Submitting a SART Research Proposal: Set Yourself Up for Success

Learning Objectives

- What is SART CORS?
- What kind of research can I do?
- How do I submit a research proposal?

What is SART CORS?

- SART Clinic Outcome Reporting System

- SART members are encouraged to use the national SART CORS database to ask powerful retrospective research questions

Your Research Question

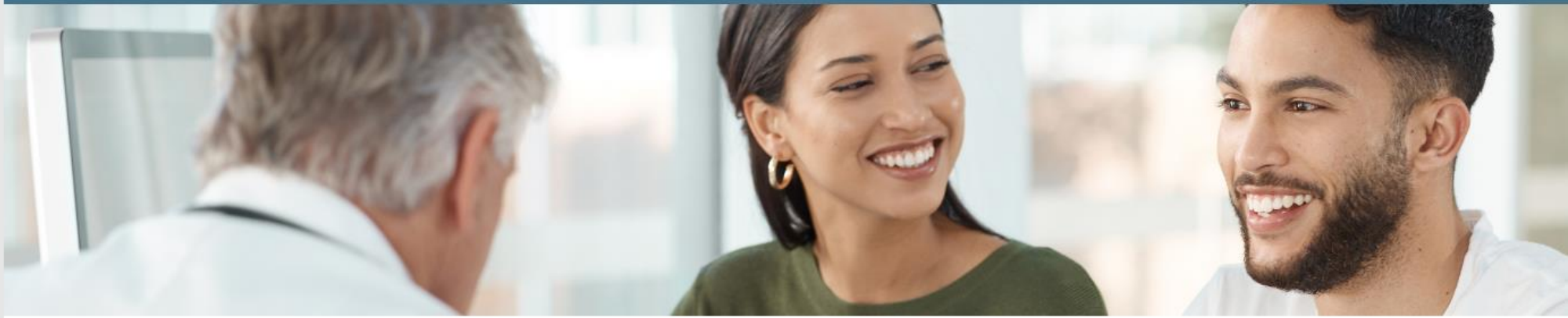
- You may have a question or hypothesis you'd like to test using SART CORS data
- Collaboration is strongly encouraged in order to utilize available resources for statisticians, IRB approval, experience working with SART CORS datasets
- Network and connect with SART CORS researchers

Publications From SART CORS

- For a current list of publications, go to the members only section of **www.sart.org**
- Over 200 publications have resulted from datasets generated from SART CORS

A few highlights:

- Powerful linkage studies between SART and state birth registries
- Prediction models



Publications Using SART CORS

Publications **are listed in chronological order with most recent first.**

1) Walsh TJ, Raheem O, Chen T, Alukal J, Nangia A, Luke B. Impact of male factors on pregnancy outcomes with assisted reproductive technologies. In preparation.
2) Bocca S, Mahesan A, Luke B, Brown MB, Wantman E, Oehninger S. Risk of congenital malformations in ICSI with surgically obtained sperm: A US study in four States. In preparation.
3) Luke B, Brown MB, Wantman E, Meyer RE, Foresteri N, Watkins S, Yazdy M, Browne M, Fisher S, Canfield MA, Ethen M, Nichols HB, Oehninger S, Doody K. Risk of blastogenesis birth defects in IVF, non-IVF ART, and fertile births. In preparation.
4) Park H, Sundaram R, Bell EM, Bell G, Ghassabian A, Lawrence DA, Luke B, Yeung E. Newborn biomarkers on infectious and respiratory diseases during early childhood. In preparation.

FAQs

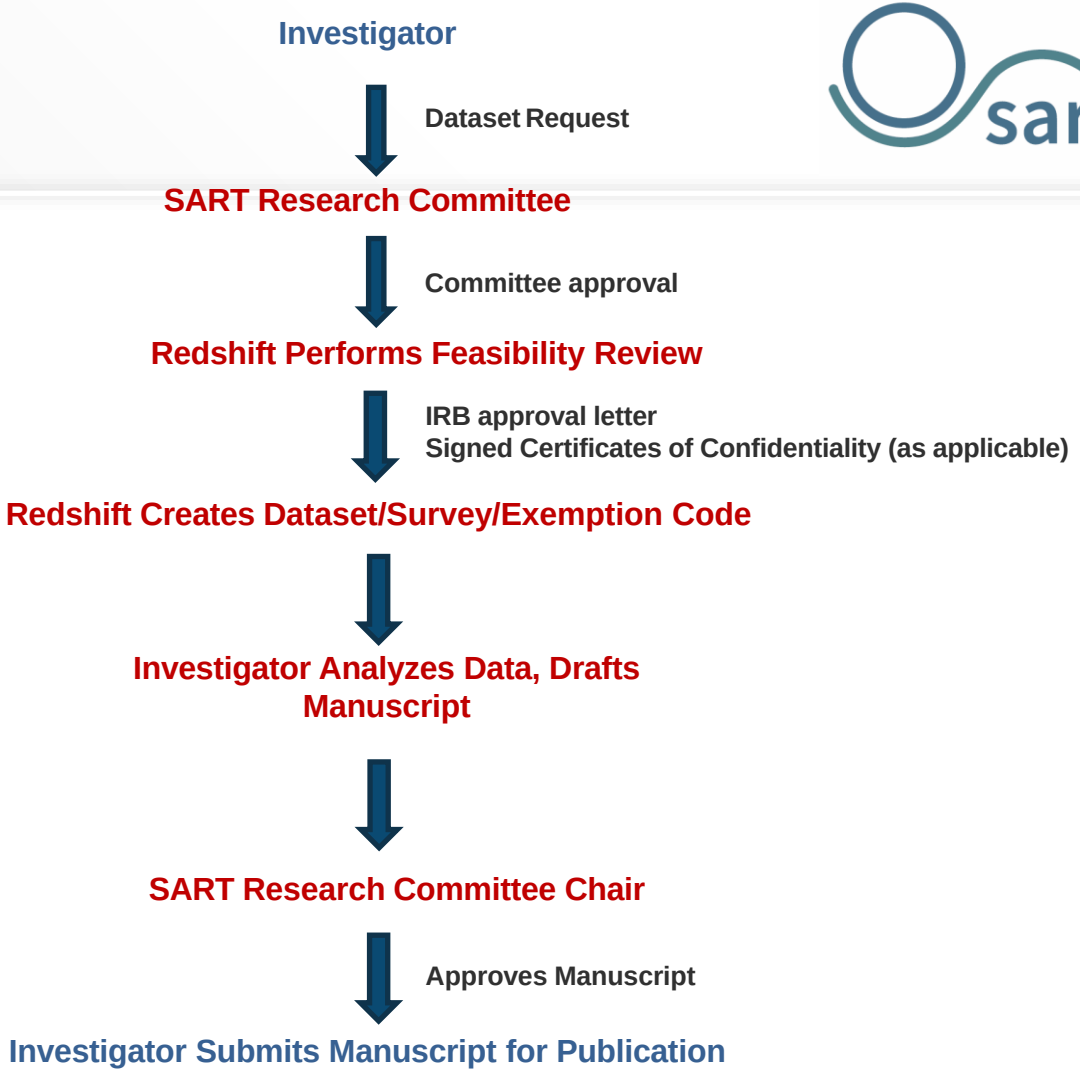
Have questions about IVF and infertility? We have answers.

