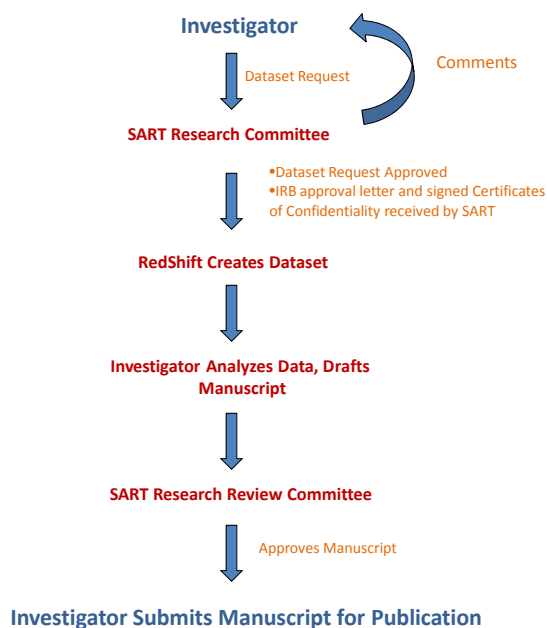


Guidelines for Investigators Requesting a Dataset from SART CORS for Research Purposes

Overview

If you are interested in considering requesting data from SART, you will first want to consult the list of fields that are collected to determine if the database would be able to answer your research question. You can find a list of fields with a description of what is included in each field at www.SARTCORSONline.com. Click the “Help” link at the top of any screen except the Home Page. Note that the PI of the project must be a SART member.

Please see the figure below for an overview of the process. Step-by-step instructions are provided below.



Step-by-Step Instructions

1. Please complete the “Application for a SART CORS Dataset” available on the members-only section of the SART website under “Research.”

(a) When formulating your request, please consider the enormous size of SART-CORS. A single year will contain information for over 125,000 cycles with many available fields for each of the cycles. Please request only fields that are justified by your project (i.e. a dataset containing the minimum number of data fields for the minimum number of years to adequately conduct the research). On the other hand, please try to request all fields that you need at the time of the initial request.

(b) Before taking the time to complete this application, you may wish to send an email with a brief (two or three sentence) description of your planned project to determine if a similar project is already in progress. Please also feel free to contact Kelly Jefferson kjefferson@asrm.org or SART Research Committee Chair, Valerie Baker at vlbaker@stanford.edu with questions.

2. The SART Research Committee will review the proposal and provide comments back to you. The Research Committee can help you to know if your research questions are appropriate for SART CORS. We also want to inform you if a very similar study is already in progress, and provide you an opportunity to refine your request. In consultation with Redshift, the Research Committee will determine if the requested data can be released.
3. Redshift and the SART Research Committee will provide you with an estimate of the cost of generating the dataset before processing the request. A rough estimate of range of costs is \$500 to \$2000.
4. Before the dataset can be released, Kelly Jefferson at SART must receive:
 - (a) A letter from your IRB documenting that the project has been reviewed and approved
 - (b) Signed Certificates of Confidentiality for each person involved with the project. The Certificate of Confidentiality is available on-line in the members-only section of the SART website. It is the responsibility of the PI to gather the signatures, then scan and submit these certificates to Kelley Jefferson.
5. Once the proposal is approved by SART, and the documentation of IRB approval, Certificates of Confidentiality, and payment is received, the project will be listed on the queue for obtaining a dataset. Priorities on the queue will be set according to the recommendation of the Research Committee with high consideration given to the date when the final proposal and all documentation were received.
6. Data will be provided in Access as a series of columns with each cycle listed as a row and the requested fields listed as columns. Protected Health Information (PHI) such as names and dates cannot be released to any individuals outside of SART. SART also cannot release data from cycles which took place prior to 2004.
7. SART strongly urges researchers to work closely with a statistician to correctly handle missing data (which is very frequent for some fields) and to choose appropriate methods for manipulating the data (importing from Access, exploring and categorizing, modeling and analyzing, and designing tables).
8. After you have analyzed your dataset and written your manuscript, the manuscript must next be submitted to Kelly Jefferson who will forward it to the Research Review Committee (which is distinct from the Research Committee). Data may not be submitted for publication without prior approval of the SART Research Review Committee. The

manuscript must acknowledge SART and its members with a statement such as: "SART wishes to thank all of its members for providing clinical information to the SART CORS database for use by patients and researchers. Without the efforts of our members, this research would not have been possible."

9. A yearly progress report must be submitted for all projects which are not submitted for publication within a year of the PI receiving the data. The report should include: title, updated list of the names of co-investigators, progress toward project goals, specific information about the security under which the data are held. This report will be reviewed and must be approved by the SART Research Committee. The Research Committee reserves the right to terminate the activities of any project and require immediate destruction of the datasets for reasons including but not limited to: suspected misuse of data, failure to report progress on a yearly basis, lack of progress, particularly if another investigator has interest in pursuing a similar research question using the dataset.

Other Requirements

Any investigator who wishes to have a dataset created from SART CORS must agree to follow the step-by-step process described above and also abide by the following conditions:

- The PI of the project must be a SART member.
- Access to the data will be permitted solely for the proposed project. Subsequent requests for data analysis must be submitted as new study protocols and are subject to the review and approval process described above.
- The dataset may not be copied or transmitted in any form to any individual who is not listed as an approved investigator and who has not signed the required Certificate of Confidentiality.