



## Venous thromboEmbollism Network U.S.

# Study Approval Process

### Rationale

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Clinical studies, and especially randomized controlled trials (RCT), frequently require collaboration and participation from multiple clinical centers to meet sample size requirements in a timely manner. Conducting clinical research in multiple centers offers the advantages of faster participant recruitment and study completion, and greater generalizability of results.

### Objective

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VENUS' study review and approval process is intended to identify studies that align with the VENUS' mission and which the network will endorse.

The formal review process provides a mechanism for VENUS Executive Committee members to jointly determine which studies the network will promote and support.

### Eligibility

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**Applicants:** the proposed study must be supported/developed by members of a VENUS committee. Applicants must be committed to collaboration, ethical research practices, and fair recognition of co-investigators' research contributions.

**Study stage:** research at any stage of development is eligible for endorsement. Investigators may apply for approval of a research idea or preliminary protocol, a study with a fully-developed protocol, or one that is actively recruiting participants.

**Research design:** academically-driven clinical research studies that are seeking to recruit participants.

**Competing studies:** ideally, the proposed study is unique and does not replicate or compete with an ongoing study. Applicants are expected to make efforts to identify other studies that are in progress that are seeking to answer the same or a similar research question. Justification for undertaking a similar study must be provided.

### Application Process

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- 1) A VENUS member should submit an idea to respective committee co-chairs
- 2) Discussion of project at committee meeting
- 3) If approved, the VENUS member sends the VENUS Executive Committee Chair an application package consisting of the following documents:



### **Venous thromboEmbollism Network U.S.**

- 1) A completed **VENUS Study Approval Application Form**
- 2) A one-page proposal for the study
- 3) Email of approval from VENUS committee co-chair or minutes from committee meeting

#### **Review and Approval Process**

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1. The VENUS Staff and Chair conduct an initial review for completeness and clarity
2. The VENUS Chair circulates the application via email to Executive Committee for review
  - a. The proposal may be sent back to proponents for refinement/comments/questions prior to approval and endorsement
  - b. Applicants requesting approval of a research idea or preliminary proposal are expected to provide additional study details once the proposal is developed. Studies that have already received approval will not require formal review again.
3. At the next VENUS Executive Committee Meeting (teleconference or in-person), and a minimum of 1-month after the proposal was circulated, a vote will be conducted to establish support for the study and approval for calling it a VENUS study
4. All Executive Council members may vote, in person or by proxy, to approve a study, regardless of their involvement or interest in the study. For the voting process, quorum is 60% (in person or by proxy) and a majority vote in one where more than half of the members of Council present and voting vote in the affirmative.

#### **VENUS Support of Endorsed Studies**

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1. A letter of endorsement will be provided (upon request, the letter may be tailored to include in a funding application, etc.)
2. The study will be promoted to members via email
3. VENUS Executive Committee Members will actively promote endorsed studies
4. Consideration for expansion to INVENT network with involvement of another network