The SART Research Portal

- ***The SART Research Portal is available to SART members who are interested in:***

  - Requesting a dataset from SART CORS for research
  - Submitting a survey to SART members for research
  - Requesting an exemption from reporting IVF cycles to SART CORS

How do I submit a research proposal?



The Portal is Seasonal

- New Requests: November-February
- Committee Review: February-April
- Redshift Review: April-May
- Dataset Release: estimated June-December

How many proposals are approved annually?

- SART will fund the programming of up to 20 datasets per year
- Surveys separate
  - Surveys about IVF practice patterns (IVF clinics) are appropriate for SART
  - Surveys about individual practice patterns (REIs) should be submitted to SREI

Proposals May Also be Submitted Outside the Annual Window

- Investigators must be able to fund the creation of the dataset
- Approximately $2,000 per dataset (exact amount to be determined by Redshift)
- Estimated timeline for proposal review and dataset generation: 3-6 months

Contact Support

Sign in to SART CORS

Username

drjleaton

Password

••••••••••••

Clinic

Women and Infants Fertility Center (0695)

Forgot Password

Login

TREATMENT DATA AND ANALYSIS

Patients

Cycles

Reports / QA

CLINIC AND USER PROFILES

My Clinic

My Account

User List

PORTALS

Research

Validation

Advertising

Quality Assurance

Billing

HOME | PATIENTS | CYCLES | REPORTS / QA | MY CLINIC | MY ACCOUNT | USER LIST

Research Portal

Research Introduction Documentation | Overdue settings

+ Create New Research Application or Survey | Request for Research Cycle Exemption Code | Data Dictionary | Subcommittees

Application ID
SART #
Title
P.I.
New Messages: All

Application Type: Research
Creation Date
Affiliated: All

Application Status

- [ ] New
- [ ] Assigned to Research Chair
- [ ] Assigned to Research Committee for Review
- [ ] Feasibility Review
- [ ] Open: Assigned to Applicant
- [ ] Document Review: Assigned to Research Admin
- [ ] Approved for Release
- [ ] Released
- [ ] Rejected

Apply Filter | Reset Filter | More Filters | Hide All Filters

Application ID	Status	SART #	Clinic	Creation Date	Application Type	Principal Investigator	Title	Objective
4	Released	0341	Massachusetts General Hospital Fertility Center	9/29/2014	Research	Aaron Styer	Implementation of Elective Single Embryo Transfer and the Impact on Term Singleton Live Birth in the United States 2004-2012	The hypotheses of this study include: 1. The rate of eSET utilization has increased in the U.S from 2004-2012. 2. During 2004-2012, an increase in eSET rates resulted in an increase in the rate of term singleton live births and a reduction of twin gestation live births (preterm and term). The primary objectives of this proposal include: 1.To quantify the trend of eSET and rate of singleton live births in the U.S. from 2004 through 2012. 2. To compare the live birth outcomes for patients undergoing eSET or 2ET in selected patient groups in which eSET would be performed (i.e. < 35 yo, 35-37 yo) from 2004-2012 [i.e. singleton live birth conceived with eSET versus 2ET and all singleton live births compared to all multiple gestation live births]. The secondary objective is: To determine if any specific factors are associated with the rate of eSET in 2004-2012
10	Open: Assigned to Applicant	0363	NYU Langone Fertility Center	10/27/2014	Research	David McCulloh	Body Mass Index of IVF Patients	We plan to compare the distribution of body mass indices (BMIs) from our patients (in an already submitted manuscript) to the distribution of BMIs in the general United States' pool of IVF patients.
12	Released	0160	UF Health Reproductive Medicine at Springhill	12/4/2014	Research	R. Stan Williams	Determining the Source of High Order Multiple Pregnancies	We will determine the number of high order multiple pregnancies generated from IVF cycle to those generated from COH and natural cycles

Research Portal

Back to List

Important Information

- Please check to see if an existing application that asked your question has already been submitted and either approved or rejected in the portal – your clinic's applications, and other clinic's approved and rejected applications, can be viewed; just clear all filters on the Research Portal Home Page, and click Apply Filter.
- If you are planning to re-use an existing dataset to ask a new / different question, you must create a new application and reference the existing application for which data was released.
- The schedule for SART funded application reviews is typically late November through early February, with data released between the following June and December. Self-funded applications can be submitted at any time. You may request your application to be considered as self-funded by sending a message to the Research Chair in the Communication Tab.

Create New Research Application

Type

Research

Title

200/200 remaining

Years of Data Requested

Start **End**

2004 2004

Create Application

General Information | Details | Security | Field Selection | Communication | Documentation

You can review the request's status, enter the participants on this request, and the PI information. Each time you change tabs, the system will automatically save. Once you have filled out all fields (on all tabs), click "Save and Submit to SART".

Researchers, Authors & Documentation

Application-Exempt Data Request ☐

Affiliation

Principal Investigator Jennifer Eaton

Sart Collaborator Add Other Investigator / Co-Author | Make same as PI

Add Other Investigator / Co-Author

Principal Investigator Contact Information

Address

Address 2

City

State

Zip Code

Phone

Fax

Email jleaton@wihri.org

General Information | Details | Security | Field Selection | Communication | Documentation

You can review the request's status, enter the participants on this request, and the PI information. Each time you change tabs, the system will automatically save. Once you have filled out all fields (on all tabs), click "Save and Submit to SART".

