MUSC-Siemens Ultrasound Pilot Project Grant Request for Applications (RFA)

KEY DATES

RFA Release Date: December 7, 2020
Application Due: 5 PM EST, January 15, 2021
Earliest Anticipated Project Start Date: March 1st, 2021

OVERVIEW

This RFA solicits grant applications proposing novel, advanced, or enhanced **uses of Siemens ultrasound technology.** Co-sponsored by the MUSC Office of Innovation, Siemens Healthineers, and South Carolina Clinical and Translational Research (SCTR) Institute, this RFA provides one grant of up to $50,000 for a 12-month period in funding and access to Siemens technology, supporting an ultrasound-related pilot project designed to yield preliminary findings to expand clinical utility of a technology, support subsequent extramural grant applications, and/or result in joint product or service development. Clinical teams utilizing ultrasound technology are encouraged to apply. The aims specified by the application must be distinguishable from those funded by other grants.

While any potentially impactful Siemens ultrasound technology application proposal will be considered, specific priority areas include:

Siemens Healthineers ACUSON SC2000 PRIME Ultrasound System
- **Cardio-oncology:** Velocity Vector Imaging (VVI) strain quantification (for oncology or another patient group) for early detection of cardiotoxicity
- **Interventional Guidance:** Premarket collaboration "internal jugular access 4D intra-cardiac echocardiography (ICE) access for use in Trans-catheter Aortic Valve Replacement (TAVR) cases" feasibility (~15-20 patients)
- **Continuum of Care for Cardiac Valve Patients:** Pre-procedural, procedural, and follow up for TAVR, Trans-catheter Mitral Valve Replacement (TMVR), and Right Heart studies
- **True Fusion:** Structural Heart Disease (SHD) [Left Atrial Appendage Closure (LAAC), Paravalvular Leak (PVL)] studies to evaluate procedure time, fluoroscopy time, contrast usage, and outcomes

Siemens Sequoia
- **Radiology:**
  o Post gross organ transplant evaluation
  o Chronic liver disease stiffness quantification
  o Bariatric imaging – pre/post op, follow-up
  o Deep Abdominal – Technically difficult exams
  o Focal liver lesion characterization [Contrast-Enhanced Ultrasound (CEUS)]

- **Vascular:**
  o Deep/superficial venous disease (focus on technically difficult exams)
  o Atherosclerosis (pre-post intervention)
  o Abdominal vasculature (focus on technically difficult exams)
- **Pediatrics:**
  o Neonatal brain
  o Acute abdomen
  o Liver disease (stiffness qualification)
  o Sickle cell (Transcranial Doppler Imaging [TCI])
  o Vesicoureteral reflux (CEUS)

PROGRAM REQUIRMENTS:

Investigators
- Principal Investigator(s) (PI) and Co-Investigators should be full-time or part-time faculty at MUSC.
- An applicant can serve as the PI and/or Co-PI on only one application.
- CVs or biosketches for all investigators are required.

Intellectual Property (IP) Rights
- IP rights will follow the provisions agreed upon in the MUSC-Siemens Healthineers Joint Development Addendum to the Enterprise Framework Agreement. Please contact the Office of Innovation for more details (officeofinnovation@musc.edu).

Proposal Aim(s)
- Aims should include novel application of a Siemens ultrasound technology with potential to expand clinical utility and improve patient care.
- Aims will preferably drive an innovative idea toward a larger-scale study with a subsequent extramural grant application, e.g. National Institutes of Health, and/or results in new jointly developed technology or service offerings.
- The aims specified by the application must be distinguishable from those funded by other grants.

Project Timelines, Milestones, & Deliverables
- Projects must be completed within one year of funding/Date of the Notice of Award is issued.
- Projects must include quarterly milestones with deliverables to ensure timely progress towards completion.
- Projects must include a minimum of 10 case studies.
- Projects should include a plan to publish and/or present the findings at a national conference.

Terms of Access to Loaned Siemens Equipment
- For projects focused on Siemens technology not otherwise available to the investigative team, Siemens Healthineers will provide loaned equipment at no cost for the duration required for project completion.
- Loaned equipment must be returned to Siemens when no longer required for the project.

APPLICATION SUBMISSION:
- All applications must be submitted through InfoReady, an online application and review system at https://musc.infoready4.com/#competitionDetail/1829626
- Incomplete or late applications will not be reviewed.

