Participant User File (PUF) Research Funding Requirements.

The Call for Participant User File (PUF) Research Grant Proposal is scheduled to open July 18, 2022. Each selected applicant will be awarded up to \$15,000 to apply for and complete an STS Participant User File (PUF) Grant.

PUF applications being accepted for research projects based on data from the Adult Cardiac Surgery Database, General Thoracic Surgery Database, Congenital Heart Surgery Database, and the INTERMACS Database.

Please Note: SCA will <u>not</u> consider applications from primary investigators (PI's) currently receiving SCA research funding. However, they may serve as a co-investigator on a PUF application.

All STS Database related documents are available after a free registration through the STS website: www.sts.org.

First Step - Letter of Intent Required Documents (All documents will be required to be uploaded as a PDF):

- The Letter of Intent (LOI) should not be more than two pages.
- The LOI should detail the proposed title of the project and a statement that the PI/applicants
 checked and verified that their proposed work is not similar to a previously completed or
 presently active STS approved research proposal.
 - List of active STS research proposals from all programs
 - o List of recently published STS research studies based on STS National Database data
- The LOI should describe the roles of the key personnel including PI, co-investigators, cardiac surgeon who are also an active STS member, and a PhD level biostatistician. Their backgrounds/connection to the topic area, the key personnel, and the unique skills or resources they and their institutions bring to the project.
- Details of the proposed study, including background, specific aims, the study design, and target
 patient population or disease process, along with a description of any translational/mechanistic
 components.
- Biosketch in the new NIH formatting for the PI.

Second Step – Full Application Requirements (If chosen for full application submission)
(All documents will be required to be uploaded as a PDF, Ariel font, 11 pt., 0.5 margin):

- 1. PI, co-investigator, cardiac surgeon, and PhD level biostatistician Biosketches required.
 - NIH required new formatting 5-page limit each single upload

- 2. Letter of Support from Department Chair for PI (PDF)
 - o Including outline of clinical vs. non-clinical time commitments, availability of non-clinical time corresponding to the proposed percent effort, resource availability, and provision of resource support, support for additional institutionally required indirect costs, and/or support of additional non-clinical time to fulfill each co-PIs commitment to the project. In addition, please include a statement that all unused funds will be returned at the end of the award.
- 3. Research Environment and Facilities (each site, 1-page for each site) single upload
- 4. Budget Detail -
 - Cost of obtaining the data from STS and statistical analysis conducted by a PhD level biostatistician.
- 5. Hypothesis and Specific Aims (Max 1 page, Ariel font, 11 pt. font, 0.5-inch margin)
- 6. Research Plan (Max 5 pages, Ariel font, 11 pt. font, 0.5-inch margins, NIH style)
 - 1. Study Background
 - 2. Study Plan/Approach
 - 2.1 Study Patients
 - 2.1.1 Study Inclusion Criteria
 - 2.1.2 Study Exclusion Criteria
 - 2.2 Statistical Methods
 - 2.3 Timetable for Executing the Study
 - 2.4 Dissemination Plans -
 - SCA strongly suggest for the investigators to target the SCA Annual Meeting and Anesthesia and Analgesia as the publication forum for dissemination of PUF-based research. Additionally, if PUF research output is presented at the STS Annual Meeting, then the STS Board of Directors or Executive Committee may waive the requirement that it be published in The Annals in exceptional circumstances.
- 7. Literature Cited (no limit)
- 8. Documentation of IRB approval for all study sites is required at the time of grant execution.
 - o PI's institution is willing to work and accept STS Data Use Agreement.
- Conflict of interest statements for all co-investigators, cardiac surgeon, PhD level biostatistician, and all persons involved in the project – (Single PDF listing any COIs for all investigators)