Objective: Please state the hypothesis to be tested or the objective(s) of your project.

Rationale: Please provide one to two paragraphs of background.

Planned methods of data analysis (one to two paragraphs).

References

Funding

General Information | Details | Security | Field Selection | Communication | Documentation

You can review the request's status, enter the participants on this request, and the PI information. Each time you change tabs, the system will automatically save. Once you have filled out all fields (on all tabs), click "Save and Submit to SART".

Where will the data be stored?

How will the data be protected?

Who will have access to the full dataset?

- [ ] Jennifer Eaton

Who will be reviewing summary tables only (and not be working with the dataset directly)?

- [ ] Jennifer Eaton
- [ ] No One

What data should I request?

- First consult the list of fields that are collected to determine if the database would be able to answer your research question.
  - *Click the 'Help/FAQ' link at the top of any screen.*
    Click the "Data Dictionary" button in the Research Portal
- A single year can contain information for over 200,000 cycles with many available fields for each of the cycles. Please request only fields that are justified by your project.

General Information | Details | Security | Field Selection | Communication | Documentation

You can review the request's status, enter the participants on this request, and the PI information. Each time you change tabs, the system will automatically save. Once you have filled out all fields (on all tabs), click "Save and Submit to SART".

Important Instructions

Please make sure to include all fields and data against which you plan to compare. This form is designed to ensure you do not receive a dataset with unscoped results, but only the data that you need. Selections and filters made must be inclusive of ALL treatments that would need to be part of your analysis and NONE of those that are unrelated.

General Guidance

- Check all fields you are requesting.
- Please only request what can be justified by your objective, while requesting the data you need to avoid the need for a supplementary dataset to be generated.
- Some fields are selected by default and must be a part of every dataset.

Field Selection Guide and Definitions

- Hover over any of the information symbols in the Fields Requested for more information about specific sections.
- **Applying A Filter:** Limit the data you are requesting by setting filters on requested fields. Only cycles that meet the filter criteria will be included in the dataset.
  - ***Include/Exclude Filter:*** *This filter is section specific. Cycles will be included in the dataset if they match ANY ONE of the Include values and NONE of the Exclude values per section. Sections begin with each large blue header (Clinic Information, General Information, etc.).*
  - ***= (Equal to):*** *Cycles will be included in the dataset if they match the specificed value exactly.*
    - *For example, if you would like to ONLY include cycles where 1 oocyte was retrieved, you would set the filter on the NumberRetrieved Field Selection = 1.*
  - ***!= (Not equal to):*** *Select this filter option if there is a specific value you would like excluded from the dataset.*
    - *For example, if you would like to exclude cycles where 0 embryos were suitable for transfer, you would set the filter on the NumSuitableFortransfer Field Selection != 0.*
  - *If you find you cannot filter by the field you want please fill out a special request in the 'Special Requests' section below.*
- If you have additional questions about filters, please reach out to the Research Chair or Data Provider in the Communcation tab of this research application.

Data Linkage

Check the box below to include reference IDs to linked retrievals on thaw type cycle records. This provides cycles with the same constraints set in this application to those source cycles for thaw type cycles, but allows analysis when multiple freezes from multiple retrievals are involved with a given thaw. The complexity of the output and analysis will therefor increase as grouping multiple cycles into categorizations may be difficult.

Notes on linked data availability

- Linkage data is available starting with Reporting Year 2014
- Only Autologous Cycles where no donor eggs were used are linked

☐ **Include Links to Source Retrieval Cycles for Thaw Cycles**

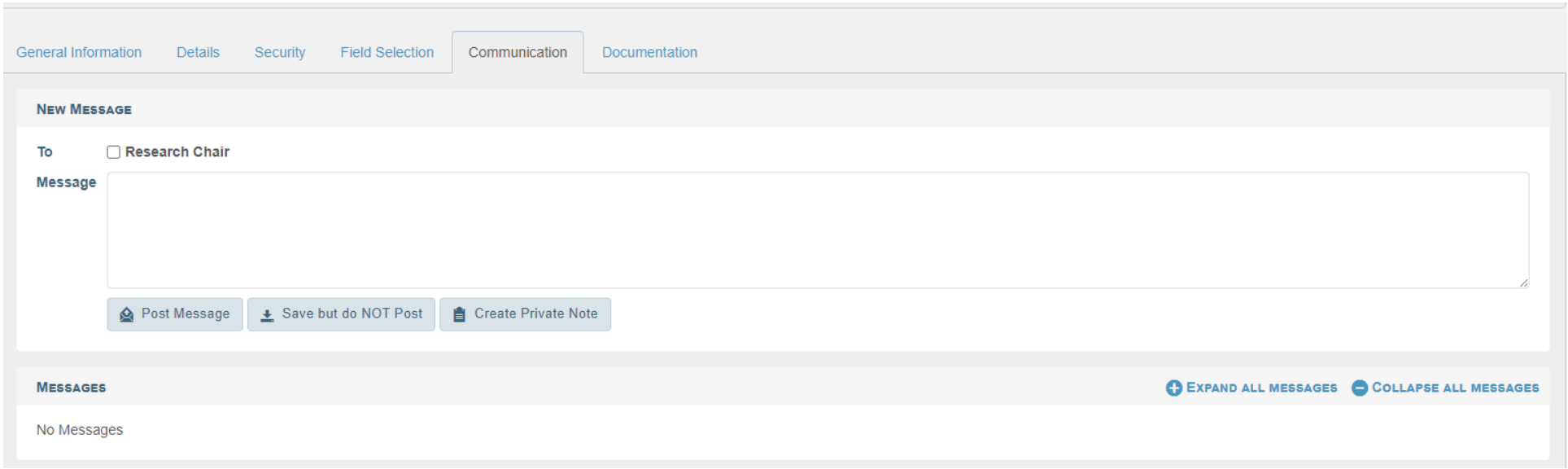
☐ **Include Links to Subsequent Thaw Cycles for Retrieval Cycles**

