

**South Carolina Clinical & Translational Research Institute (SCTR) &  
MUSC Foundation for Research Development  
Request for Applications (RFA) for Technology Development Grants  
2019-2020 Funding Cycle**

**RFA Release Date: December 17, 2019**

**OVERVIEW**

SCTR's Therapeutics Translation Core (TTC), in conjunction with the MUSC Foundation for Research Development (FRD) and the MUSC Drug Discovery Core, aims to accelerate academic innovations into marketed products by providing gap funding of up to \$25,000 to advance innovative, clinically relevant technologies. The awards support short-term (six month) studies designed to improve the commercial value of the technologies by strengthening the intellectual property (IP) and moving technologies further down the development pathway, thus increasing the partnerships and licensing opportunities with pharmaceutical and biotechnology companies.

The primary objective of the gap funding awards is to support projects that have a high chance of being commercialized, but that are not likely to get there without gap funding. Funds are intended to **advance projects to the next developmental milestone** by enabling investigators to conduct additional experiments, such as those that

- Optimize compounds, conduct toxicology studies, or help define a pharmacological target or translational biomarker
- Prototype a device
- Build or validate a software program

Projects to be supported and allocated budgets will be determined through applications reviewed by an external review board (ERB), TTC leadership, and FRD.

This RFA is open to advance **technologies protected by, or protectable by, IP that is assigned or assignable to MUSC pursuant the MUSC IP Policy**. If a patent or patent application is not currently assigned to FRD, a Record of Invention must be on file with FRD at least one month in advance of the open date.

Projects are expected to be completed in the allotted six-month timeframe.

**KEY DATES**

**CYCLE 1**

Pre-Application Opens: June 7, 2019  
Pre-Application Due: July 3, 2019  
Invitation to Submit Full Application:  
July 19, 2019  
Full Application Due: Aug 2, 2019  
Notice of Award: Aug 21, 2019

**CYCLE 2**

Pre-Application Opens: Dec 17, 2019  
Pre-Application Due: Jan 15, 2020  
Invitation to Submit Full Application:  
Jan 31, 2020  
Full Application Due: Feb 14, 2020  
Notice of Award: Mar 9, 2020

## PROGRAM ELIGIBILITY

### Investigators

- Principal Investigators (PI) may serve as the PI of only one application or SCTR-funded award at any given time, with the exception of a voucher.
- Co-Investigators (Co-I) should have helped conceive of the experimental idea, contributed to the intellectual development of the concept, and/or designed the study or part thereof (scientific or technical details).
- NIH biosketches for all investigators are required in the **new 5-page format** (General Biographical Sketch Format Page – Forms Version C). DO NOT use the PDF fillable form, you must use the MS WORD form and convert the document to a PDF as the fillable forms are not compatible with the application system.

<http://grants.nih.gov/grants/funding/424/index.htm#format>

### Consultants

- Please include consultant(s) names and their roles/duties in the research proposal. You do not have to include their information on the online submission form.

### Intellectual Property (IP)

- Supported technologies must be assigned or assignable to MUSC.
- Inter-institutional collaborations resulting in assignment with MUSC and one or more other universities are allowed.
- If a patent or patent application is not currently pending through FRD, a Record of Invention must be on file with FRD at least one month in advance of the Pre-application open date, such that the patentability of the technology and/or method of use can be assessed.
- Copies of any consulting agreement and/or MTA related to the technology or materials used in the proposed study must be provided with the application.
- Technologies licensed or optioned to a startup are eligible for funding, so long as the IP is assigned or assignable to MUSC. Please note that the gap funds will be given to the MUSC PI as a traditional grant and not to the company.

### Research Aims

- Fundamental discovery, such as elucidation of novel targets, is not fundable under the gap fund award mechanism. Disease pathways are not patentable substances, even if a novel target is identified, and studies focused on such are not supported. However, studies aiming to understand how a *patentable therapy* modulates a target will strengthen the IP and are eligible for funding.
- Proposals for prototyping of a medical device are encouraged. Detailed drawings of the proposed device must be included in the proposal. The proposal also must include a parts list for the proposed functioning prototype with a cost-estimate for each part. If awarded, the PI's role will be to determine the specifications for the prototype. The outsourcing of prototyping will be managed by FRD.
- The aims specified by the application must be distinguishable from those funded by other grants.

