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Abbreviations

ORS: Online Request System

DBU: Data and Biospecimen Use Committee. Reviews Data Access, Data Analysis, Biospecimens & Data and Ancillary Study requests

PI: Principal Investigator

Registration and Logging In

If you do not already have an account, you will need to [register with the site](#) using a valid and verifiable email address (preferably one affiliated with your institution). If this is your first time visiting the ORS Version 3 (released Fall 2018), you will need to [perform a password reset](#) in order to regain access to your account.

When registering (or updating your account info) be sure to enter as many details as possible, including any additional emails you use (aids co-investigators in adding you to their research efforts if they have a different email than that which you used for your ORS account) and your mobile number (this can be used to reset forgotten passwords and to receive text updates on your submitted requests). Please note that you must confirm a mobile number while you are actually logged in, via [your account page](#) using the button adjacent to the mobile number (a confirmation code will be texted to you).

If you are not an SCCS Investigator, while updating your account details please upload your NIH formatted biosketch. Note that the list of SCCS Investigators is determined by the SCCS Principal Investigators (PIs). Your biosketch will be required for every Request submitted to the SCCS Data and Biospecimen Use (DBU) Committee or SCCS Publications Committee.

As an added layer of account security, the ORS has an optional system called [2 Factor Authentication \(2FA\)](#). If you [choose to enable 2FA](#), you will need to install an app on your mobile phone, such as Google Authenticator for [Android](#) and [iOS](#). Within the phone app you will scan the ORS supplied QR code, which will link your phone and ORS account. Future login attempts would then require you to start the app and retrieve a short code to type into the ORS login screen. Note that in the future the use of 2FA may be required for ORS access.

Site Documentation

Site Documents can be viewed or downloaded via the [Documentation](#) menu bar link. Documents are grouped by type and show the last revised date. You may view documents in a card or grid display. Documents updated within the past month are tagged by a “New” icon.

Documentation

View Mode: [Card View](#) [Grid View](#)

The following codebooks and documentation files are available, grouped by category:

Miscellaneous

Cohort Guidelines Guidelines for the Use of Data and Biologic Specimens, Permission to Contact Study Participants for Ancillary Studies, and Publication of Study Results View Download Last updated 1/8/2018 11:42 AM	Site Tutorial Site Tutorial View Download Last updated 1/2/2018 1:39 PM	Human Subjects Information Human Subjects Information New View Download Last updated 9/26/2018 11:23 AM
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Reports

SCCS Baseline Codebook Variable Distribution SCCS Baseline Codebook Variable Distribution View Download Last updated 4/27/2015 10:54 AM	SCCS First Follow-up Codebook Variable Distribution SCCS First Follow-up Codebook Variable Distribution View Download Last updated 4/30/2015 10:41 AM	SCCS Second Follow-up Codebook Variable Distribution SCCS Second Follow-up Codebook Variable Distribution View Download Last updated 8/22/2016 3:17 PM	SCCS Third Follow-up Codebook Variable Distribution SCCS Third Follow-up Codebook Variable Distribution New View Download Last updated 10/18/2018 1:40 PM
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Reporting

SCCS Investigators can view a report of Requests currently approved by the SCCS DBU Committee via the [Reporting](#) menu bar link.

The list can be filtered by Request type, id, investigator name, title, keywords, submission date and DBU meeting date by typing into the bar at the bottom of the report.

Approved DBU Requests - [select a row to view additional detail](#)

Show entries Search:

Type	Req Id	Investigator	Title	Keywords	Submitted	Meeting
Ancillary Study	24	Thomas Wang	Cardiovascular disease and cancer prevention among underserved populations: the SCCS polypill pilot trial	Cardiovascular Prevention, Hypertension, Hyperlipidemia, Cancer Prevention, Aspirin	1/21/2014	2/4/2014
Biospecimen & Data	24	William Blot	Obesity and colorectal cancer: Exploring underlying mechanisms using metabolomics	obesity, colorectal cancer, metabolomics	3/12/2013	
Data Access	248	Yong Cui	Depression and total and disease-specific mortality in a low socioeconomic and African-American dominant population	Depression, CES-D, socio-economic status, race, mortality outcomes, comorbidity	2/20/2018	3/6/2018
Data Access	24	Jay Fowke	Hypertension and diabetes medication and lower urinary tract symptoms in the Southern Community Cohort Study	hypertension, diabetes, medication, lower urinary tract	2/14/2012	
Data Access	124	Xiao-Ou Shu	Dairy food intake and total and cause-specific mortality	dairy products, calcium, fatty acids, mortality, cardiovascular diseases, African Americans	3/13/2014	4/1/2014

Select type Type to filter Type to filter From To From To

Showing 1 to 5 of 9 entries (filtered from 296 total entries) Previous Next

Clicking a Request will display selected details at the bottom of the page, including any co-investigators and the abstract.

