

**The Society
of Thoracic
Surgeons**

Access & Publications

Program Description, Processes and
Procedures

A&P Task Force
STS Research Center

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Abbreviations

ACSD	=	Adult Cardiac Surgery Database
A&P	=	Access and Publications
CHSD	=	Congenital Heart Surgery Database
DCRI	=	Duke Clinical Research Institute
DAC	=	Data Analytic Center
GTSD	=	General Thoracic Surgery Database
ID	=	Intermacs Database
ND	=	National Databases
STS-ND	=	STS National Database
STS-RC	=	STS Research Center
WoRD	=	Workforce on Research and Development

1. Overview & Aims

The Access and Publications (A&P) Research Program is a well-established STS research program based on patient data records in the STS National Database (ND). The program facilitates ND participant-led research from the Adult Cardiac Surgery Database (ACSD), Congenital Heart Surgery Database (CHSD), General Thoracic Surgery (GTSD), and Intermacs Database (ID) that is funded by the Society. All approved A&P research proposals will be analyzed at an STS approved Data Analytic Center, and are limited to 1 abstract presentation and 1 published article.

The A&P research program is led by the A&P Task Force under the Workforce on Research Development (WoRD) and administered by the STS Research Center (STS-RC). The A&P Task Force Structure, its current membership, and the membership of its four specialty review committees, are detailed in the program flow chart (Figure 1).

Questions about the A&P program can be directed to the Research Center Coordinator, Kristin Mathis:

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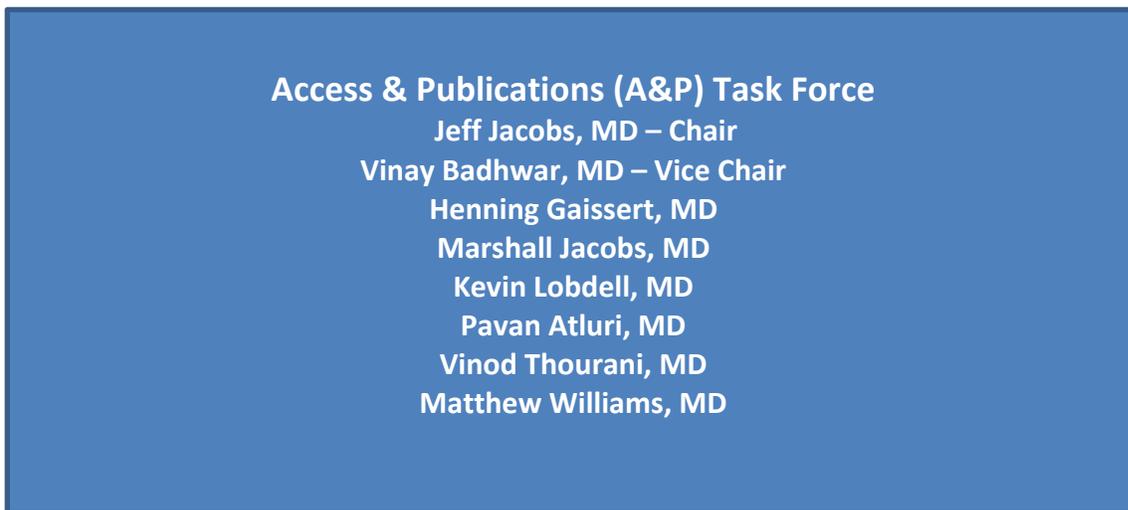
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Figure 1. Flow Chart depicting A&P Task Force structure, leadership, and committee composition:



ACSD Committee	GTSD Committee	CHSD Committee	Intermacs/Pedimacs Committee
Vinod Thourani, MD (Chair) Vinay Badhwar, MD Faisal Bakaeen, MD Edward Chen, MD Joanna Chikwe, MD Richard D’Agostino, MD Nimesh Desai, MD James Gammie, MD Michael Halkos, MD Tsuyoshi Kaneko, MD S. Chris Malaisrie, MD Tom Nguyen, MD Danny Muehlschlegel, MD ¹ Matthew Romano, MD	Henning Gaissert, MD (Chair) Mark Allen, MD Mark Block, MD William Burfeind, MD Elizabeth David, MD James Donahue, MD Andrzej Kosinski, PhD (DCRI) John Mitchell, MD Paul Schipper, MD Mark Onaitis, MD	Marshall Jacobs, MD (Chair) Erle Austin, MD Karen Chiswell, PhD (DCRI) Pirooz Eghtesady, MD Bill Gaynor, MD Kevin Hill, MD (DCRI) Tara Karamlou, MD John Mayer, MD Sara Pasquali, MD Christian Pizarro, MD Jim St. Louis, MD David Vener, MD ²	Francis Pagani, MD (Chair) Francisco Arabia, MD (I) Jennifer Cowger, MD (I) Simon Maltais, MD (I) David Morales, MD (P) Jeffrey Morgan, MD (I) Eduardo Rame, MD (I) David Rosenthal, MD (P) Viv Rao, MD (I) Jeffrey Teuteberg, MD (I) (I): Intermacs; (P): Pedimacs

¹ Society of Cardiovascular Anesthesiologists; ² Congenital Cardiac Anesthesia Society

ACSD = Adult Cardiac Surgery Database
 GTSD = General Thoracic Surgery Database
 CHSD = Congenital Heart Surgery Database

2. A&P Research Process

The A&P proposal submission and review process is conducted in two cycles for each of the four STS sub-specialty databases. The work flow for STS A&P research proposals includes three sequential phases: i) Application and Review, ii) Data Analysis, and iii) Dissemination of A&P research.

2.1 General Rules for A&P Research

- A principal investigator requesting A&P research support must be an STS ND participant in good standing. More information on becoming an STS ND participant can be found [here](#).
- **Investigators must submit proposals according to applicable deadlines (see Table 1; section 2.2).**
- The principal investigator must hold the primary scientific role on approved A&P research, including actual research effort, eventual authorship and other related responsibilities. The principal investigator will select the presenter of an abstract presentation and authorship of the abstract and manuscript, including the lead author, senior author, and order of authors. Authorship should be based on the guidelines developed by the International Committee of Medical Journal Editors (ICMJE).
- The principal investigator and other members of the investigative teams are expected to be responsive to questions from the DAC and the STS Research Center about their project.
- The principal investigator and other members of the investigative teams are expected to accommodate and participate in conference calls and other discussion forums with the DAC and the STS Research Center in relation to the conduct of their A&P project.
- The Society aims to equitably and fairly distribute its limited A&P resources such that a maximum number of projects are approved and benefitting the largest possible number of STS ND participant investigators and as many contributing institutions as possible.
- The STS A&P Task Force reserves the right to reject feasible and scientifically sound proposals if a similar proposal on the same topic has previously been approved.
- Similarly, if the STS A&P Task Force receives highly related and overlapping A&P proposals within a given review cycle, it may deny the later received proposal(s), or it could attempt to bring investigative teams together to conduct the research jointly.
- The A&P Program includes investigator and institutional limitations on approved A&P projects. New proposals will not be reviewed if any of the following limits have been exceeded. Investigators will be advised accordingly.

- **Investigator Limits** are as follows:
 - 1) A principal investigator can have only 1 approved and active A&P study at any given time, where active means a manuscript has not yet been submitted to a peer reviewed journal for publication.
 - 2) The analytic output of an A&P project may only be used by an investigator in conjunction with 1 abstract and 1 manuscript.
 - 3) Investigators with approved A&P projects will be allocated a fixed number of analytic hours from the STS designated analytic center. The number of hours will be specified in the decision letter.
 - 4) STS considers a limited number of A&P projects annually that link STS ND datasets to other sources of medical data (e.g., CMS claims data).
 - 5) Principal Investigators overseeing projects that exceed the analytic hour limits specified in the decision letter will be notified and asked to pay the added expense for additional analytic hours needed to complete the project.