## BUDGET AND ALLOWABLE COSTS

- **Faculty Salary Support.** Salary and fringe benefits are not allowable budget items for faculty.
- **Effort Reporting.** For federal/institutional compliance purposes, it is PI's responsibility to make sure all the investigators efforts listed in the budget are in compliance with their institutional effort policy.
- Please note that investigators are not required to accommodate their efforts on the project budget. However, they have to be in compliance with their respective institution's effort policy should they choose to charge the effort to other funding sources.
- In compliance with the MUSC effort policy, MUSC PIs who plan to charge investigators' efforts to other funding sources will have to provide the appropriate UDAKs during the Just-in-Time period. Please note that "other sponsored projects" or "in-kind support" cannot be used to cover the efforts.
- **Other Personnel Support.** Salary and fringe benefits are allowed for technical support, such as; Research Fellows, Research Assistants/Coordinators, Research Nurses, etc. Please confirm fringe benefit rates on your respective institution's Sponsored Awards Office website.
- **Students.** The SCTR gap funds cannot be used to cover student tuition, fees or health insurance costs in any way, directly or indirectly as a stipend.
- **Ancillary Personnel.** Salary support for ancillary personnel, such as Mentors, Secretaries, and Administrative Assistants, is not allowed.
- **Non-personnel Research Expenses.** Some allowable expenses are: supplies, equipment (under limited circumstances), animal purchase cost and care, study subject stipends, study subject transportation costs, in- and out-patient care costs, and statistical and computational services including personnel and computer time. All expenses must be directly related to the proposed research.
- **Unallowable costs.** General office supplies and equipment, computers and laptops (unless specifically requested and justified), membership dues and fees, traveling costs to meetings, publication and subscription costs, mailing costs and rent.
- **Facilities & Administrative (Overhead/Indirect) Costs.** Facilities and administrative costs, also known as indirect/overhead costs, are not permitted.
- **Subawards.** Please indicate potential subaward(s) to other institutions clearly on the budget. No signed documents from subaward institution(s) are needed at the time of application submission. The SCTR Finance Office will work with PIs and their Business Managers to establish subawards once an application is approved for funding.
- **Business Manager Responsibilities.** PI's Department/Division Business Manager shall be responsible for all human resource, procurement and reconciliation activities for the funded project account(s).

## AWARD DETAILS

- Gap funding cannot be released until all required regulatory documents have been approved and copies submitted to SCTR via a REDCap Survey during the just-in-time (JIT) period. If the required documents are not available at the time of the JIT information is due, **only** those documents should be sent to the SCTR office to Michael Watson at [watsomic@musc.edu](mailto:watsomic@musc.edu). Please note that the TTC will continue to follow longitudinal progress of the technology. Progress reports are due at 3-month intervals while the project is active. Brief annual progress follow-ups are due for 5 years after project closing for NIH reporting.
- By accepting SCTR funds and support, you agree to cite the National Institute of Health's (NIH) National Center for Advancing Translational Sciences' (NCATS) grant support in each publication, press release or any other document(s) and presentations similar to the following. **The grant number is: UL1TR001450.**
- Technologies advanced with gap funding awards are subject to Bayh-Dole provisions. <http://grants.nih.gov/grants/bayh-dole.htm>

## THE APPLICATION PROCESS

- Applications are submitted through the SCTR Pilot Project website. [http://academicdepartments.musc.edu/sctr/programs/pilot\\_projects](http://academicdepartments.musc.edu/sctr/programs/pilot_projects)
- Incomplete or late applications will not be reviewed.
- Investigators without an eRACommons user name should enter "N/A" in the appropriate box on the online application.
- See the instructions for the Pre-Application and the Full Application at the end of this document for content and formatting instructions.

## APPLICATION REVIEW CRITERIA AND PROCESS

### Overview

Applications will be reviewed by a panel assembled by TTC leadership. The panel will be composed of member from an external review board (ERB), TTC leadership, and FRD.

