C-TRACT Study Site Application
Dr. Suresh Vedantham – Protocol Principal Investigator

I. KEY PERSONNEL CONTACT INFORMATION

Name of Site: _____

Address _____

City, State, Zip Code: _____

Primary Contact Person: _____

E-Mail Address: _____ Phone: _____

Site Principal Investigator (PI): _____

E-Mail Address: _____ Phone: _____

PI Subspecialty: _____

II. FACILITY INFORMATION

Please list the Primary Hospital at which you plan to enroll patients, as well as up to two major affiliate hospital that fall within your IRB's jurisdiction.

Primary Hospital: _____

Estimated yearly number of DVT Cases (irrespective of treatment type): _____

Estimated yearly number of patients with moderate-severe PTS (any treatment type) _____

Which category best describes the nature of your Primary Hospital?

University Hospital

Community Hospital with Strong Academic Affiliation

Private Hospital without Strong Academic Affiliation

Affiliate Hospital #1: _____

Which of the following categories best describes the nature of Affiliate Hospital #1?

University Hospital

Community Hospital with Strong Academic Affiliation

Private Hospital without Strong Academic Affiliation

Affiliate Hospital #2: _____

Which of the following categories best describes the nature of Affiliate Hospital #1?

University Hospital

Community Hospital with Strong Academic Affiliation

Private Hospital without Strong Academic Affiliation

Wound or Ulcer Care Clinic: _____

Yearly number of patients seen: _____

III. RESEARCH COORDINATOR INFORMATION

Research Coordinator: _____

Address: (Needed to send Compression Stockings and Blood tubes) _____

Address: _____

City, State, Zip Code: _____

E-Mail: _____ **Phone:** _____

Number of Years Research Experience: _____

REGULATORY COORDINATOR INFORMATION

Research Coordinator: _____

E-Mail: _____ **Phone:** _____

Number of Years Research Experience: _____

IV. FINANCIAL CONTACT INFORMATION

Financial Contact for NIH Research _____

E-Mail Address: _____ **Phone:**_____

Financial Contact (if more than one) _____

E-Mail Address: _____ **Phone:** _____

V. ENDOVASCULAR THERAPY (EVT)

Primary Endovascular Co-Investigator (will oversee EVT): _____

E-Mail: _____ **Phone:** _____

Subspecialty: _____

Number of years since completion of training: _____

How many iliac vein stent procedures are performed in the group yearly? _____

How many are for treatment of chronic DVT with moderate-severe PTS? _____

What stent do you prefer? _____

VI. MEDICAL AND COMPRESSIVE PTS THERAPY

Primary Medical Co-Investigator (will oversee standard PTS care): _____

E-Mail: _____ Phone: _____

Subspecialty: _____

Number of years since completion of training: _____

VII. VENOUS ULCER CARE

Primary Ulcer Care Co-Investigator (will oversee venous ulcer care): _____

E-Mail: _____ Phone: _____

Subspecialty: _____

Number of years since completion of training: _____

How many venous ulcers has <u>this investigator</u> managed? _____

VIII. SITE-SPECIFIC ENROLLMENT AND DATA COLLECTION

1. **Is your research team willing to engage in an active ongoing quality improvement program with study leadership to maximize the potential for enrollment? Yes No**

2. **Have you or your institution utilized electronic (e.g. EHR-based or electronic queries of other databases) methods of identifying patients for clinical research? Yes No**

   If yes, please specify:
   _____
   _____

3. **Vascular Ultrasound capabilities:**

   Is your ultrasound lab willing to identify patients for the C-TRACT study? Yes No

   Is your ultrasound lab willing to complete web-based training to become qualified to submit ultrasound exams for study patients to a core lab? Yes No

4. **Venogram Imaging capabilities:**

   Is your angiography lab willing and able to transfer pre- and post-procedure venograms to a core lab using a DICOM-compatible interface? Yes No

IX. COMPETITIVE ENROLLMENT

Please name any studies at your site that expect to enroll patients with DVT or PTS from 2017-2020, and indicate how problems with competitive enrollment will be avoided.

X. STATEMENT OF CLINICAL EQUIPOISE

Does each co-investigator accept the premise that it is ethical and appropriate to randomize patients with moderate-severe PTS (including patients with venous ulcers less than 6 cm) to receive either EVT or no EVT in a trial (along with medical therapy, compression, and venous ulcer care as needed), and maintain them in their assigned treatment arm for 6-18 months (with rare exceptions)? Yes No

If the answer to this question is anything but an unequivocal YES, please explain:

THANKS VERY MUCH !!!