Fields Requested

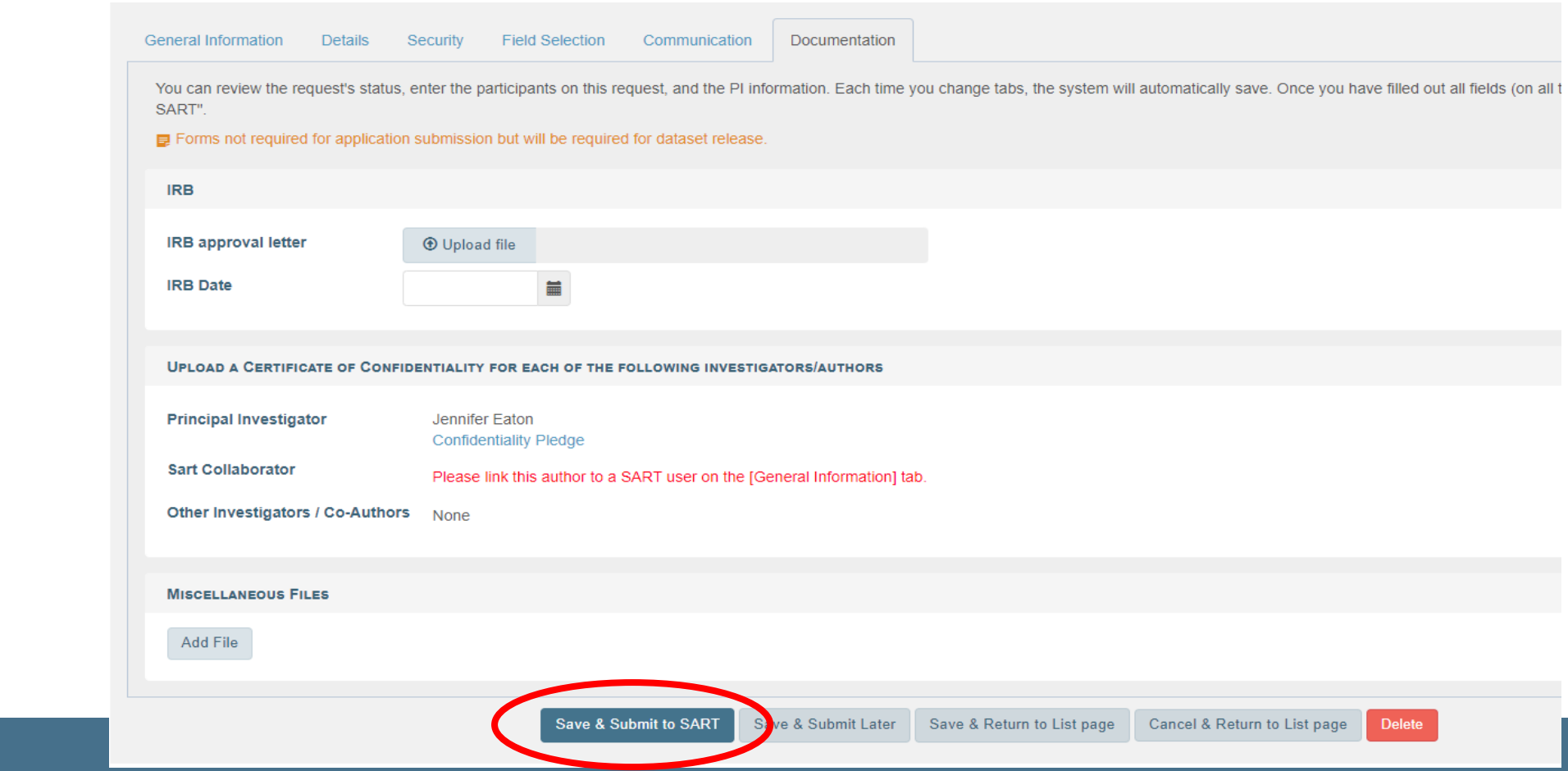
Collapse All Sections | Expand All Sections

Select Fields Check all fields you are requesting. Quick Jump to Section	Apply Filter (Yes / No)	Filter Details Limit the data you are requesting by setting filters on requested fields.
Clinic Information	Apply Filter?	Filter Details
ClinicState (Restricted)	Select field to filter	-
Clinic Region USA	Cannot filter on field	-
General Information	Apply Filter?	Filter Details
ReportingYear	Yes	Between (incl.) 2004 To 2021
CycleOrder	Cannot filter on field	-
ExternalCycleId	Cannot filter on field	-
ExternalPatientID	Cannot filter on field	-
Patient Information	Apply Filter?	Filter Details
Patient Sex	Select field to filter	-
PatientAgeAtStart	Select field to filter	-
Partner Information	Apply Filter?	Filter Details
PartnerIdentityKnown	Select field to filter	-
PartnerAgeAtStart	Select field to filter	-
Patient Residency	Apply Filter?	Filter Details
PatientState	Select field to filter	-
Patient Region USA	Cannot filter on field	-
PatientCountry	Select field to filter	-
PatientUSResident	Select field to filter	-

