



## **Request for Proposals**

# **South Carolina Medical Translational Technology Program**

**April 3, 2013**

**This Request for Proposals is a revision of one that was released on March 4, 2013.**

This Request for Proposals (RFP) solicits applications for competitive research awards to develop innovative clinically-relevant technologies (devices, materials, processes, or approaches) and to rapidly transfer the advances to healthcare applications. The awards support short-term (six months to one year) collaborative research aimed at demonstrating technical feasibility and high potential for commercialization of novel technologies which will improve patient care. The following text provides information about the program, research objectives and scope, types of awards, application procedures, important dates, and contact information.

### **SC MedTransTech Program**

The South Carolina Medical Translational Technology (SC MedTransTech) Program is a partnership of academic, healthcare, and industry organizations aimed at enabling biomedical innovation (discovery put to use) and accelerating the transfer of resulting advances to the patient community. Current partners include (1) the academic and research universities of the South Carolina Bioengineering Alliance (SCBA - Clemson University, the Medical University of South Carolina, and the University of South Carolina); (2) six South Carolina hospitals and surgery/diagnostic centers (Anderson Medical Health System, Bon Secours St. Francis Health System, Greenville Hospital System, Medical University of South Carolina, Oconee Medical Center, and Palmetto Health); and (3) Stryker Corporation (a leading international medical technology and device manufacturer). The Program is governed by a Master Service Agreement executed on August 21, 2009; administered by the SCBA (<http://scba.musc.edu>); overseen by an Advisory Council that includes representatives from all participating organizations; and implemented by a Steering Committee which consists of representatives of the Alliance universities and Stryker Corporation. The Program Administrator is Dr. Richard Swaja, Director of the South Carolina Bioengineering Alliance.

## **Research Objectives and Scope**

The primary objectives of research projects funded by the SC MedTransTech Program are to (1) develop novel medical advances that address clinical needs and will improve healthcare delivery, (2) demonstrate technical feasibility and potential for commercialization, and (3) accelerate the transfer of the advances to the patient community through interactions with industry and technology transfer offices.

Research projects can focus on devices, processes, materials, procedures, or approaches, and must have the following characteristics:

1. Clinical relevance and impact– The projects must be clinically-driven and address healthcare problems or needs that will improve patient care.
2. Innovative – Resulting advances are expected to include a unique component towards the creation of new intellectual property without being limited by prior inventions.
3. Scientifically and clinically feasible – Proposed projects or studies must be doable in a short time frame (six months to one year) and have access to resources to conduct the proposed effort.
4. Collaborative – Research projects or studies must be conducted by teams that include at least one member from a participating healthcare organization and at least one member from a Bioengineering Alliance university.
5. Commercializable – Resulting advances must have (1) a high potential for rapid (2-3 year) transfer to the patient community and (2) a plan for commercialization or distribution of the study outcomes. When appropriate, interaction with the principal investigator’s technology transfer office is expected throughout the effort.

Applications which relate to the following research areas and medical applications will be given priority consideration for this RFP:

1. Orthobiologic treatments or instruments that leverage the body’s resources and healing potential to treat musculoskeletal diseases (e.g., meniscus fixation repair).
2. Collagen-based products to repair tissues such as dura, nerve, skin (wound), or tendon.
3. Treatments, therapies, or approaches that expand the continuum of care such as earlier, less invasive, and less traumatic intervention for orthopaedic and/or neurosurgical patients.
4. Investigator-initiated clinical studies on medical outcomes and economics – Studies that demonstrate the benefits of a clinical approach, patient flow logistics, product application, cost reduction, and efficiencies in delivery of care and surgery, and/or impact on medical economics. Of particular interest are studies of bone void fillers for trauma and extremities, surgical hemostats, and bone anchors for shoulder tissue repair and stability.

## **Types of Awards and Funding Limits**

This RFP supports two types of awards:

1. Regular – One-year grants for up to \$ 100,000 direct costs. Funding extensions are possible depending on progress and promise as determined by the Advisory Council.
2. Fast Track – Six month grants for up to \$ 50,000 direct costs for projects that are close to proof of feasibility and have a high potential for short-term commercialization.

