STS Research Center

Participant User File Research Program

Abbreviations:

ACSD	=	Adult Cardiac Surgery Database
CHSD	=	Congenital Heart Surgery Database
DUA	=	Date Use agreement
GTSD	=	General Thoracic Surgery Database
ND	=	National Database
PHI	=	Protected Health Information
PUF	=	Participant Use File
STS-RC	=	STS Research Center

1. Purpose

The Society of Thoracic Surgeons aims to streamline and facilitate STS National Database participant-led research with analyses performed at investigators' institutions.

To accomplish this aim, STS has initiated a new research initiative to make de-identified and quality checked STS national data available to its database participant investigators for research purposes. The de-identified data will be provided in the form of Participant User Files (PUFs) derived from the Society's three specialized databases (ACSD, CHSD, GTSD).

This STS initiative will be steered by a PUF Task Force, and will be guided by three primary principles: 1) facilitating STS ND participant research, 2) ensuring research output of the highest quality, and 3) protection of STS and participant data, as well as patient privacy.

2. STS PUF Research Process

The workflow for STS PUF-based research will include three sequential phases: i) Proposal Submission and Assessment, ii) PUF-based Data Analysis, and iii) Dissemination of PUF-based Research.

2.1 Phase I - PUF Proposal Submission and Assessment

- Prior to preparation of PUF proposal applications, investigators are advised to consult with STS-RC staff about their proposal topic/aims. This step is meant to avoid wasted effort on a proposal that would overlap with a previously approved PUF data request or another STS project.
- Investigators will complete a web-based PUF Application. A $500 PUF Application review fee will be required at the time of submission.

- STS-RC staff, working with investigators, will confirm application completeness and forward it to the PUF Task Force for review.

- PUF proposals will be reviewed and processed on a continuous and rolling basis.

- The PUF proposal review will focus on various key criteria, including 1) the scientific merit of the proposed research, 2) the feasibility of the research, 3) overlap with ongoing approved STS research, and 4) the analytic resources available to the investigative team.

- Assessment of the statistical analysis team's experience and capacity to carry out the proposed research and analyses is an integral part of the review process***. The applicant's analytics team must include a PhD biostatistician in order for the proposal to be approved, unless the PUF Task Force specifies otherwise.***

- Following review of the proposal, STS-RC staff will notify the principal investigator of the PUF Task Force decision in a timely manner.

- Investigators on approved PUF research projects must complete and sign the STS PUF Research Program DUA prior to the initiation of the project.

- The principal investigator of an approved PUF study will be invoiced pursuant to the following schedule of fees:

    i. STS Administrative and Scientific Review Fee = $2,000

    ii. PUF Data Access Fee - Research PUFs will fall into one of three categories based on the volume of data requested *[Volume (data points) = # patient records (surgical cases) x # data fields].* The three categories and corresponding data access fees are reflected below:

PUF – Volume (data points)	**Data Access Fee**
Standard (≤1 million):	$2,500
Large (1-5 million):	$5,000
Very large (5-50 million):	$7,500

For example, a PUF study involving 20,000 patient records (surgical cases) and requiring 50 data fields per patient record will have a PUF total volume = (50 × 20,000) or 1 million data points.

PUF requests exceeding the very large file limit of 50 million data points in volume must be justified and will be considered for approval by the PUF Task Force on a case-by-case basis. If approved, such PUF requests may incur additional data access fees.

- Upon receipt of payment, STS-RC staff will send the PUF data to the principal investigator as soon as it is available, using password protected media.

2.2 Phase II: PUF-based Data Analysis

- The analysis will be conducted at the investigators' institution(s) according to the approved research design. As per the DUA, the PUF Task Force must be notified about any material changes to the approved analysis plan that are proposed by the investigator(s), which may necessitate additional review and approval.

- After receiving their PUF data and as per the DUA, investigators will be required to submit progress reports to the PUF Task Force at least once every 2 months.

- The PUF Task Force must be informed of changes to the statistical/analysis team and in particular changes affecting the biostatistics resources available to the investigative team, which will require PUF Task Force review and approval.

- Investigators may consult with STS-RC staff at any time in case of questions related to the PUF research project.

- PUF investigator requests for research support from STS-RC staff will be discussed on a case-by-case basis, will depend on available resources at STS-RC, and may entail additional fees.