Send Any Questions to the Research Chair Through the Communications Tab



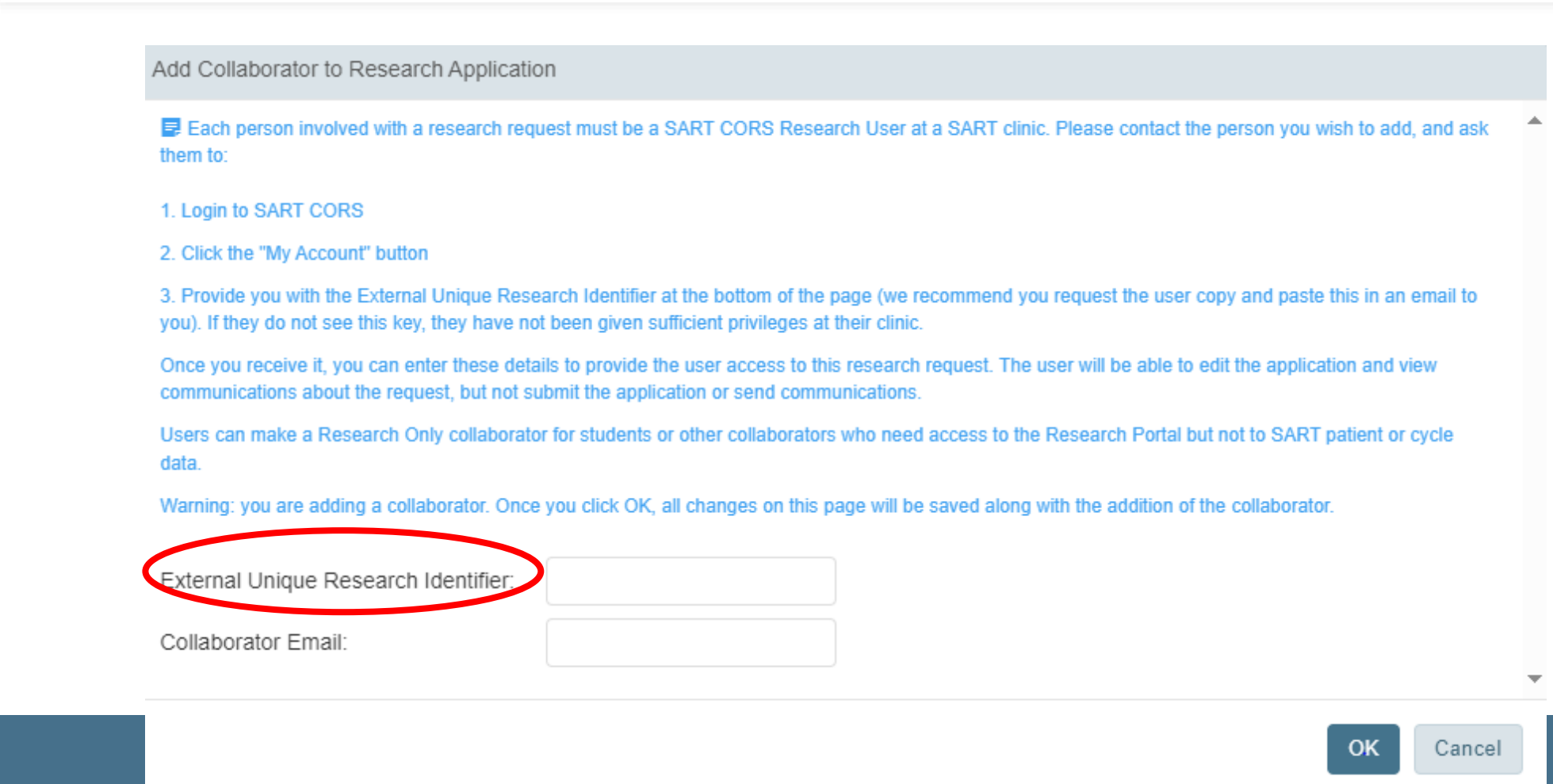
Submit Your Proposal



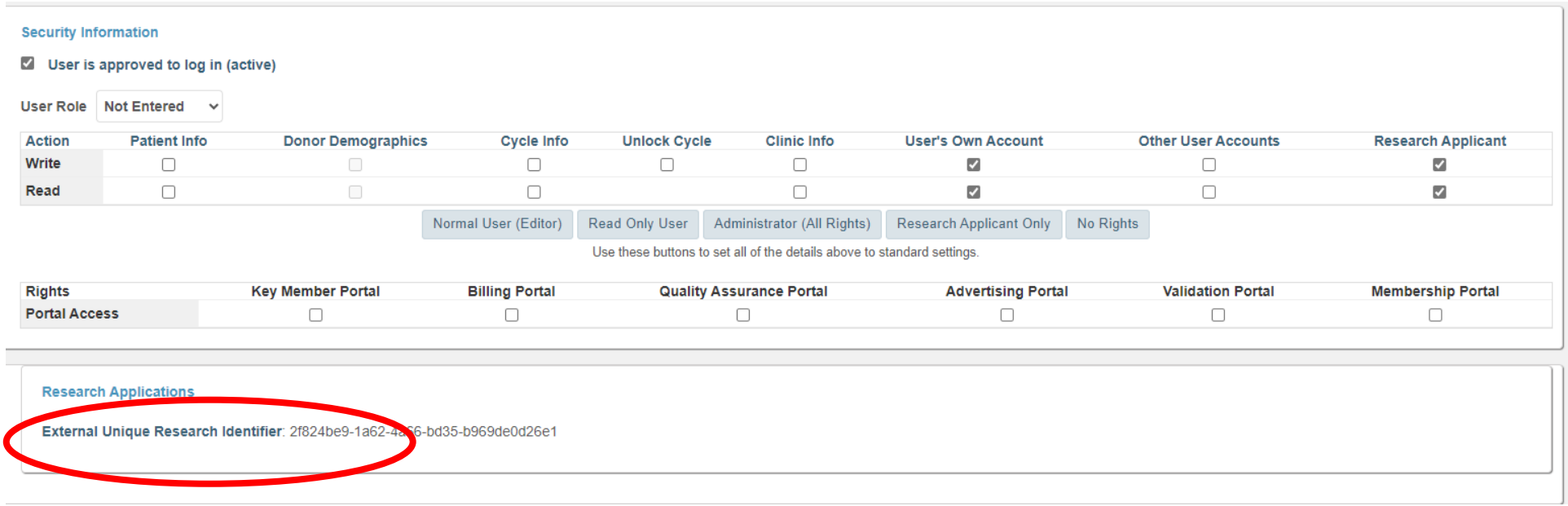
Important Points

- Your proposal is not submitted until you click the “Save and Submit to SART” button
- The PI must be a SART member and cannot be a trainee
- All coinvestigators must be named in the proposal
  - Coinvestigators from different programs can be included as long as they have an *External Unique Research Identifier*