- **Institutional Limits** are as follows: The number of active A&P projects led by principal investigators from the same institution is set at a maximum of 2 projects for each specialty database in which principal investigators from the same institution are participants. Projects are considered active until a manuscript has been submitted to a peer-reviewed journal for publication.

2.2 Specialty Review Cycles

- A&P proposals based on ACSD, CHSD, GTSD, and ID will be reviewed and processed in 2 cycles per year. The annual deadlines for each cycle are summarized in Table 1.

Table 1. Proposal Submission Deadlines

Specialty Database	Cycle I	Cycle II
ACSD	1-Feb	1-Aug
CHSD	1-Apr	1-Oct
GTSD	1-Mar	1-Sept
ID	1-May	1-Nov

Proposal submission deadlines are subject to change. Please contact the Research Center for the most up to date information regarding deadlines for a specific cycle.

2.3 Phase I: Application and Review

- Prior to submitting an application for an A&P research proposal, PIs are strongly encouraged to review the [list of active STS research proposals](#) maintained on the STS Research Center web page and consult with RC staff regarding research topic availability in order to guard against scientific

overlap. PIs are also strongly encouraged to review the [list of recently published STS research studies](#) based on the STS-ND maintained on the STS Research Center web page.

- PIs and their co-investigators must carefully review, complete, and submit an A&P proposal application. The web based application form can be found [here](#). The A&P application includes mandatory sections (e.g., full research proposal, PI information and biosketch, list of investigators) that will be used to evaluate the proposal following submission. Proposals should be complete and sufficiently detailed to enable a feasibility assessment based on data available in the STS National Database.
- *Administrative Review* - For a given review cycle, STS RC staff will conduct an administrative review of all submitted applications and check for completeness, PI eligibility (investigator and institutional limits), and scientific overlap. STS RC staff will provide the results of the administrative review to the respective A&P Specialty Review Committee chair. The Specialty Review Committee chair will make the final decision on whether proposals move forward for feasibility assessment.
- *Feasibility Assessment* - Proposals that pass administrative review will be sent immediately to the STS DAC for an initial feasibility assessment. The STS DAC will convey the results of the feasibility assessment to the STS Research Center and the respective Specialty Review Committee chair for final decision on feasibility and whether the project should move to formal review.
- Proposals that are deemed feasible will enter the formal review process, and the PI will be informed of a final decision once available.

2.4 Notification of A&P Task Force Decisions

- The A&P Task Force will render one of three possible decisions for any given proposal:

Not Approved. The principal investigator will receive a decision letter with comments explaining the negative outcome. The investigators involved with the proposed project may:

- discuss the decision with an assigned A&P Task Force member at a time coordinated by Research Center Coordinator;
- re-submit a revised proposal that would be considered as a new application in a future review cycle.

Approved STS-Funded. The principal investigator will receive an A&P approval letter with relevant instructions regarding next steps.

Approved for Self-Funding. Projects that have scientific merit but do not rank high enough to be an STS-funded project (in light of limited resources), can be approved for self-funding. The principal investigator will receive a self-funded approval letter with relevant instructions regarding next steps.

- Following the A&P Task Force decisions for each review cycle, the STS RC will send out decision letters on behalf of the Task Force to PIs within one week. The decision letter will include:
 - full reviewer comments;
 - if approved, number of analytic hours, and consequences for exceeding the approved allotment of hours; and
 - description of STS expectations of the PI, his/her responsibilities, and consequences for non-adherence. Expectations include: 1) being responsive to inquiries from the data analytic center; 2) maximizing availability of the investigative team for project related conference calls; and 3) adhering to journal and ICMJE authorship guidelines.