Formatting
- Font Type and Size - Arial, 11pt.
- Page Margins - No less than 0.5 inch on all sides

Application Components
The Application consists of five components:
1) Project Summary, 1-page limit
2) Project Proposal, 5-page limit
3) Budget and Justification in PHS 398 format
4) Letter(s) of Support
5) Each investigator's CV or biosketch

Project Summary (1-page limit)
Describe on a single page the unmet clinical need, current state of the art, description of planned use for Siemens ultrasound technology, and the goals for the award

Project Proposal (5-page limit, not including Literature Cited)
• Specific Aims - State concisely the goals of the proposed study and summarize the expected outcome(s) including potential impact.
• Strategy - Describe how the aims will be achieved, how the project will expand utility of a Siemens ultrasound technology and improve patient care, what criteria will be used for determining a successful outcome, and the significance of such criteria. Be sure to explain the roles/duties of each team member. This section must be informative enough for reviewers to understand the proposed study without any supporting documents.
• Quarterly Milestones - Provide a table outlining the milestones and deliverables to be achieved on a quarterly basis until project completion.
• Future Development Plan - Provide a description of how the results of this award will be parlayed into additional funding strategies, translation, technology development, and/or implementation into practice. Proposals with clear pathways toward extramural grant applications (e.g., National Institutes of Health Research Project Grants) will be prioritized.
• Literature Cited - Include at the end of the Project Proposal.

Budget and Justification
Applicants must provide a detailed, itemized budget using the PHS 398 Form Page 4 "Detailed Budget for Initial Budget Period" and a budget justification using the PHS 398 "Continuation Format Page" (http://grants.nih.gov/grants/funding/phs398/phs398.html). Each budget line item must be clearly justified.

Allowable Budget Items
• Educational Support for Sonographers - Proposal budgets are encouraged to allocate a portion of funds to support continuing education credits for sonographers, should the study require substantial assistance from technician(s).

• Other Personnel Support - Salary and fringe benefits are allowed for research support, such as Research Fellows, Research Assistants/Coordinators, Research Nurses, etc. Please confirm fringe benefit rates on the Sponsored Awards Office website.

• Non-personnel Research Expenses - Some allowable expenses are: supplies, equipment (under limited circumstances), study participant stipends, study participant 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.

• Travel - Costs for travel/registration/attendance at a conference to present pilot study findings are allowable.

Unallowable Budget Items
• Faculty Salary Support - Salary and fringe benefits are not allowable budget items for faculty.
• Effort Reporting - Investigators are not required to accommodate their efforts on the project budget.

- Students - The 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.
- Unallowable costs - General office supplies and equipment, computers and laptops (unless specifically requested and justified), membership dues and fees, 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 - Subawards to other institutions are not allowed.

Letter(s) of Support
- If the proposed specific aims require support or service from a research core a letter of support must be provided which acknowledges the group's ability to provide said support or service within the award period.
- If the specific aims and/or final product (post-award) require integration with EPIC or other IT support, a letter of acknowledgment from Information Solutions must be provided which verifies that the proposed approach is allowable.

APPLICATION REVIEW
Applications will be reviewed by a panel including scientific/technical evaluators, members from an external review board comprising MUSC and Siemens representatives, and Office of Innovation leadership.

Applications will be assessed to determine the potential for a project to:
- Expand the clinical utility of a Siemens ultrasound technology and improve patient care.
- Produce data that can be the basis for a larger-scale study with a subsequent extramural grant application, e.g., National Institutes of Health.
- Result in new, jointly developed innovations.

Additionally, work proposed in the application will be reviewed for:
- Likely completion of the aims within one-year timeframe
- Appropriateness of the proposed budget expenditures with respect to the development plan for the innovation
- Measurable, meaningful milestones for quarterly reporting

RELEASE OF FUNDS AND REPORTING REQUIREMENTS
- Funded PI should obtain regulatory approvals such as IRB in a timely manner. Funding cannot be released until all required regulatory documents have been approved and copies submitted to the SCTR Pilot Project Program. More details will be provided to the funded PI via Just-In-Time Notice.
- PI's Department/Division Business Manager shall be responsible for all human resource, procurement and reconciliation activities for the funded project account.
- Please note that the Office of Innovation will continue to follow longitudinal progress of the project. Progress reports are due at 3-month intervals while the project is active. Brief annual progress follow-ups are due for a total of 5 years from the date of the NOA is issued.

CONTACT
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