Instructions for Investigators Requesting a Research Dataset from the SART Clinical Outcomes Reporting System (SART CORS)

Overview

If you are interested in requesting data from SART for research purposes, first please 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 and you can download the list of all fields with definitions.
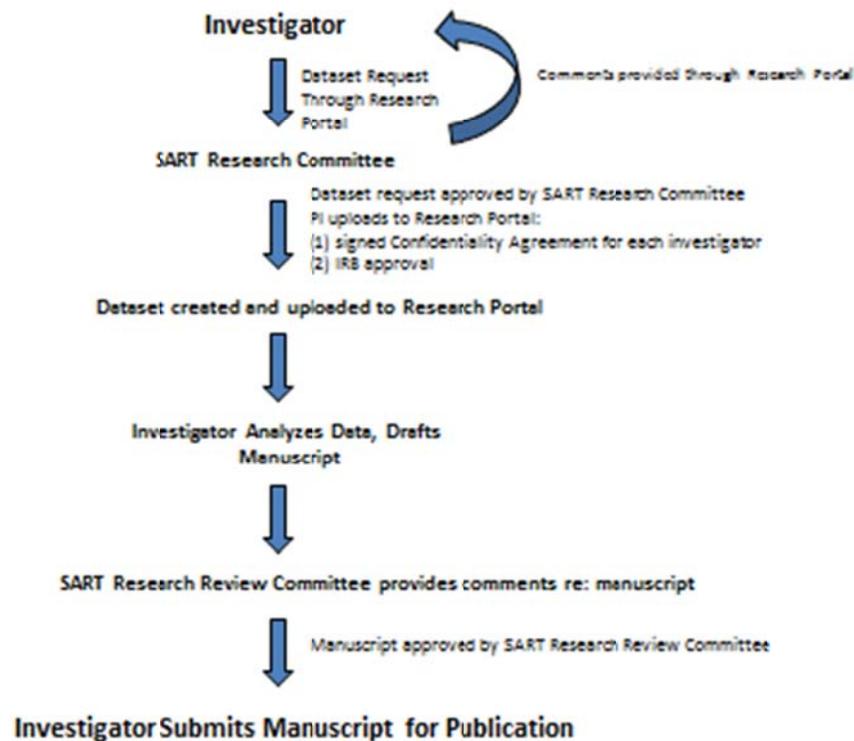
Before taking the time to complete this application, you may wish to determine if a similar project has already been done. Please consult the list of "Publications from SART CORS" on the sart.com website research tab to determine if a manuscript with your research proposal has recently been published. You can also log onto the Research Portal as described below to see if a project very similar to yours has been accepted or rejected since the Portal's release in late 2014. Please also feel free to contact Kelley Jefferson (kjefferson@asrm.org) or the SART Research Committee Chair.

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*. The requested dataset should be complete, but contain the minimum number of data fields for the minimum number of years to adequately conduct the research.

Any investigator who wishes to have a dataset created from SART CORS must agree to follow the step-by-step process described below 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.

• The dataset may not be copied nor 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.

Please see the figure below for an overview of the process, with step-by-step instructions:

Investigator

Dataset Request Through Research Portal

Comments provided through Research Portal

SART Research Committee

Dataset request approved by SART Research Committee
PI uploads to Research Portal:
(1) signed Confidentiality Agreement for each investigator
(2) IRB approval

Dataset created and uploaded to Research Portal

Investigator Analyzes Data, Drafts Manuscript

SART Research Review Committee provides comments re: manuscript

Manuscript approved by SART Research Review Committee

Investigator Submits Manuscript for Publication

Step-by-Step Instructions

1. Please log onto your program's SARTCORSONLINE.com account (which your data manager uses to enter data into SART CORS) and click the "Research" tab in the upper right corner of the toolbar at the top of the Home Page. Your database manager at your program may need to grant you access to SART CORS if you have not previously logged on. To add a user, click User List, select an account, and click the Research Applicant Write / Read boxes (Write allows a research applicant to create and submit applications, Read only allows a user to see those applications, neither box checked hides the entire Portal from that user).