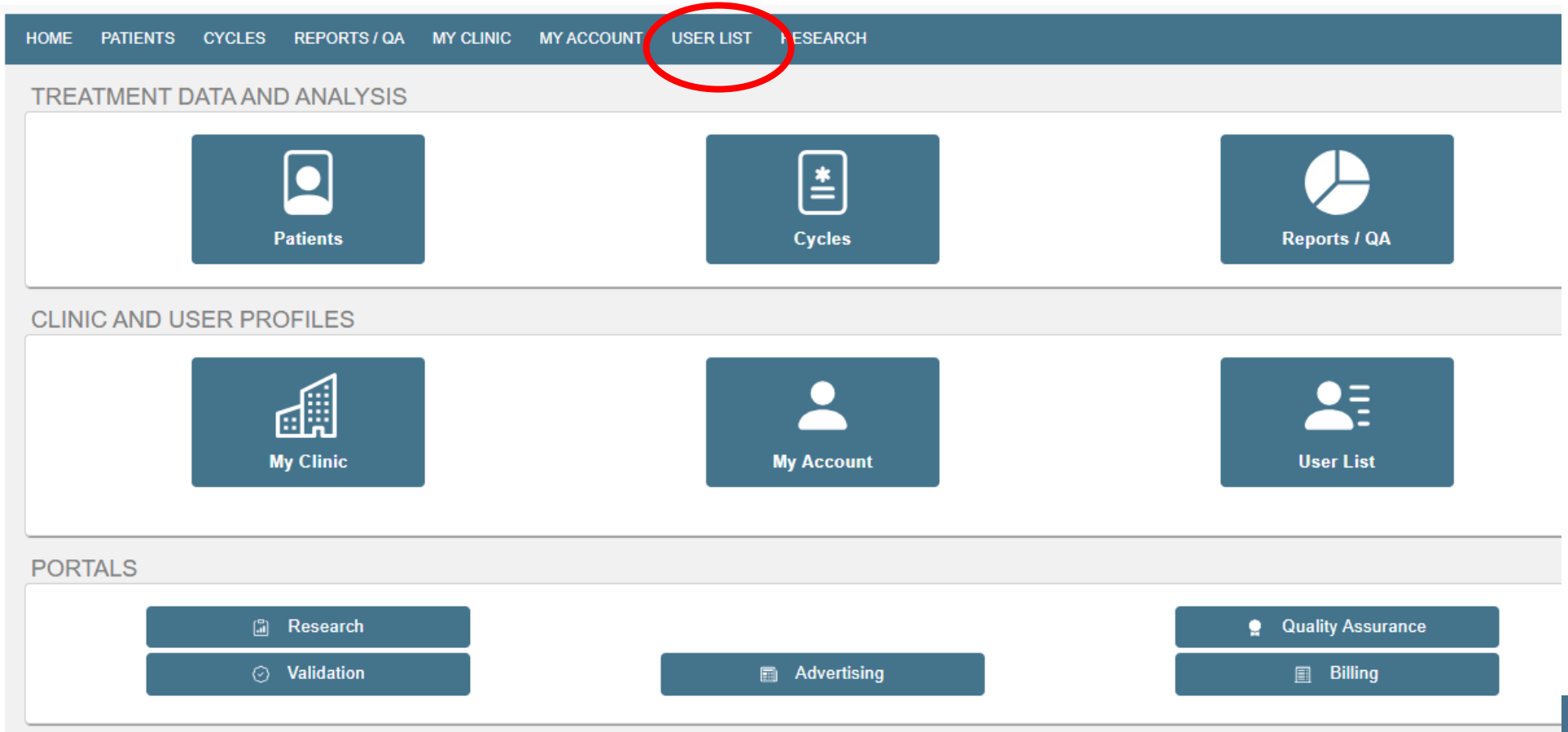
Adding a Coinvestigator



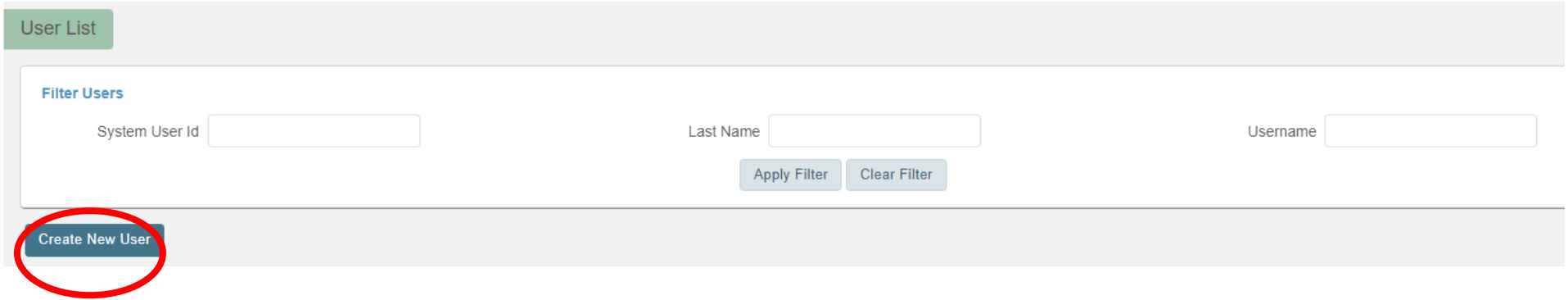
Go to Each User's SART CORS Profile to Find the External Unique Research Identifier



How to Create a User Profile for Investigators Who Don't Currently Have SART CORS Access



How to Create a User Profile for Investigators Who Don't Currently Have SART CORS Access



User Entry

User Information

Username

Password

Confirm password

Last Name

First Name

Middle Initial

Email

Phone

Fax

Title

Suffix/Degree

Profile Display Order

User Bio

Profile Image

No image file uploaded

Please select a jpg, png, or gif file, then click Save at the bottom to complete the image upload. Portrait aspect ratio (3:2) is recommended for optimal display on the sart.org clinic profile.

Select File | Choose File | Clear

Security Information

User is approved to log in (active)

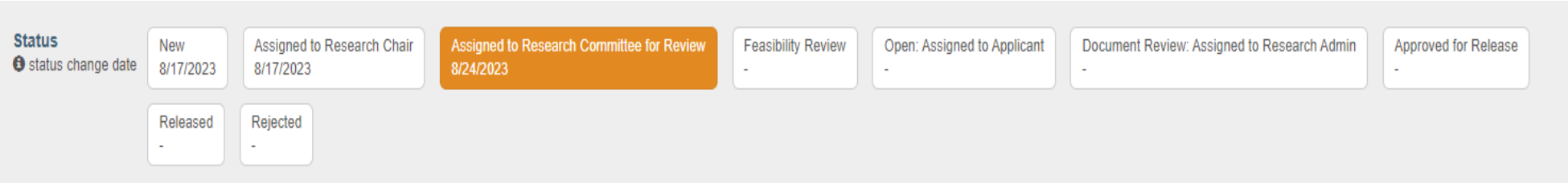
User Role Not Entered

Action	Patient Info	Donor Demographics	Cycle Info	Unlock Cycle	Clinic Info	User's Own Account	Other User Accounts	Research Applicant
Write	☐	☐	☐	☐	☐	☐	☐	☐
Read	☐	☐	☐		☐	☐	☐	☐

Normal User (Editor) | Read Only User | Administrator (All Rights) | Research Applicant Only | No Rights

After You Submit Your Proposal

- Your request gets a Research Protocol Number and it will be in your portal dashboard. The status indicators at the top of your request will help you understand where your request is in the pipeline.



