

**STS Access and Publications
Processes, Procedures and Leadership**

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STS Access and Publications (A&P) Processes, Procedures and Leadership

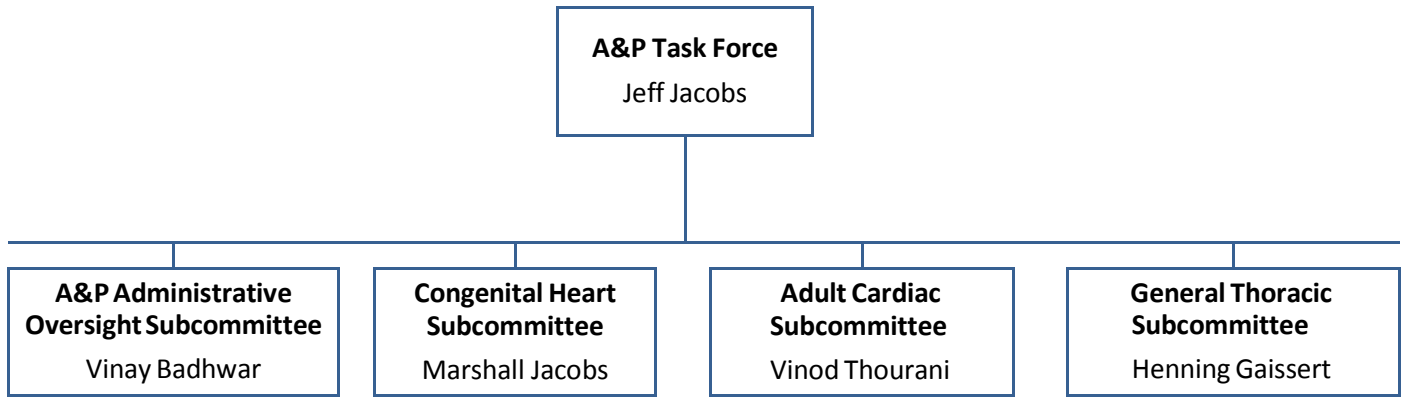
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STS A&P Task Force Structure and Leadership



Minor Data Request Review Process

In general, minor data requests require a maximum of four hours of statistical analytic time and are reviewed by the chair of the subcommittee to which a request pertains. In rare situations, requests that require additional hours may be considered by the subcommittee chair and A&P Task Force Chair on a case-by-case basis.

Minor data requests are intended for internal purposes and are not intended to be used for presentation or publication. Data generated for a minor data request does not include multivariable modeling or complex statistical analysis and cannot be combined with or compared against externally sourced data. Data generated for a minor data request may be used as background information for a major data request. In exceptional circumstances, an investigator of a minor data request may intend to use data as supplemental information in a publication or presentation. Authorization for such uses may be granted with the express written consent of the A&P Task Force Oversight Subcommittee. Publications and presentations, in which data from a minor request are used, must be submitted to STS for the A&P Task Force Oversight Subcommittee's review.

Review Process

- STS receives a data request form and sends an email response to the requestor to confirm receipt.
- STS sends the form via email to the appropriate subcommittee chair to request review.
- The subcommittee chair reviews the form and either grants or denies approval. If the minor data request is not approved, STS notifies the requestor accordingly. If approved, the request continues through the review process.
- Duke Clinical Research Institute (DCRI) generates an estimate of hours required to complete the requested analysis.
 - If four hours or less are required, STS notifies the requestor regarding the approval of his/her proposal and DCRI begins work.
 - If more than four hours are required, DCRI notifies STS, the A&P Task Force Chair, and the appropriate subcommittee chair for consideration.
- DCRI provides progress updates to the requestor until analyses are completed and provides data to the requestor in the appropriate electronic format.

Major Data Request Review Process

A&P major data requests are reviewed twice a year on a rolling cycle. Each proposal review subcommittee (Adult Cardiac, General Thoracic, and Congenital Heart) is composed of 10 members, i.e., 8 STS physician members and 2 DCRI statistical or clinical team members, who are responsible for reviewing the data requests.

