**C-TRACT Study Site Questionnaire**

**Dr. Suresh Vedantham – Protocol Principal Investigator**

**I. KEY PERSONNEL CONTACT INFORMATION**

Name of Site: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address (City, State): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Primary Contact Person: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-Mail Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Site Principal Investigator (PI): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-Mail Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PI Subspecialty: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**II. FINANCIAL CONTACT INFORMATION**

Official Site Business Entity Name (for Contract): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Federal-Wide Assurance (FWA) Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Financial Contact for NIH Research Subawards: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-Mail Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**III. 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Number of Registered Beds: \_\_\_\_\_\_\_\_\_\_\_

Yearly number of DVT Cases (irrespective of treatment type): \_\_\_\_\_\_\_\_\_\_\_\_\_

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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Number of Registered Beds: \_\_\_\_\_\_\_\_\_\_\_

Yearly number of DVT Cases (irrespective of treatment type): \_\_\_\_\_\_\_\_\_\_\_\_\_

Yearly number of patients with moderate-severe PTS (any treatment type) \_\_\_\_\_\_\_\_\_\_\_\_\_

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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Number of Registered Beds: \_\_\_\_\_\_\_\_\_\_\_

Yearly number of DVT Cases (irrespective of treatment type): \_\_\_\_\_\_\_\_\_\_\_\_\_

Yearly number of patients with moderate-severe PTS (any treatment type) \_\_\_\_\_\_\_\_\_\_\_\_\_

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 Affilation

**Wound or Ulcer Care Clinic:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Yearly number of patients seen: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Yearly number of leg ulcers seen: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Yearly number of venous leg ulcers seen: \_\_\_\_\_\_\_\_\_\_-

**IV. RESEARCH COORDINATOR INFORMATION**

Research Coordinator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-Mail: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Number of Years Research Experience: \_\_\_\_\_\_\_ How Many Studies Now? \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Does this person have a nursing background? Yes No

If Yes, state specific degree/credentials \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Does this person have professional research training/credentials? Yes No

If Yes, state specific credentials/certifications: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**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 has this investigator performed (ever)? \_\_\_\_\_\_\_\_\_\_\_\_

How many were for treatment of chronic DVT with moderate-severe PTS? \_\_\_\_\_\_\_\_\_\_\_

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? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

How many **endovenous thermal ablations** has this investigator performed (ever)? \_\_\_\_\_\_\_

How many were for treatment of moderate-severe PTS? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

How many **endovenous thermal ablations** are performed in the group **yearly**? \_\_\_\_\_\_\_\_\_\_

How many are for treatment of moderate-severe PTS? \_\_\_\_\_\_\_\_\_\_\_\_\_\_

What device is used (e.g. laser versus RF, brand)? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**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 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

How many **patients with moderate-severe PTS** has this investigator managed? \_\_\_\_\_\_\_\_\_\_\_

With medical therapies beyond anticoagulation? \_\_\_\_\_\_\_\_\_\_

With elastic compression stockings? \_\_\_\_\_\_\_\_\_\_

With other compression methods? \_\_\_\_\_\_\_\_\_\_

**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 this investigator managed? \_\_\_\_\_\_\_\_\_\_\_

How many PTS-related venous ulcers has this investigator 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. From what CURRENT sources do you receive PTS patient referrals?
2. What NEW sources can you utilize to recruit PTS patients to your study team?
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

1. 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 !!!**