be an introductory section that places the problem in context in the field. A number of key references should be cited to provide scholarly background. From this section, the readers should be able to determine why it is of interest to examine the proposed problem.</td>
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<tr>
<td>• <strong>Specific Aims of the Project</strong>: An outline that lists the individual experimental</td>
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issues that are to be addressed.

- **Methods**: A somewhat detailed description of the experimental system to be examined, the materials available, procedures to be employed, expertise available in the sponsor lab, and the rationale for the design of the project. From this section, the readers should be able to determine how the data to be gathered will help solve the problem identified. The reviewers should also be able to assess feasibility of the proposal in both terms of experimental design and time frame for completion.

- **Bibliography**: Does not count toward 3 page limit

7 **Letters of Support**

Address to Perry Halushka, PhD, MD (TL1 Principal Investigator) and Carol Feghali-Bostwick, PhD (TL1 Associate Principal Investigator). Upload to the SCTR InfoReady portal as part of your application package: do not send via email, hand delivery or interoffice mail.

**Primary Mentor**

- Describe applicant’s research focus
- Describe the goals and how the mentor will foster an environment conducive to a successful clinical and/or translational career path for the mentee
- Describe additional resources/experiences the mentor might contribute during the candidate’s appointment, to enhance their training and research agenda

**Additional Mentors** (if applicable)

- Include letters from any secondary or co-mentors which should also address the above

**Department or Division Chair**

- Should speak to the applicant’s academic and research potential
- Discuss any resources the department/division will contribute to support their research and career development goals
- Confirm that they will not hold any additional positions or awards during their time on the TL1

8 **Essay of Interest in TL1 Program (trainees applying for their first year only)**

- Describe interest in becoming a member of the TL1 program and career goals

9 **TL1 Requirement Agreement Form**

- The agreement form at the end of this document should be signed by the applicant, mentor, and any co-mentors involved in the project. This indicates agreement to all terms outlined in the RFA.

10 **Progress Report (trainees applying for a second year only)**

To be submitted by current TL1 trainees requesting a second year of funding.

- Update on completed TL1 requirements to date
- Update on progress of project
- Publications, abstracts, and presentations that have been submitted and/or accepted as a result of the TL1-funded project
- Any planned publications, abstracts, and presentations and when they will be submitted
- Demonstrate the need for a second year and describe the timeline for completing the project
- Describe how the first year of the TL1 program has influenced career goals with regard to team science and clinical and translational research
- Since second year trainees are not required to attend ACTS, identify a national meeting in which work will be presented
TL1 REQUIREMENT AGREEMENT FORM

ALL PARTIES AGREE AS FOLLOWS

Cite the TL1 grant for any publications, posters, and presentations the trainee completes during and after their award relating to their research project and any work the trainee completes in their mentor’s lab/department.

“The project described was supported by the NIH National Center for Advancing Translational Sciences (NCATS) through Grant Numbers TL1 TR001451 and UL1 TR001450”

APPLICANT SIGNATURE

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 TL1 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.

Applicant Signature

Date

As Mentor(s), I take responsibility in:

• Guiding and encouraging the design and execution of an original, high quality dissertation research project.
• Guidance for these documents to include but not limited to:
  1) Initial TL1 application
  2) Individual Development Plan
  3) Semi-Annual/Final progress reports
  4) Manuscripts
  5) Abstracts/Posters
  6) Presentations
  7) TL1 Journal Club: attend one session per semester (per TL1 mentee) and provide feedback
• Providing career development and counseling by assisting trainee to apply for subsequent funding post TL1 funding.
• Providing data for the annual NIH SCTR report (December 2019)
• Including the trainee as an author - and citing the SCTR TL1 grant - on all relevant publications, posters, and presentations.
• Reading, reviewing, and complying with the AAMC Compact between Biomedical Graduate Students and Their Research Advisors.

I/We read the potential trainee’s TL1 application package and provided constructive feedback, both for the career/training components and the research plan. To the maximum extent possible, I/We will meet regularly with the trainee (at least bi-weekly), attend TL1 semi-annual progress meetings with TL1 leadership, ensure that all the requirements of the TL1 program are met and attend the annual SCTR Mentorship Training Symposium.

MENTOR SIGNATURE(s)

Primary Mentor Signature

Date

Co-Mentor Signature (if applicable)

Date