Review Process

- STS receives a data request form and sends an email response to the requestor to confirm receipt. STS will confirm application completeness and inform the requestor of any administrative issues (if applicable). If no issues are identified, the proposal continues through the review process.
- STS sends the form to the appropriate A&P Subcommittee Chair and members, as well as DCRI, for preliminary review.
 - DCRI informs STS of any issues (e.g., clarifications needed, general issues with research questions), which STS relays to the requestor. If applicable, requestors are given the opportunity to make revisions and resubmit proposals for review during the same cycle, as long as the revised proposal is submitted by the proposal due date.

	Review Cycles*					
	Adult Cardiac		General Thoracic		Congenital Heart	
Proposal Due	Feb 1	Aug 1	March 1	Sept 1	April 1	Oct 1
Initial Subcommittee Review Completed**	March 1	Sept 1	April 1	Oct 1	May 1	Nov 1
Formal DCRI Review Completed and Shared with Subcommittee	April 1	Oct 1	May 1	Nov 1	June 1	Dec 1
2 nd Subcommittee Review Completed***	May 1	Nov 1	June 1	Dec 1	July 1	Jan 1
A&P Administrative Oversight Subcommittee Sign-off	May 10	Nov 10	June 10	Dec 10	July 10	Jan 10
Requestors Notified of A&P Task Force Decision	May 15	Nov 15	June 15	Dec 15	July 15	Jan 15

*Dates listed are subject to change at the discretion of the A&P Adult Cardiac, General Thoracic or Congenital Heart Subcommittee Chair. The STS Research Center will send out relevant notifications when such changes are made. Please contact the Research Center for the most recent information regarding deadlines for a specific cycle.

**During initial review, Subcommittee members submit votes on each proposal across 5 domains, i.e., scientific merit, feasibility, impact of proposal, appropriate use of the database, and nature of investigative team. A detailed conference call discussion takes place regarding the proposals received. During the call, one of the following decisions is made:

1. Proposal is approved and DCRI begins formal review.
2. Proposal is returned to requestor for refinement. The requestor may then submit a revised proposal to be considered during the NEXT cycle of proposal review.
3. Proposal is rejected.

*** Second review includes a conference call during which DCRI results are reviewed and one of the following decisions is made:

1. Proposal is approved for STS funding and DCRI begins work.
2. Proposal is approved and eligible for self-funding.
3. Proposal is rejected.

Major Data Request Review Process

- Subcommittee chairs assign a subcommittee member to serve as the A&P mentor for each approved proposal. **During each cycle, the subcommittee prioritizes approved proposals based on scientific merit and quality. If two proposals are of equal scientific merit and quality, they are prioritized by date of submission.** Exceptions may be made if a proposal takes precedence over others, e.g., a unique study that helps the specialty as a whole or a request from the STS President. If the STS A&P Task Force receives multiple highly-related and overlapping A&P proposals within a short time frame, it may deny the later proposal, or it could attempt to bring investigative teams together to conduct the research jointly.

Abstract and Manuscript Submission and Review Process

The A&P Task Force reviews and approves abstracts and manuscripts prior to both presentation and publication. Upon completion of the data analyses, DCRI disseminates the results to the requestor and his/her investigative team, assigned A&P mentor, appropriate subcommittee chair, A&P Task Force Chair, and STS. Upon receipt of the data, the requestor must submit an abstract or a manuscript for A&P Task Force review within 8 or 12 weeks, respectively.

Abstracts and manuscripts intended for presentation at a scientific conference must be sent to STS for A&P Task Force review at least 2 and 4 weeks prior to submission deadlines, respectively. It is critically important to move research questions from abstract to manuscript in a timely manner. A manuscript draft must be provided to the A&P Task Force no later than 12 weeks after an abstract is presented at a scientific conference.

Investigative teams are strongly encouraged to share with the DCRI analytic team the draft 'Results' section (including tables) of manuscripts that are under development as early as possible but well in advance of manuscript completion.

The A&P Task Force reviews each abstract and manuscript and subsequently submits votes which are collated by STS. If the voting majority approves the abstract or manuscript, the requestor is granted approval to move forward with his/her submission. If the voting majority denies approval of the abstract or manuscript, the requestor is granted 4 weeks to make modifications to his/her work and to resubmit it for A&P Task Force review.

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 manuscript to another interested investigator. The previous lead author remains on the author byline.