Detail of Chosen Request

Req ID:	24
Title:	Cardiovascular disease and cancer prevention among underserved populations: the SCCS polypill pilot trial
Investigator:	Thomas Wang
Co-Applicants:	Jen Sirko, Joseph McLaughlin, William Blot, Debra Friedman, Wei Zheng
Keywords:	Cardiovascular Prevention, Hypertension, Hyperlipidemia, Cancer Prevention, Aspirin
Abstract:	Advances in understanding the biological and genetic underpinnings of disease risk have led to individualized strategies for disease prevention. The benefits of "personalized medicine," however, are less likely to reach those with limited means, the populations which tend to be at the highest risk of chronic illnesses such as cardiovascular disease (CVD) and cancer. Approaches that are broad-based, effective, and efficient are needed to reduce the burden of these conditions in underserved populations. We propose to test the feasibility of daily administration of a "polypill" in a medically--underserved population. The polypill is a fixed combination of low-dose generic medications with known benefits in primary prevention. The proposed ancillary study is intended to be a pilot for a larger trial to assess the effectiveness of the polypill in reducing the incidence of cardiovascular events and cancer.

Submitting a Request for Data Access, Data Analysis, Biospecimen & Data, Ancillary Study, Review of Abstract, or Review of Manuscript

The SCCS ORS organizes Requests via containers known as “Application Concepts”. For example, a Request for “numbers”, a request for a dataset and the resulting manuscript or ancillary study application should be created within the same Application Concept. When creating an Application Concept, you may state your general goals, describe keywords and designate your co-investigators. All Requests created within a specific Application Concept will then inherit these base attributes. Application Concepts are specific to individual investigators, and viewable by designated co-investigators.

Therefore, to submit an ORS Request to the SCCS DBU Committee or Publications Committee, you must first have an Application Concept. Using the Requests menu bar link, select the sub item “[Application Concepts](#)”. This page will list all your existing Application Concepts, allowing both editing of those existing and the creation of new.

Your Application Concepts - these are containers for the organization of requests

An Application Concept should be created for each of your research efforts and should contain all of the related ORS Requests for that effort. Each Application Concept contains a list of your co-applicants which are automatically associated with each child ORS Request.

Existing Applications - select a row to manage your requests for a specific application

Show 5 entries Search: z

App Id	Title	Keywords	# Co-applicants	Created	Changed
No matching records found					

Showing 0 to 0 of 0 entries (filtered from 3 total entries)

Previous Next

Create Application Concept Edit Application

Creation of a new Application Concept

Click “Create Application Concept” and then complete all entries. Each co-applicant must be verified by clicking the “verify” button after entering their email address. If you are not an SCCS Investigator, the first co-applicant you add is suggested to be an SCCS Investigator. If you attempt to add someone without an SCCS ORS account, an invitation may be sent for them to join (you would then need to edit this Application Concept to add the co-applicant once their account exists).

Create Application Concept

Title
Describe your general research goals

Keywords
enter your keywords

Add a co-applicant using their email address
investigator@institution.com Verify Co-applicant

Chosen co-applicant(s)
None chosen

Receive a copy of this application via email?

Cancel Submit

Upon clicking the save button, the grid will display your new Application Concept as below:

Your Application Concepts - these are containers for the organization of requests

An Application Concept should be created for each of your research efforts and should contain all of the related ORS Requests for that effort. Each Application Concept contains a list of your co-applicants which are automatically associated with each child ORS Request.

