



Clinical Research Study Approval Program

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The goals of the Society for Vascular Surgery® (SVS) Clinical Research Study Approval Program are to facilitate clinical research addressing important questions in vascular disease management and to maximize participation of SVS members in the conduct of this research. Clinical research studies meeting the criteria established by the SVS Research Council shall be eligible for recognition as an "SVS Approved Clinical Research Study Proposal" or "SVS Approved Clinical Research Study."

Background

SVS is committed to the application of principles of evidence-based medicine to improve the care of all patients with vascular disease. Clinical studies, particularly randomized, controlled trials (RCTs), are key sources of data that determine regulatory approval for devices and therapeutics. They also provide critical evidence for the development of practice guidelines and support clinical decision-making. Such investigations are designed with several purposes and reflect the interests of their primary sponsors which include individual investigators, institutions, governmental or non-profit organizations, and the medical device, biological and pharmaceutical industries.

Optimal design of clinical research in vascular disease is critical to the future care of patients and to the practice of vascular surgery as a specialty. Clinical studies can exert profound influences on technology development, market availability of new treatments, and evidence-based practice. However, many clinical studies (e.g. RCTs) are costly, challenging to complete, may expose subjects to risk, and come with inherent ethical and conflict-of-interest challenges. Study design must be based upon sound principles of clinical science including the selection of appropriate target populations, knowledgeable selection of patient-oriented safety and efficacy endpoints, adverse event monitoring, event adjudication, and adequate statistical power and analysis plans.

SVS, as a primary stakeholder in the care of patients with vascular disease, as well as a steward of the profession of vascular surgery, promotes basic and clinical research through its diverse educational and research programs. The overall goal of the Program is to facilitate the development and timely completion of clinical research addressing

important questions in vascular disease management.

The specific goals of the Program are:

- To promote clinical research studies to address critical gaps in evidence for the treatment of patients with vascular diseases
- To encourage the highest level of ethical and safety considerations in the design and execution of clinical trials in vascular patients
- To promote scientific rigor to maximize the likelihood of meaningful benefits to study subjects and to society as a whole
- To encourage minimal bias and appropriate management of conflicts-of-interest (COI) in the design, execution, and reporting of clinical trials
- To encourage the development of clinical scientists, and to promote adequate representation of vascular surgeons in the processes of study design, execution, adjudication, and monitoring as well as involvement as participating investigators in multi-center studies

Program Information

Eligible Clinical Research Studies

In order to be eligible for the Program:

- The study must be a multi-center investigation, any phase
- The study must be investigator-initiated (Government, non-profit, or industry support allowable provided the study is Investigator-initiated)
- The principal investigator must be an Active SVS member

Evaluation Criteria

The clinical priority, scientific rigor and ethical integrity of the study will be assessed to determine whether the study meets the following criteria:

- Public health impact of the area of study, and relationship to SVS priority areas
- Overall hypothesis and study design - including state of equipoise, appropriate evaluation of risk/benefit, rigorous design
- Study population - appropriate inclusion/exclusion criteria, representation of minority or underserved populations, etc.
- Selection of endpoints - appropriate definition and selection of primary and secondary endpoints, methods of adjudication, statistical methodology
- Study management plan - composition and function of leadership and monitoring committees, data safety monitoring board, etc
- Ethical issues and management of COI
- Statement regarding data ownership, and plan for results reporting (regardless of outcome)
- Agreement to register the trial with NIH ClinicalTrials.gov

Evaluation Process

The Research Council is responsible for initiating and overseeing the evaluation of studies submitted for review under

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the program. Studies accepted for review will be reviewed by an ad hoc Clinical Research Review Committee (CRCC), which shall submit its recommendation to the Research Council. The Research Council shall review the CRCC's recommendations and present a final recommendation to the Executive Committee for approval. All members of the Research Council, CRCC, and Executive Committee are bound to abide by the terms of the program's Conflict of Interest, Confidentiality and Non-Disclosure Policy.

- The Research Council:
 - Will review applications and supporting materials for suitability and shall determine whether or not to form an ad hoc CRCC
 - Will assign SVS Member experts to ad hoc CRCCs. Members will be selected based on knowledge, expertise and other criteria, including breadth and complexity of the study under consideration.
 - Will review the CRCC Summary Report and Recommendation and submit recommendations for approval to the Executive Committee
- The CRCC:
 - Will provide expert peer review for individual studies or a subset of related studies and provide a confidential, written review to be shared with the other members of the CRCC
 - Will prepare a Summary Report and Recommendation (approval or non-approval) for distribution to the Research Council, Executive Committee (if applicable) and the principal investigator
 - Will remain anonymous to the principal investigator
 - Members are bound by the COI Policy and may not evaluate a study if such participation raises a Conflict of Interest situation, as determined by the Research Council pursuant to the COI Policy on a case by case basis.
- The Executive Committee:
 - Will review the Summary Report and Recommendation (those recommended for approval only) and make final decision on approval

Deliverables

If approved, the principal investigator will receive:

- Confidential Summary Report and Recommendation
- Approval Letter signed by both the SVS President and Research Council Chair and formally recognizing the submission as an SVS Approved Clinical Research Study Proposal or SVS Approved Clinical Research Study. The rules controlling the use of the Approval Letter and designation will be provided to the principal investigator.

If a study fails to meet the program criteria, the principal investigator may request a conference call with the Research Council Chair or his/her designee. The principal investigator may reapply after revision, subject to the Research Council's approval. Accepted resubmissions will be reviewed as de novo submissions.

Application Materials

The principal investigator must submit the following materials to participate in the Program and initiate the review process:

- Signed Application / Agreement
- Study rationale and background (including any preliminary data serving a justification for conduct of the study or its design)
- Study protocol (including statistical plans and power analysis; human subjects considerations)
- Investigator biosketches in NIH format
- Proposed budget per site or per subject

Evaluation Timeline

- Applications may be submitted at any time, ideally before first patient enrollment.
- Two months review period is required.
- Requests for expedited review will be considered on a case-by-case basis.

Contact Information

For questions regarding eligibility requirements and the application process, email smurphy@vascularsociety.org ;
phone 800-258-7188; fax 312-334-2320