Indirect costs are not covered by either of these awards. In accordance with the Master Service Agreement, participating institutions have agreed to waive the collection of indirect funds for SC MedTransTech grants.

The number of awards is contingent on the availability of funds and the merit of the proposals.

### **Eligibility**

Projects must be conducted by teams which include at least (1) one investigator from a Bioengineering Alliance institution (Clemson, MUSC, or USC) and (2) one healthcare provider (clinician, nurse, therapist, etc.) or health systems staff member who is employed by or affiliated with a participating SC MedTransTech clinical partner (Anderson Medical Health System, Bon Secours St. Francis Health System, Greenville Hospital System, Medical University of South Carolina, Oconee Medical Center, and Palmetto Health).

For full proposed statements of work, research team participants must be certified as appropriate and eligible by the lead investigator and lead (i.e., the organization that will receive the funding) and partner institutions' research officials (e.g., Vice President for Research, Research Director, etc.). Certification of investigator eligibility is indicated by their signatures at the bottom of the cover page of the proposed statement of work as described in the "Proposed Statement of Work" section of this RFP. Proposed statements of work that do not have these signatures will not be considered. These certifications are not needed for letters of intent.

Eligibility issues will be addressed by the Advisory Council which consists of representatives of Alliance universities, partner hospitals, and Stryker Corporation.

### **Important Dates (2013)**

April 17 – Letters of intent due by close of business

May 24 – Notification of applicants to proceed with proposed statement of work

July 12 – Statement of work due by close of business

August 16 (Target) – Notification of awards

September 27 (Target) – Distribution of grants to awarded organizations

### **Letter of Intent**

Both options require an initial letter of intent which will be evaluated by the Steering Committee with regard to program relevance and potential for success in accordance with the "Research

Objectives and Scope” section of this RFP. Letters of intent should emphasize the problem being addressed and goal of the project, clinical relevance, scientific feasibility in a six-month or one-year time frame, and potential for rapid commercialization.

Letters of intent must not exceed one page (single space, 12 point, Times New Roman), skip a space between major section headings, and must include the following information and section headings:

1. Type “REGULAR” or “FAST TRACK” at the center of the top of the page to indicate which award type is desired.
2. TITLE - Title of project
3. RESEARCH TEAM - The name, affiliation, and contact information for the lead investigator; and the names and affiliations of the co-investigators.
4. ABSTRACT - A one paragraph summary that describes the healthcare problem being addressed, the general approach, the goal of the research or study, the impact of the results, and the potential for commercialization or diffusion of the study outcomes.

Letters of intent must be sent in pdf format to [scba@musc.edu](mailto:scba@musc.edu) by close of business on April 17, 2013. Review comments will not be transmitted to applicants. Approval by the Steering Committee is necessary for the applicant to proceed with a proposed statement of work. Applicants will be notified whether or not to prepare a proposed statement of work by close of business on May 24, 2013.

### **Proposed Statement of Work**

After notification of approval by the Steering Committee, the proposed statement of work must be prepared in the following format (cover page and section headings) using single space, 12 point, Times New Roman type. Skip a space between major section headings given below. The total proposal must not exceed five pages including the cover page.

Cover page – A one-page cover page must be prepared with the following headings and information:

1. Type “REGULAR” or “FAST TRACK” at the center of the top of the cover page to indicate which award type is desired.
2. TITLE - Project title
3. LEAD INVESTIGATOR – Name, title, affiliation, and contact information
4. RESEARCH TEAM - Co-investigators and affiliations
5. ACKNOWLEDGEMENT OF ELIGIBILITY AND MASTER SERVICE AGREEMENT TERMS AND CONDITIONS - After this heading, (1) the following text in italics must be included on the cover page and (2) the lead investigator and the head research officials (e.g., Vice President for Research, Research Director, etc.) of the lead and participating partner institutions must sign at the bottom of the cover page to indicate that they are aware of, have considered, are in compliance with, and accept the terms and conditions. The signatures should be above a printed name and title for the lead investigator and lead and participating institution research officials.

