

**SVS Clinical Research Study Approval Program  
Principal Investigator Application/Agreement**

**Title of Clinical Research Study:**

**Principal Investigator Contact Information:**

**Name:**

**Title:**

**Institution:**

**Mailing Address:**

**City/State/Zip:**

**Phone:**

**Email:**

**Principal Investigator Representations:**

I request to participate in the SVS Clinical Research Study Approval Program. Once accepted for the Program, I understand that SVS will submit the contents of this application in a confidential manner to members of the SVS Research Council; an ad hoc Clinical Research Review Committee; and, if recommended for approval, the SVS Executive Committee.

I understand that the designations “SVS Approved Clinical Research Study Proposal” and “SVS Approved Clinical Research Study” signify only that:

- the Study has undergone peer review by SVS members experienced in clinical research
- the Study’s rationale and protocol have scientific merit
- the successful completion of the protocol would likely deliver important new knowledge about vascular disease, its management, or both
- the Study otherwise meets the evaluation criteria established by the SVS Research Council

In addition, I understand that the designations “SVS Approved Clinical Research Study Proposal” and “SVS Approved Clinical Research Study” do not:

- Confer an endorsement, accreditation or certification by SVS of the Study’s actual conduct, compliance with the protocol or other applicable rules and regulations, or its results
- Confer in any other way an endorsement, accreditation or certification by the SVS of the investigators or institutions conducting the Study.

On behalf of each investigator participating in the Study, I agree to observe the Rules of Use for the Approval Letter and Designation (Attachment 1).

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Signature of Principal Investigator

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Date

## Attachment 1

### SVS Clinical Research Study Approval Program

#### Rules of Use for the Approval Letter and Designation

Your clinical research study entitled *[insert title of clinical research study]* (the “Study Proposal” or, once initiated, the “Study”) has met the Society for Vascular Surgery® (“SVS”) criteria and qualifies for the designation of “SVS Approved Clinical Research Study Proposal” or “SVS Approved Clinical Research Study” (the “designation”). Use of the Approval Letter (“Approval Letter”) indicating SVS’ determination and the designation is subject to the rules of use set forth below.

1. The Approval Letter and designation may only be used by the Principal Investigator(s). Misuse of the Approval Letter and designation or failure to comply with these Rules of Use may result in the revocation of the right to use the Approval Letter and designation in connection with the Study Proposal or Study.
2. Recognition as an “SVS Approved Clinical Research Study Proposal” or “SVS Approved Clinical Research Study” is solely a statement of professional external validation of the trial design, and does not indicate SVS review or approval of the results, outcome or effectiveness of such study or an individual or institution’s interpretation of such results. Use of the Approval Letter or designation to imply or indicate otherwise is prohibited.
3. Below are examples of acceptable uses of the Approval Letter and designation. The Principal Investigator(s) may:
  - Refer to the designation and include the Approval Letter in applications for extramural funding.
  - Refer to the designation and include the Approval Letter in local Institutional Review Board (IRB) applications.
  - Refer to the Approval Letter and designation in communications focused on study recruitment and promotion (including oral presentations, letters to referring physicians, web/radio/print/other media ads, and interview opportunities discussing the trial).
  - Refer to the Approval Letter and designation in peer reviewed publications.
  - Refer to the Approval Letter and designation in presentations at professional meetings on interim or final results of the study.
  - Refer to the Approval Letter and designation in discussions with the Food and Drug Administration (“FDA”) in connection an Investigational New Drug (IND) or Investigational Device Exemption (IDE) trial.

If you have any questions regarding the acceptability of a proposed use, please contact SVS.

4. You may not omit part of, or make any additions or alterations to, the Approval Letter or the designation.
5. You are only authorized to use the Approval Letter and the designation. You may **NOT** use SVS’ name, logo or other trademarks without SVS’ prior written permission.

6. You may not use or refer to the Approval Letter or designation in a manner which is deceptive or misleading, or which would harm SVS' reputation. Among other things:
  - a. The Approval Letter or designation may not be used in a manner that could be inferred that the actual results, outcome, or effectiveness of the Study Proposal or Study have been approved, guaranteed or have been otherwise evaluated, endorsed or approved by SVS.
  - b. You may only use the Approval Letter and designation in connection with the Study Proposal or Study and not in connection with the Principal Investigator(s), their employer(s) or any other organization or institution.
7. The Study Proposal or Study and all subsequent research conducted thereunder must comply with all applicable laws, codes of practice, ethical obligations, standards and regulations in effect in your locality, state, and country.

### **Supervision and Control:**

As the designating body, SVS controls use of the Approval Letter and designation. Any complaints by the public or other third parties of misuse of the Approval Letter or designation will be investigated and handled solely by SVS or its designee. SVS may terminate your right to use (or refer to) the Approval Letter or designation and revoke the designation if you fail to comply with these Rules of Use or any other requirements established by SVS in connection with use of the Approval Letter or designation.

### **Term of Use:**

In addition to compliance with these Rules of Use, you may only use the Approval Letter and designation in connection with and in reference to the Study Proposal or, once initiated, the Study.

### **Sanctions for Misuse:**

Sanctions for misuse of the Approval Letter and/or designation may include but are not limited to private or public censure, suspension or being barred from submitting future clinical research study proposals, participating in the SVS Clinical Research Study Approval Program, suspension or revocation of the designation, or legal action.

### **Amendment of Regulations:**

All matters not covered by these Rules of Use are subject to the decision of SVS. SVS may amend or supplement these Rules of Use in its discretion at any time.

### **Questions**

Any questions about these Rules of Use or use of the Approval Letter or designation should be directed to:

Sarah Murphy  
Director of Research  
Society for Vascular Surgery  
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Chicago, IL 60611  
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