2. The PI who initiates the request for a dataset must be a SART member affiliated with a SART program. However, others can assist in the process. If the PI wishes to have co-investigators work on the request, the PI should start the request, save, and add co-investigators who can work on the request. All participants on your research project must be listed on your application and the list must be updated if changes are made over time.

3. You can create a user who only has access to the Research Portal (and no other SART PHI data). To create a user with access only to the Research Portal: (a) Click User List from the SARTCORSONLINE.com Home Page; (b) Click New Account; (c) Enter details and click the "Research Applicant Only" button; (d) Click Save. This user can now be listed on a Research Application in the Portal, and this account can be modified/made inactive/removed as needed by the clinic. When only "Read" and "Write" checkboxes are selected under the Research Applicant column in the user screen, the only access the

user has is to the Portal within SART CORS. Please make sure all other "Read" and "Write" boxes are unchecked.

4. Once you have a user with sufficient rights, login as that user, and click Research Requests on the Home Page. You'll see filters at the top that will allow you to view different types of requests at various stages. You may wish to choose to review previously rejected and approved requests to find out if your idea has already been considered. You will also want to consult the list of current SART publications which is also listed on the SART.com website to see if your idea has already led to a publication before you attempt to submit a new application.

5. Click "Create New Research Request", and fill out all fields on all tabs.

- The checkboxes down the left side of the "Field Selection" tab under "Select fields to include in dataset" allow you to include or exclude fields from your requested dataset. Checking these boxes includes a column for the respective field's response.
- The checkboxes and filters to the right of the field names under "Limit data by field response (if required)" allow you to restrict your data set by those variables. Depending on the field type, you can control how fields are delivered. For example, if you only want to include fresh, non-donor cycles where more than 10 oocytes were retrieved, you would select only the "Autologous = Y" box under the "ART Treatment - Oocyte Source" section, only the "Fresh = Y" box under the "ART Treatment - Oocyte/Embryo State" section, and enter >10 next to "NumberOocytesRetrieved" in the "Retrieval Information" section.

6. Feel free to fill out part or all of the application, and return to it at any time by clicking Save. If you change tabs, your work is automatically saved. Your request gets an ID, and it will be in your list. Once done, click "**Save & Submit to SART**" - and that's it - the status indicators at the top of your request will help you understand where your request is in the pipeline. Your request will no longer show, by default, in your list (as per default filters) until you either have pending messages in the Portal about your application, or if your application is assigned back to you for revision.

7. The SART Research Committee will review the proposal and provide comments back to you through the Research Portal. 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. The Research Committee will determine if the requested data can be released.

8. All communication about your application will be managed in the Portal. You can use the "Communication" tab within a given request to post messages. When new messages come in addressed to you, you'll receive an email notification to check the Portal.

9. We hope you find the new SART Research Portal useful and easy - however - creating a research request can be complicated depending on what you are trying to do. We are here to help - please contact support@sartcors.com or click "Contact Support" within SART CORS for answers to questions you have as you navigate the Portal. We want your feedback to make the system better and to add clarity - so please don't hesitate to contact us.

While you don't need these documents to apply, before a dataset can be released, you must upload the following to the Research Portal: (a) A letter from your IRB documenting that the project has been reviewed and approved, and (b) Signed Certificates of Confidentiality for each person involved with the project. You may upload these documents once your application is approved by clicking the Documents tab within your application, and then following the prompts on-screen for each person linked to your application. The Certificate of Confidentiality is

available online in the member's only section of sart.org. It is the responsibility of the PI to gather the signatures, then scan and submit these certificates through the Research Portal.

Once the proposal is approved by the SART Research Committee, and SART has received the documentation of IRB approval and Certificates of Confidentiality, a dataset will be generated.

Data will be provided in a Comma Separated Values text file (CSV). Protected Health Information (PHI) such as names and dates are not released. SART also cannot release data from cycles which took place prior to 2004.

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 (exploring and categorizing, modeling and analyzing, and designing tables).

After you have analyzed your dataset and written your manuscript, the manuscript must be submitted to Kelly Jefferson (kjefferson@asrm.org) and the SART Research Committee Chair for review by 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."

A yearly progress report must be submitted for all projects which are not submitted for publication within one 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, and lack of progress, particularly if another investigator has interest in pursuing a similar research question using the dataset.