### Review Criteria

Applications will be assessed to determine the impact that the gap funding will have on:

- Advancing a technology to the next developmental milestone
- Attracting commercial interest in the technology
- Attracting additional development funding for the technology
- Strengthening the related patent application
- Allowing a go/no-go decision to be made on future development

Additionally, work proposed in the application will be reviewed

- Likely completion of the study within 6-month timeframe
- Appropriateness of the proposed budget expenditures with respect to the development plan for the technology

## EMAIL QUESTIONS TO

Michael Watson at [watsomic@musc.edu](mailto:watsomic@musc.edu)

## PRE-APPLICATION INSTRUCTIONS

**PIs are REQUIRED to submit a pre-application. The TTC will review the pre-application and invite only selected applicants to submit full applications.**

## FOR ALL DOCUMENTS

<b>Font Type and Size</b>	Arial, 11pt.
<b>Page Margins</b>	No less than 0.5" on all sides (one-halfinch)
<b>Document Type</b>	PDF

**The pre-application consists of three uploads:**

- 1) Each investigator's biosketch in the **new 5-page NIH biosketch format\***
- 2) Project Summary and Relevance, 1-page limit
- 3) Pre-proposal Page: 1-page limit

\*(REMINDER: do not use the PDF fillable form, you must use the MS WORD form and convert it to a PDF in order for the system to accept your application)

## Special Online Application Instructions

Application Link: [http://academicdepartments.musc.edu/sctr/programs/pilot\\_projects](http://academicdepartments.musc.edu/sctr/programs/pilot_projects)

Reminder: Investigators without an eRA Commons ID, enter "N/A" same for Middle Initial  
For the Project Information section of the application form, please:

- Begin your project title with the words "TECH FUND – [then enter your projecttitle]"
- For the question, "Is this a Translational Roadblock Application?," select "No" from the dropdown list

## Project Summary and Relevance (1-page limit)

*Upload in the "Upload Description" box at the bottom of the online application*

- This section should serve as a succinct and accurate description of the technology and the milestone to be achieved with the gap funding award. Describe the current state of the art and limitations thereof and the state of the IP for the subject technology. This section should be informative to others working in the same or related fields and understandable to a scientifically or technically literate reader.

## Pre-proposal Page (1-page limit)

*Upload in the "Upload Pre-proposal" box at the bottom of the online application*

- Brief description of the aims and the research design and methods for achieving the stated goals. Include each team member's name and role; how the study will advance the technology to the next development milestone and what criteria will be used for determining a successful outcome; plans/potential to secure future extramural funding including funding agency and mechanism (SBIR, STTR, other) or companies who may be interested in the technology.
- The project budget should be reported, but does not need to be justified. Justification will be required in the full application.
- Literature Cited should be included at the end of the Research Proposal and is not counted towards the Research Proposal page limit.

## FULL APPLICATION INSTRUCTIONS

### For Investigators Invited to Submit Full Applications

#### The Full Application consists of four uploads:

- 1) Each investigator's biosketch in the **new 5-page limit NIH biosketch format\***
- 2) Project Summary and Relevance, 1-page limit
- 3) Budget and Justification: PHS 398 format\*
- 4) Research Proposal, 5-page limit

\*(REMINDER: do not use the PDF fillable form, you must use the MS WORD form and convert it to a PDF in order for the system to accept your application)

#### Project Description (1-page limit)

- Please submit the Project Summary and Relevance included in the pre-application packet.

#### Budget and Justification

- Applicants must use the PHS 398 Form Page 4 (MS WORD version – converted to PDF): Detailed Budget for Initial Budget Period for the budget page, and use the Continuation Format Page for the budget justification. Each budget line item must be clearly justified. **Combine your budget and justification into a single PDF file** to submit via the online application.

<http://grants.nih.gov/grants/funding/phs398/phs398.html>

#### Research Proposal (5-page limit, combined into a single PDF file)

- **Specific Aims** should state concisely the goals of the proposed study and summarize the expected outcome(s) including the impact that the results of the proposed research will exert on the development of the technology.
- Provide a **Research Strategy** section that is informative enough for reviewers to understand the proposed research without any supporting documents. Describe how the study will advance the technology to the next development milestone, what criteria will be used for determining a successful outcome, and the commercial significance of such criteria. Be sure to explain the roles/duties of each team member.
- **Patentability:** Investigators must describe and provide citations of the closest known related technology or use thereof.
- **Freedom-to-operate:** Investigators must note whether they are aware of any patents covering all or part of their technology. As examples:
  - If the technology is a combination drug therapy, investigators must note whether one or both drugs are patented, in clinical trials, or sold by another company.
  - If any part of the technology is patented by another university, even if the investigator is the named inventor.
- **Literature Cited** should be included at the end of the Research Proposal and is not counted towards the Research Proposal page limit.