Applications for the Multicenter Clinical Studies Planning Grant are not being accepted at this time.

The SVS Foundation announces a funding opportunity directed to Society for Vascular Surgery (SVS) members developing grant applications for high-impact multicenter clinical studies in the treatment and/or prevention of vascular diseases.

Purpose

The SVS Foundation Multicenter Clinical Studies Planning Grant is one component of a broad strategy to facilitate clinical research directed at solving high-impact questions in the care of patients with vascular diseases. SVS recognizes that members face significant gaps in knowledge in their day to day care of patients with vascular disease and acknowledges the challenge of designing and executing clinical studies to provide concrete clinical guidance. Prospective multi-center studies are particularly challenging; yet these studies may be the only practical approach to recruit the large numbers of patients required to achieve statistical power to provide practicing surgeons clear guidance. A major hurdle for investigators preparing grant applications for multicenter studies are the costs of developing compelling preliminary data, recruiting and training collaborators, and creating tools in support of a competitive proposal.

The purpose of the Planning Grant is to help investigators complete competitive applications for external funding (e.g. NIH) of full-scale prospective multicenter clinical studies. The Planning Grant is broadly modeled after R34 awards from the National Institutes of Health (NIH Clinical Trial Planning Grant Program and NHLBI Clinical Trial Pilot Studies). These programs permit early peer review of the rationale and experimental design of a proposed Phase III or IV clinical trial and support development of a research team, assessment tools, and oversight necessary in a competitive application. Support might also be used to obtain critical preliminary data important for the design of a larger study. Examples include: defining the appropriate study population and feasibility of recruitment; demonstrating the feasibility of an intervention or an outcome measure; estimating sample size, effect size, attrition or response rates; or developing
and piloting survey instruments. Funds might also be used to prepare an investigator’s brochure or procedure manual, or to recruit and train collaborating centers and trial oversight. Proposals for phase I trials will not be considered responsive to this mechanism.

The Planning Grant specifically targets SVS member investigators with a track-record of productive clinical research. Applications addressing “high impact” areas in the management of patients with vascular disease will be considered most responsive. For example, SVS has recently identified a number of clinical research priorities:

SVS Clinical Research Priorities

1. Further investigate the optimal management of asymptomatic carotid stenosis
2. Compare effectiveness of medical versus invasive therapy (open or endovascular) for claudication
3. Compare effectiveness of initial open versus endovascular infra-inguinal revascularization for critical limb ischemia
4. Develop and compare effectiveness of clinical strategies to reduce cardiovascular and other perioperative complications (e.g. wound) following vascular intervention
5. Determine the effectiveness of strategies to enhance arteriovenous fistula maturation and durability
6. Develop best practices for management of chronic venous ulcer
7. Further investigate the optimal adjunctive medical therapy to enhance the success of lower extremity intervention
8. Identify and evaluate medical therapy to prevent abdominal aortic aneurysm growth
9. Evaluate ultrasound versus computed tomography angiography surveillance post-endovascular aneurysm repair

The Planning Grant application must describe the full-scale study that it is intended to support in sufficient detail to establish its significance and potential clinical impact and to define the need for this award. The full-scale clinical study application must be fairly well developed, so that a targeted investment could be expected to significantly strengthen the research plan and facilitate grant preparation and submission. Planning Grant funding will be for no more than one year and up to $100,000 USD (direct costs only) and is expected to culminate in the submission of an application for external funding of a multi-center clinical study within six months of its completion, or the first possible grant cycle from the targeted funding agency, if more than six months later. Applications proposing activities that cannot be completed with this level and duration of funding will not be considered responsive.

Principal Investigator (PI) Eligibility Requirements

- PI must hold an MD or equivalent degree with postgraduate clinical training in vascular surgery
- PI must be an SVS Active Member
- PI must have demonstrated experience in the conduct of clinical research
- Individuals with active extramural research support are eligible, provided there is limited scientific or budgetary overlap

Review Considerations

A two-page Letter of Intent will be evaluated based on the following:

- Investigator-initiated multi-center clinical study targeting an external funding mechanism compatible with the
The Multicenter Clinical Studies Planning Grant is intended for investigators to develop multicenter clinical studies. The planning grant supports the development of a larger application for external funding. The criteria for the planning grant include:

- **Scope of the research proposed (e.g., NIH, applicant must identify targeted funding agency)**
- **Impact and importance of the clinical question being addressed in the multi-center clinical study**
- **Experimental design of the multi-center clinical study, including biostatistical strategy and support and design of the Planning Grant activities proposed in support of the larger application**
- **Maturity of the multi-center clinical study application that the Planning Grant would support (the application should be fairly well-developed so that targeted investment via the Planning Grant is likely to yield a competitive submission for external funding)**
- **Environment (PI and collaborating study sites)**
- **Experience of the PI and team of proposed collaborators**
- **Feasibility of accomplishing proposed Planning Grant activities within the period of support**

Upon review of Letters of Intent, those deemed most competitive will be invited to submit a full application. Full applications (if invited) will be evaluated based on the following:

- **Planning Grant Specific Aims**
- **Planning Grant Research Strategy**
  - **Significance, Innovation, Experimental Approach, and Time-Line**
  - **Experimental approach describing statistical methods and issues of power and sample size**
  - **Demographics for the proposed study patient populations, inclusion and exclusion criteria, availability and plans for recruitment, outreach, follow-up, and challenges to adherence to the proposed protocol**
- **Planning Grant Budget and Justification for up to one year and up to US$100,000 direct costs**
- **Description of how the subsequent full-scale, multi-center clinical study would be conducted to provide context for the Planning Grant activities. Specifically,**
  - **the rationale, significance and need, potential impact on health care, policy or practice**
  - **the proposed preliminary studies or preparations are both necessary and sufficient for the design and submission of the full-scale, multi-center clinical study**
  - **the team of investigators at each study site are defined**

**Application Process**

- **Date to be determined**
- **Instructions for the Letter of Intent**
  - **If invited, a full Planning Grant application must be received by a date to be determined.**
    - **Instructions for the Multicenter Clinical Studies Planning Grant Application?**
    - **Multicenter Clinical Studies Planning Grant Face Page**
    - **Budget Template**

**Resubmissions**

Unfunded applications may be revised and resubmitted in a subsequent Planning Grant cycle but should include a one-page introduction summarizing specific changes made in response to the previous critique. The competitiveness of revised applications will be considered in the context of the other submissions received that cycle.

**Financial Support and Award Period**

Awards will be for up to $100,000 USD (direct costs only) for a period up to one year.
Progress Reports

A brief progress report is due six months after receiving funding. Completion of the Planning Grant is expected to culminate in a mature full-scale application submitted for external funding within six months, or on the first grant cycle for the targeted funding agency, if beyond six months. A final progress report should include a copy of the application for external funding.

Contact Information

For questions, email Sarah Murphy ?; phone 800-258-7188; fax 312-334-2320

Grant Recipients

2014 - 2015

Philip P. Goodney, MD  
Dartmouth-Hitchcock Medical Center  
Alik Farber, MD  
Boston University School of Medicine  
Project title: The Vascular Physician Offer and Report (VAPOR) Trial

2012 - 2013

Thomas S. Hatsukami, MD  
University of Washington  
Project title: MRI of High-Risk Carotid Plaque?