- A 3- to 6-month suggested timeline is recommended for completion of PUF analyses, depending on scope and complexity. If a PUF analysis is not completed within the suggested timeline, then the PUF Task Force may approve a similar or closely related PUF proposal submitted by other investigators.

2.3 Phase III: Dissemination of PUF-based Research

- Investigators will be expected to disseminate their PUF research results in the form of scientific research abstracts and manuscripts.

- Investigators should send their research reports to STS-RC staff at least 15 days prior to meeting abstract submission deadlines and at least 30 days prior to journal article submission deadlines. Shorter time windows may not be sufficient to secure PUF Task Force input and approval.

- The PUF Task Force will provide timely feedback to the principal investigator, and both parties will discuss in good faith the comments and suggested edits for the benefit of the project.

- The PUF Task Force will not exercise veto power over final submission decisions but:
    - may require the prominent inclusion of the following disclaimer statement if differences arise that are not adequately resolved:

      "The views and opinions presented in this article (or abstract or presentation as applicable) are solely those of the author(s) and do not represent those of The Society of Thoracic Surgeons."

    - In addition, STS reserves the right to publicly critique the PUF research output as it deems appropriate.

- STS strongly suggests that the investigators target the STS Annual Meeting and *The Annals of Thoracic Surgery* as the meeting and publication forums, respectively, 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.

- All published articles based on STS ND PUF data must recognize the STS PUF research program contribution by including the following statement in the Acknowledgement section:

  "The data for this research were provided by The Society of Thoracic Surgeons' National Database Participant User File Research Program. Data analysis was performed at the investigators' institution(s)".

3. General Rules for STS PUF-based Research

- A principal investigator requesting PUF research files must be an STS ND surgeon participant in good standing. A research scientist affiliated with an STS ND surgeon participant in good standing also may be eligible.

- STS expects that the principal investigator will hold the primary scientific roles on the approved PUF research, including actual research effort, eventual authorship, and other related responsibilities.

- All investigators involved in STS PUF research projects must complete and sign the STS PUF DUA prior to the initiation of the project. Note, a PUF DUA is always specific to the project approved by the PUF Task Force and will include the project title, as well as a unique PUF study number (e.g., PUF2016-ACSD-001) assigned by STS-RC staff.

- The principal investigator must inform the PUF Task Force of any additional investigators joining the project research team after its launch. Added investigators also must sign the STS PUF DUA.

- A principal investigator can have **only one approved active PUF-based study** in which he or she is principal investigator at any given time, where active means before formal submission of manuscript for publication.

- A principal investigator can be a co-investigator on other PUF projects.

- A principal investigator cannot submit more than one PUF research application within 1 year of a previously approved PUF application.

- A PUF proposal should request only the data fields that are pertinent to the research aim of the proposal. The PUF Task Force will not approve broad ND download requests that are not justified.

- The PUF data provided to the investigator may be used only in conjunction with the approved project – typically one abstract and one manuscript. In rare instances, an additional related (same general theme) abstract/manuscript may be justifiable but must be approved by the PUF Task Force.

- PUF files will not include PHI, nor will they include any information that could identify ND participants (surgeons, other physicians, or institutions) corresponding to any patient record provided. Thus, each PUF data file will be outside the scope of the Health Insurance Portability and Accountability Act and will not contain STS ND participant information.

- STS-provided PUF data may not be used to link to other sources of medical data (e.g., CMS Medicare Data). Research utilizing linked data is covered under other STS-RC programs, and ND participants can be directed to them accordingly.

- The PUF Task Force will base its decision to approve or not approve a PUF research proposal predominantly on the proposed research question and study analysis plan, but also will consider the research team strengths.

- One of the factors that the PUF Task Force will balance when evaluating PUF research proposals is the need to make the best use of available resources for processing requests. For example, the PUF Task Force reserves the right to reject feasible and scientifically sound proposals if it has previously approved a similar proposal on the same topic.

- Similarly, if the PUF Task Force receives multiple highly related and overlapping PUF proposals within a short time frame, it may deny the later proposal, or it could attempt to bring investigative teams together for jointly conducted research.

- Access to the provided PUF file should be restricted to the principal investigator and the statistics/analysis investigator. Investigators may not copy and distribute PUF files outside their investigative teams.

- All investigators must destroy all copies of the provided PUF file and any derived patient-level data files within 1 year after acceptance of the research for publication in final form.