2.5 Phase II: A&P Data Analysis

- STS staff will schedule a kick-off call for the investigators and analytic team. All analyses will be conducted at the STS designated DAC according to a study analysis plan that is finalized between the investigators and the analytic team.
- The A&P Specialty Review Committee will typically assign one mentor to each project. The mentor is an expert in observational research with the STS National Database. The role of the mentor is to track progress, facilitate interaction with the STS Research Center and the DAC, and provide scientific input as needed. Authorship for the mentor is at the discretion of the study PI, and will follow standard authorship criteria. The Specialty Review Committee may assign additional mentors to an individual project as needed.
- The analytic report completed by the STS DAC will be shared with the PI and co-investigators, Committee chair, Specialty Review Committee mentor, and the STS Research Center. Investigators may consult with the DAC and Research Center about the analytic report and any additional analysis required for preparation of articles and abstracts.
- The Specialty Review Committee will monitor the progress of A&P project analyses and seek to facilitate timely completion of the analytic process.
- A 3- to 6-month time-line is anticipated for completion of A&P analyses and production of a final analytic report, depending on scope and complexity.

2.6 Phase III: Dissemination of A&P Research

- Upon receipt of the final analytic report, the principal investigator must submit an abstract or a manuscript for review by the relevant A&P Specialty Review Committee within 8 or 12 weeks, respectively.

- Investigative teams are strongly encouraged to share with the analytic team the draft “Methods” and “Results” sections (including tables) of manuscripts that are under development as early as possible, but well in advance of manuscript completion.
- Investigators should send their abstracts to the STS-RC staff at least 15 days prior to meeting abstract submission deadlines and manuscripts at least 30 days prior to journal article submission. Abstracts and manuscripts will be reviewed by the relevant Specialty Review Committee.
- If a lead author does not produce abstracts and/or manuscripts in compliance with the aforementioned timeframes, the A&P Task Force Chair reserves the right to offer lead authorship on the respective project to another investigator on the original team or someone else if necessary. The previous lead author would remain on the author byline.
- The Specialty Review Committee 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 Specialty Review Committee will not exercise veto power over final abstract/manuscript 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 any A&P research proposal output (abstract or manuscript) as it deems appropriate.

- STS strongly suggests that A&P investigators target the STS Annual Meeting and *The Annals of Thoracic Surgery* as the meeting and publication forums, respectively, for dissemination of A&P-based research. If A&P 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 data must recognize the STS A&P 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 Access and Publications Research Program.”

- Failure to meet dissemination of A&P Research obligations may result in the PI being ineligible to participate in STS Research through the A&P program for a period of 2 years.

3. Minor Data Requests

The A&P Specialty Review Committee chairs will consider minor data and analysis requests for approval. In general, minor data requests (MDR) will require no more than 2-4 hours of statistical analytic time.

MDRs are intended for internal research purposes and not to be used for presentation or publication. Data generated for a minor data request will not include multivariable modeling or complex statistical analysis. Data generated from a MDR may be used as background information for a subsequent A&P project proposal. In exceptional circumstances, an investigator may request permission to use the results of a MDR as supplemental information in a publication or presentation. The A&P Task Force will consider these exceptional requests. Publications and presentations in which data from a MDR are used must be reviewed and approved by the A&P Task Force.

Application Form and Review Process:

- Investigators seeking minor data requests must complete and submit a [minor data request form](#). (STS Research Center staff will confirm receipt of the request via email, review the form for completeness, and seek clarifying information if necessary. STS Research Center staff will disseminate completed MDR forms to the appropriate A&P Specialty Committee Chair requesting review and approval/denial of the request.
- STS Research Center staff will share approved MDRs with the STS data analytic center and request an estimate of hours required to complete the minor data analysis.
- Approved MDRs that require less than 4 hours of analytic time are executed by the STS data analytic center and the data/analytic output is provided to the investigator.
- Investigators with approved MDRs that require more than 4 hours of analytic time are advised by the A&P Specialty Committee Chair to modify their request to stay within the 4-hour limit.
- Approved MDRs are typically completed from submission to data/analytic output in 4-6 weeks.