Participant User File (PUF) Research Funding

Full Application Requirements

The PUF full application requirements are 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. Each selected applicant (up to a maximum of 4 applicants) will be awarded up to $15,000 to apply for and complete an STS Participant User File (PUF) project.

Application Requirements

1. **Personnel Requirements**: The Principal Investigator (PI) must currently be an active SCA member in good standing. The PI must currently not be receiving any other SCA research funding. SCA will **not** consider applications from PI's currently receiving other SCA research funding. However, members who currently do receive other research funding from the SCA may serve as a co-investigators on a PUF application. Per STS requirements, the research team must include a STS member surgeon as well as a PhD level Biostatistician.

2. **Research Work Requirements**: The planned research work must not be similar to any previously completed or presently active STS research proposal. A list of current and recently published work based on the STS databases can be found in the STS website. Applicants are encouraged to review the literature as well to ensure there is no overlap between their proposal and previous projects.
   - [List of active STS research proposals from all programs](#)
   - [List of recently published STS research studies based on STS data](#)

Letter of Intent Document Submission Checklist

(All documents will be required to be uploaded as a PDF)

1. **Letter of Intent** (Max 2 Pages): The LOI should detail the proposed title of the project and 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, if relevant. The LOI must include 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 and that they have checked and verified that the key variables of interest for their project are collected in the STS database. 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.

2. **PI Biosketch** (Max 5 pages): In the new NIH formatting. Please do not include Co-investigators Biosketches.

Full Application Document Submission Checklist
(All documents will be required to be uploaded as a PDF)

1. PI, co-investigator, cardiac surgeon, and PhD level biostatistician Biosketches in the latest NIH formatting – 5-page limit each – all Biosketches should be combined to a single PDF upload
2. Letter of Support from Department Chair for PI – (PDF)
3. 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.
4. Research Environment and Facilities (each site, 1-page for each site) – single upload
5. Budget Detail : Including 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 – the SCA strongly suggests that investigators target the SCA Annual Meeting and Anesthesia and Analgesia as the publication forum for dissemination of PUF-based research. 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. IRB approval: If already obtained. Documentation of IRB approval for all study sites is required at the time of grant execution.
9. Conflict of interest statements for all co-investigators, cardiac surgeon, PhD level biostatistician, and all persons involved in the project – (Single PDF listing all COIs for all investigators)

Frequently Asked Questions

What do the application process and timeline look like?
The SCA reviews proposals in the fall typically selects up to 4 for funding. PIs for these teams are notified that they have been selected for SCA funding, typically in January-February. However, this funding is also contingent on the normal STS review and approval process, so proposals selected for SCA funded are then submitted to STS for review, which is typically completed by late spring or early summer. After receiving STS approval, investigative teams then pursue a DUA with STS. SCA funding is typically dispersed at the time of DUA completion, payment of STS fees, and delivery of the data.

Do I need to have worked with STS data before?
Although there is no strict requirement that the PI have conducted research with STS data before, experience with this data source on the study team is extremely helpful and strongly encouraged.

How can I find out which variables the STS database collects and maintains?
To review the variables that are collected in the ACSD, GTSD, CHSD, please visit the STS Website and follow the steps below.
- o Visit www.sts.org
- o Click on LogIn >> Get Started >> Create a STS website Login Account. Follow the steps to create a free STS Website Login account. You **do not** have to be a member of the STS to create an account on the website.
- o Once you have logged in, the Data collection forms that describe the variables that are collected for the ACDS, GTSD and the CHSD (including previous versions) can be found www.sts.org/data-collection-forms.

To review the variables included in the INTERMACS dataset use the following link https://intermacs.kirso.net/intermacs-documents/ (An STS website account is not needed for this step).

Are there any requirements for who can be on an investigative team?
Please note that STS requires proposal teams to have both a PhD-level biostatistician and an STS-participating surgeon as members.

Can my investigative team include members of different institutions?
Yes, but it is advisable to have the PI and data analyst(s) at the same institution. Any location that will manage or handle raw STS data will need a DUA, and multiple DUAs for a single project are strongly discouraged. Team members who are at other institutions who will advise on study design and intellectual content but will not interact with the raw data are ok.

Does my proposal need to involve the Adult Cardiac Anesthesiology module?
Great question! "STS Data" comprises 4 main databases administered by STS: the Adult Cardiac Surgery Database, General Thoracic Surgery Database, Congenital Heart Surgery Database, and the INTERMACS Database. The most commonly used by SCA members is the Adult Cardiac Surgery Database, or ACSD. But you can apply to use data from any of the 4 databases. Within the ACSD, there is an Adult Cardiac Anesthesiology (ACA) module, which many proposals take advantage of. However, it's important to understand that while the ACSD is very large, the ACA is considerably smaller and there are only ACA data for a subset of observations within the ACSD (based on whether an institution contributes to both the ACSD and the ACA or just the ACSD).

Can I propose linking STS data to other data sources?
Generally no, but please feel free to check in with us about this if you have an idea you would like to explore.

What goes in the budget?
SCA funding is primarily used to fund data fees charged by STS. These fees are based on the number of data points requested and can be estimated using a copy of the STS DUA available on the website. These fees usually comprise the majority of the budget, with the remainder going towards statistical analysis or publication costs. Of note, the budget cannot be used to cover PI salary support or indirects.

Any other tips for a strong proposal?
Yes, we're so glad you asked! There are a few common pieces of advice that successful proposals follow:
1. Check STS data manuals and forms (available on the STS website after free registration) for the key variables that are needed to answer your research question. Check that these variables are present across the STS versions that you intend to use. Sometimes variables change with new releases and investigative teams should only propose using variables that actually exist in the STS versions they are proposing to use. Include the references to these specific variables and the STS versions you intend to use in your proposal.
2. Consider submitting a "minor data request" to the STS. This is a quick turnaround summary data request to the STS database that can be used to figure out whether key variables in your proposal are missing at a high rate. This can be particularly important for variables within the Adult Cardiac Anesthesia module, which may be very interesting but not commonly collected. If you complete a minor data request, please include either the results or that you have submitted it. It is strongly encouraged to submit it prior to submitting your LOI so that the results can be included in your full proposal.
3. Respond to LOI comments. LOI proposals are typically reviewed by 10-15 different people and the comments are delivered back to applicants. Successful full proposals are generally responsive to comments on LOIs.

Any questions regarding the application process, please contact the SCA Team at grants@scahq.org.