SOCIETY FOR VASCULAR SURGERY
SVS PSO
PATIENT SAFETY ORGANIZATION

Request for Non-Identifiable Regional Datasets

Non-identifiable datasets for regional or national quality research may be prepared by the Society for Vascular Surgery® Patient Safety Organization (SVS PSO), with permission of the involved Centers (the hospitals or physician groups that have contracted with the SVS PSO). Each regional quality group must specify a mechanism for review and approval of such requests, normally through a Research Advisory Committee (RAC). Only SVS PSO members who are members of a regional quality group may request non- identifiable datasets for regional or national quality research. Each participating Center whose data would be included in a non-identifiable dataset must approve this, as outlined below. Independent Centers not part of a regional quality group only have access to their own clinical data. Procedures vary slightly for requesting non-identifiable data from a single regional quality group versus multiple regional quality groups.

Request for a Single Region Dataset:

- PSO member request for non-identifiable regional dataset must first be approved by their regional quality group as specified in the regional group bylaws approved by the SVS PSO.
- Once approved, the regional group requests release of the non-identifiable dataset from the SVS PSO to the regional group member, providing documentation of regional group approval. This request for regional data release must include:
  - Intended quality research project name
  - Description of the project
  - Name and contact information for the principal investigator of the regional group
- SVS PSO requests permission from the designated authority of each regional contracted Center in order to include their data, in the manner set forth in their contract with the PSO.
- PSO prepares a non-identifiable dataset from all Centers that approve participation in the project.
- PSO obtains signed agreement from the designated regional group principal investigator indicating that they will only use the dataset for the specified project.
- PSO releases non-identifiable dataset and logs the release.

Request for a Multi-Region Dataset:

- PSO member request for non-identifiable regional dataset must first be approved by their regional quality group as specified in the regional group bylaws approved by the SVS PSO.
- The regional group representative to the PSO Quality Committee invites participation of other regional groups.
- PSO Quality Committee reviews the proposal, negotiates any recommended changes with the initiating regional group Quality Committee representative, and then approves the quality research project for multi-region participation.
- Each regional group must approve inclusion of their regional data through their representative on the Quality Committee. Each regional group that approves participation shall have one or more members on the investigation team, with ultimate authorship of scientific papers dependent on meeting authorship requirements. Any resulting presentations or publications will be designated as originating from the participating regional quality groups.
- PSO requests permission from the designated authority of each contracted Center from regions that have approved the multi-regional project in order to include their data, in the manner set forth in their contract with the PSO.
- PSO prepares a non-identifiable dataset from all Centers that approve participation in the project.
- PSO obtains signed agreement from the designated multi-regional group principal investigator indicating that they will only use the dataset for the specified project.
- PSO releases non-identifiable dataset and logs the release.

Notice Regarding IRB Approvals:

- If your institutional policies require IRB approval for de-identified data used for research and publication, the recipient agrees that this study will be approved by the IRB of the institution that takes responsibility for performing the research prior to publication.
- Since only fully de-identified data are used for this research, such projects are normally deemed as not requiring human subjects review by an IRB.