Review of Your Proposal

- The SART Research Committee will review the proposal and provide comments back to you. In consultation with Redshift, the Research Committee will determine if the requested data can be released. Proposals may be sent back to the investigators for revisions.

- All communication with the investigators is done through the COMMUNICATION tab in the portal.

Review Process

- The committee reviews each proposal
- It is a highly structured process with a scoring tool of objective criteria that will be scored by reviewers
- The scoring process is based on the ASRM abstract scoring system

Originality of Hypothesis

0 = None

3 = many other well-designed studies

5 = a modest number of other similar studies

7 = few similar studies

10 = unique

Plan of Data Analysis

0 = inadequate analysis, hypothesis not supported by plan of analysis

5 = deficient analysis, hypothesis partially related to plan of analysis

7 = appropriate analysis, SART CORS data requested appropriate for addressing hypothesis, hypothesis supported by plan of analysis, biostatistician listed

10 = appropriate analysis, SART CORS data requested appropriate for addressing hypothesis , hypothesis supported by plan of analysis, biostatistician listed, shell tables included

Significance

0 = little if any significance, does not advance the field

5 = modest contribution to the field; advance the field modestly

10 = important contribution to the field

Study Design

0-3 = retrospective, moderately novel question, low impact

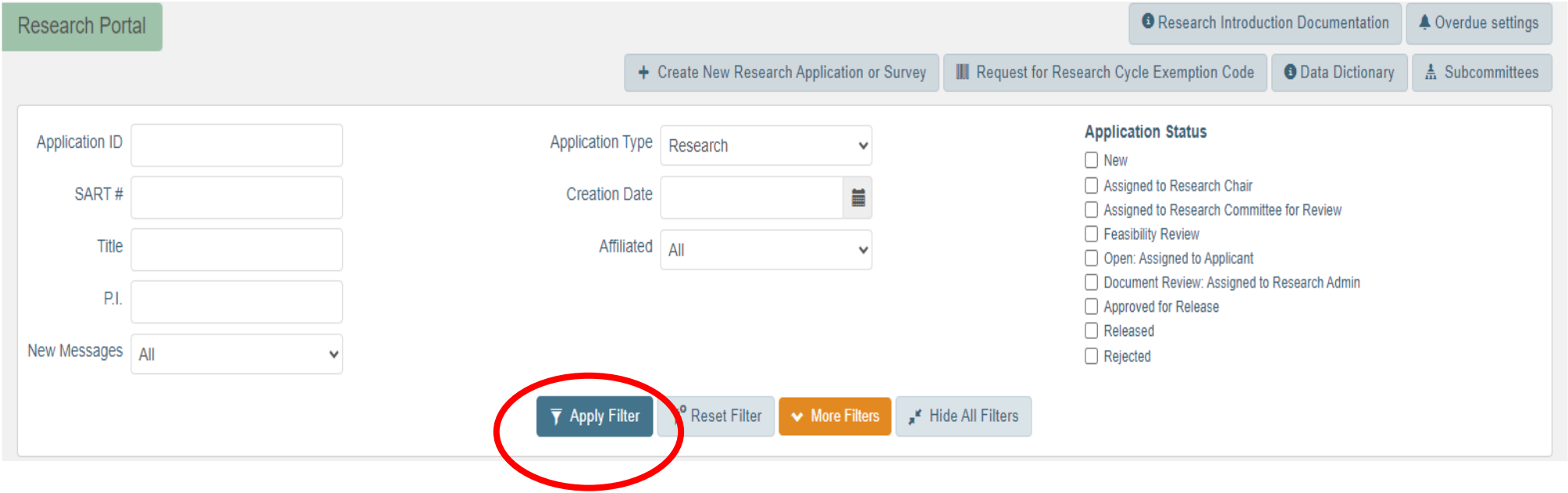
4-6 = retrospective, novel question, impactful

7-8 = simulated RCT, machine learning, prediction models, appropriate statistical modeling, impactful

9-10 = linkage study, appropriate statistical modeling, impactful

Tips for Enhancing Your Proposal

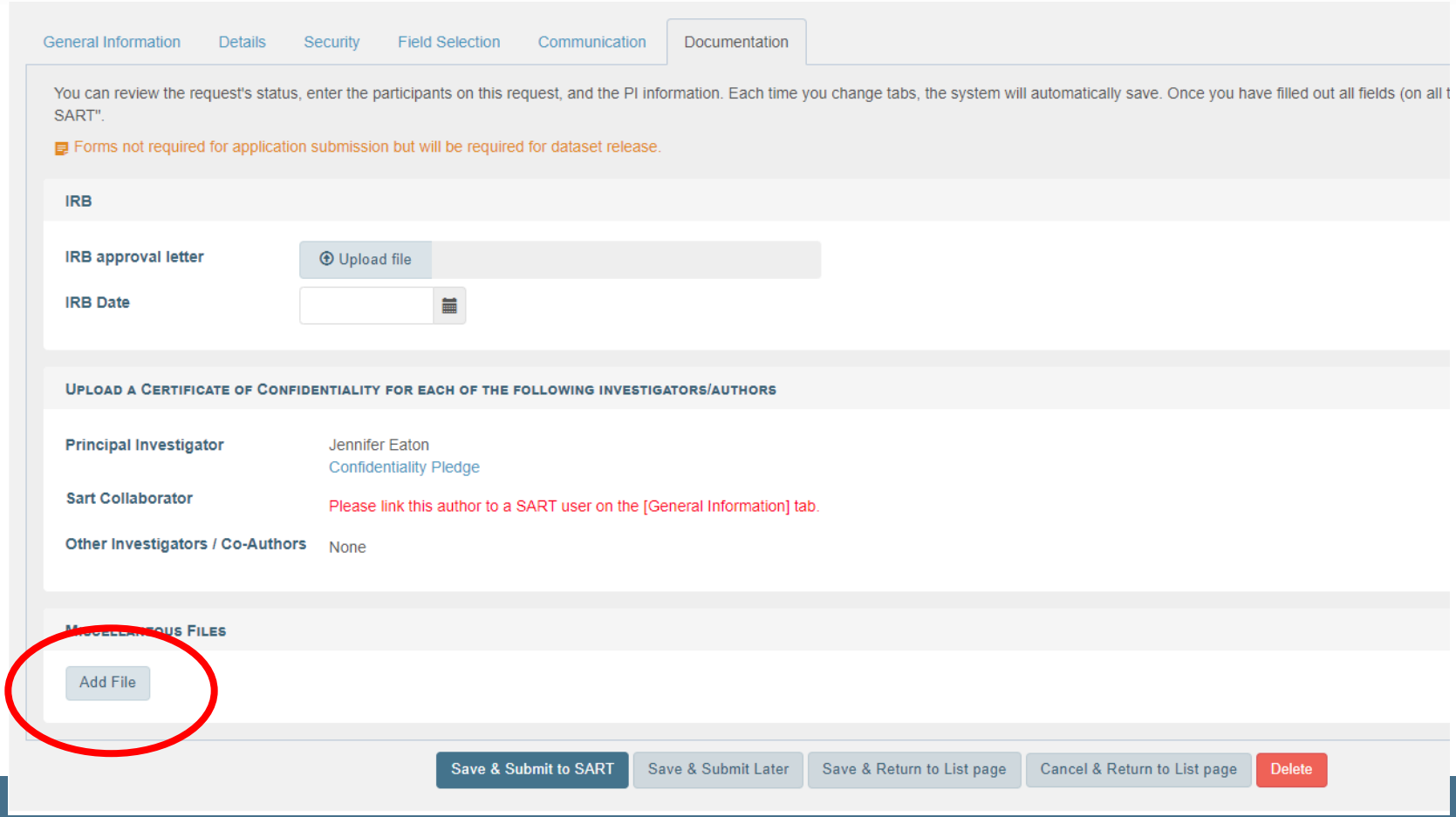
- Check the portal for other similar proposals to avoid overlap
  - Clear all filters and browse through prior proposals