The following text (italics) must be printed in this section on the cover page:

*The following signatures acknowledge that the lead investigator and lead institution are aware of, have considered, are in compliance with, and accept the following eligibility, confidentiality, and right of first refusal terms and conditions of the MedTransTech program.*

*A. ELIGIBILITY – Research team participants indicated in the proposed statement of work meet the eligibility requirements specified in the Request for Proposals and are eligible to receive funds as indicated in the proposed budget;*

*B. CONFIDENTIALITY – All parties shall observe the requirements of confidentiality specified in the Master Service Agreement with regard to content of the proposed statement of work at all times including throughout the review, approval, and funding processes; and*

*C. RIGHT OF FIRST REFUSAL – Stryker Corporation will have first right to negotiate and right of first refusal for intellectual property resulting from the award. The intent will be to negotiate fair market value intellectual property terms with the participating universities and partner hospitals.*

Proposal – The proposed statement of work must be prepared with the following headings and information and must not exceed four pages.

1. TITLE – Type the project title at the top of the first page of the statement of work.
2. LEAD INVESTIGATOR – Name, title, affiliation, and contact information
3. ABSTRACT – One paragraph summary (200 words maximum) of problem, relevance, approach, and impact.
4. PROBLEM STATEMENT AND GOAL - The clinical relevance of the problem and the impact on healthcare. What do you want to accomplish by the end of the project?
5. PROJECT PLAN – How the research or study will be conducted, a timeline for the plan, milestones for progress, and criteria for success (i.e., how you will know when the project is complete).
6. COMMERCIALIZATION – Potential for rapid commercialization or diffusion of the study outcomes and plan for interacting with your technology transfer organization.
7. BUDGET – Show a total budget for the effort and component direct costs. Remember that indirect costs are not covered, the limit for a six-month fast track award is \$50,000, and the limit for a one-year regular award is \$100,000.
8. INTELLECTUAL PROPERTY –
  - A. Verify the innovative nature of the project and the freedom to operate without being limited by prior inventions.
  - B. The research team shall identify any background intellectual property that may be necessary and useful to the practice of the project.

*Although not needed for the proposed statement of work, be advised that prior to award, (1) the research team must provide written confirmation that it has secured permission to use identified background intellectual property for the project; and (2) co-investigators must provide written*

*assignment of all rights to intellectual property developed, created, conceived, or reduced to practice as part of the project to their respective participating university or partner hospital. For a third party to participate on the research team, that party must provide written assignment of all intellectual property rights to the participating university.*

The proposed statement of work must be sent in pdf format to [scba@musc.edu](mailto:scba@musc.edu) by close of business on July 12, 2013.

### **Review and Notification**

Review of proposed statements of work will be coordinated by the Steering Committee which may use external reviewers as needed and will use a NIH format to assess strengths, weaknesses, and probability for success. Criteria for review include clinical importance, impact on healthcare, scientific feasibility, quality of the research plan, potential for commercialization, and overall relevance to the program intent. Detailed review comments will not be transmitted to applicants. The Advisory Council will make final decisions on awards based on the recommendations from the review, and awards will be announced around August 16, 2013.

### **Intellectual Property**

Stryker Corporation will have first right to negotiate and right of first refusal for intellectual property (IP) resulting from these awards. The intent will be to negotiate fair market value intellectual property terms with the participating universities and partner hospitals.

### **Project Reviews and Reporting Requirements**

Awardees of a one year “regular” grant will be required to meet at least once with the Advisory Council to present their progress and plans and discuss needs and issues. Within 90 days after the end of funding, all grantees are required to submit a final written report on the project to the Program Administrator. The report should describe (1) the goals and impact of the project, (2) progress and results of the research relative to specifications in the statement of work including publications and presentations, (3) commercial and technology transfer implications and plans, (4) challenges and issues encountered during the project, (5) expenses and budget status, and (6) future plans. The principal investigator will also be asked to present results of the project to the Advisory Council.

If no final written report is received within 90 days after project completion, no future MedTransTech Program funding will be provided to the lead institution.

### **Questions**

Questions regarding the SCMedTransTech Program and this RFP must be submitted by e-mail to [scba@musc.edu](mailto:scba@musc.edu).

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