Tips for Enhancing Your Proposal

- Use the SART Query Engine on your own clinic data, to test usage & understanding of SART CORS
- Consult SART Data Dictionary for definitions of fields, to ensure you ask for exactly what you want. Located on Research Portal Dashboard Home Page
- Create shell tables as part of proposal and upload them under the documentation tab
- Include a biostatistician as a co-investigator (mandatory)

Upload Your Table Shells



A Statistician is Mandatory

- SART requires researchers to work closely with a statistician to correctly handle missing data (which is frequent and by design for some fields) and to choose appropriate methods for manipulating the data (importing from CSV, exploring and categorizing, modeling and analyzing, and designing tables)

SART Research Committee Award for Statistical Support

- The committee will select one outstanding proposal for up to $15,000 statistical support during the 2022 annual cycle.
- The goal of the award is to support new investigators.
- The winning team of investigators must include a statistician who does not have experience with SART CORS data.
- The team will be paired with a statistician with SART CORS experience; the assigned statistician will provide feedback on study design and train the investigator's statistician to work with SART CORS data.
- The funds may only be used to compensate the assigned SART statistician. Any unused funds must be forfeited.

Supporting Documentation

- ***Before the dataset can be released, the following must be uploaded into the portal under the DOCUMENTATION tab:***
- A letter from your IRB documenting that the project has been reviewed and approved. You must also manually enter the IRB approval date.
- Signed Certificates of Confidentiality for each person involved with the project. The Certificate of Confidentiality is available as a link under the DOCUMENTATION tab.

Getting Your Dataset

- Once the proposal is approved by the committee and the documentation of IRB approval and Certificates of Confidentiality are received, the project will be listed on the queue for obtaining a dataset.
- Data will be provided as a downloadable, compressed CSV file under the DATA AND PUBLICATIONS tab within the research portal. The file is 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.

Additional Analyses Require Committee Approval

- Approval for a dataset is specific to the proposal that was submitted.
- Requests to perform additional analyses with an existing dataset must be sent using a new Research Application, referencing the existing application and indicating that an existing dataset will be used. It is not necessary to repeat the field selection.
- The committee will review the revised proposal and check for overlap with existing proposals and previously published SART CORS manuscripts.

Publishing Your Data

- Before you submit your manuscript for peer review, email it to the Research Committee Chair for approval. Only manuscripts that present serious issues and are not appropriately reporting their findings will be sent to the Research Review committee.

Required Language: Materials and Methods

The following language must be included in your materials and methods:

The data used for this study were obtained from the SART Clinic Outcome Reporting System (SART CORS). Data were collected through voluntary submission, verified by SART, and reported to the Centers for Disease Control and Prevention (CDC) in compliance with the Fertility Clinic Success Rate and Certification Act of 1992 (Public Law 102-493). SART maintains HIPAA-compliant business associate agreements with reporting clinics. In 2004, following a contract change with the CDC, SART gained access to the SART CORS data system for the purposes of conducting research. In 2020, 82% of all assisted reproductive technology (ART) clinics reporting data to the CDC were SART members.

SART annually selects up to 10 clinics, approximately 2.5% of SART clinics, for an on-site validation visit utilizing metrics and a blinded selection process to identify outlier clinics. Medical records are reviewed during the validation visit to verify the designation, outcome, and reporting of cycles. Clinics with significant systematic reporting errors undergo data correction. Six primary metrics and twenty-six secondary metrics are used for clinic selection. The metrics include low prospective reporting for both egg retrieval cycles and total cycles, high live birth rates in the various age groups, low cancellation rate, high percentage of total fertility preservation cycles, high percentage of embryo banking and oocyte banking cycles, high percentage of fertility preservation cycles where oocytes were thawed or embryos were transferred within a year, high percentage of deleted cycles, high percentage of cycles converted from IUI, and low percentage of cycles in which no embryos were suitable for transfer with and without preimplantation genetic testing (PGT). SART does not validate the accuracy of data entry fields such as gonadotropin dosage, number of oocytes retrieved, number of fertilized oocytes, number of embryos cryopreserved, PGT results, or demographic fields such age and diagnosis.

Required Acknowledgments

The following acknowledgments must be included:

The authors thank SART for the dataset, as well as all SART members for providing clinical information to the SART CORS database for use by researches. Without the efforts of SART members, this research would not have been possible.

Chair, SART Research Committee

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