[+ Create Application Concept](#)

Existing Applications - select a row to manage your requests for a specific application

Show 5 entries Search: 362

App Id	Title	Keywords	# Co-applicants	Created	Changed
362	Describe your general research goals	enter your keywords	1	10/24/2018 8:06 AM	

Showing 1 to 1 of 1 entries (filtered from 4 total entries) Previous 1 Next

[Edit Application](#)

You and your co-applicants will receive a confirmation email when the Application Concept is successfully saved. The co-applicants listed on your Application Concept will be associated with every Request that is submitted under that Concept. Co-applicants can view the Application Concepts and Requests with which they are associated, but they cannot make changes.

To remove a co-applicant from an Application Concept, click the Application Concept, then "Edit Application". Click to highlight the co-applicant's email address then click "Remove selected". Removed co-applicants will receive an email notification.

You may edit an Application Concept, including changes to associated co-applicants, at any time.

Submitting a new Request within an Application Concept

Click on the applicable Application Concept to show your designated co-applicants, any existing Requests, and to enable the "Create Request" button:

Your Application Concepts - these are containers for the organization of requests

An Application Concept should be created for each of your research efforts and should contain all of the related ORS Requests for that effort. Each Application Concept contains a list of your co-applicants which are automatically associated with each child ORS Request.

[+ Create Application Concept](#)

Existing Applications - select a row to manage your requests for a specific application

Show 5 entries Search: 362

App Id	Title	Keywords	# Co-applicants	Created	Changed
362	Describe your general research goals	enter your keywords	1	10/24/2018 8:06 AM	

Showing 1 to 1 of 1 entries (filtered from 4 total entries) 1 row selected Previous 1 Next

[Edit Application](#)

Co-Applicants

First	Last	Email	Affiliation	SCCS Investigator?
Mark	Steinwandel	mark.d.steinwandel@vumc.org	VUMC - IEF5	Yes

Existing Requests - select a row to view allowable actions for that request

Type	Id	Subtitle	Keywords	Submitted	Status	Complete?	Completed	PDF
<i>No requests have been created within this Application Concept</i>								

(gray text = withdrawn)

[+ Create Request](#)

After clicking the "Create Request" button, choose the type of Request:

Create Request

Choose the relevant request type

Non-committee: Numbers

DBU Committee: Data Access Data Analysis Biospecimen & Data Ancillary

Pub Committee: Abstract Manuscript

You will be shown a display of SCCS guidelines pertinent to the chosen Request type. To continue you must check off that you agree to the terms explained in the guidelines. You will then be shown a screen similar to the following:

Each Request type has a customized form according to the SCCS Guidelines. Note that most Request types have a multi-paged “tab” layout, requiring you to click each individual tab page in order to access and complete all necessary entries. In the example image above, these tab pages are denoted by “I”, “II”, “III” and “Files”. You have the option to only partially enter a Request (without submitting for committee review), by clicking “Save for later” (at a minimum, you must enter valid values for Request Title, Planned completion date, Keywords and “Why is the SCCS resource essential for your request”).

Each Request type has a “Files” tab or a “File Upload” option. Type as much of the Request as possible into the online forms, and use the file option to upload tables, figures, statistical programs, or other supplementary materials. Uploading a file containing requested variables is not permitted, instead utilize the supplied field for “Listing of exact variable names ...”.

Clicking “Save for Later” will save the information you have entered into the form, without formally submitting the Request. To again preview the Request before submitting it to the Committee you will see the option to “Edit/Submit” the request after selecting the specific request from the “Existing Requests” grid:

Existing Requests - select a row to view allowable actions for that request (gray text = withdrawn)

Type	Id	Subtitle	Keywords	Submitted	Status	Complete?	Completed	PDF
Data Access	276	Example Data Access request	sample request keywords			No		View

Edit/Submit

To re-enter the Edit window, click “Edit/Submit”. Clicking “Submit Request” (from the Edit window) will submit the Request to SCCS data managers (for Numbers Requests), the SCCS DBU Committee (for Data Access, Data Analysis, Biospecimen & Data, and Ancillary Study Requests), or the SCCS Publications Committee (for Review of Abstract or Manuscript Requests).

Requests that have been created under an Application Concept will be displayed together in the “Existing Requests” grid. The allowable actions depend on the state/status of the individual Request as explained below:

- The only available option for a Request that has been created but not been formally submitted (“Save for later” was previously clicked) is to “Edit/Submit” or to “View” the PDF.
- Once a Request has been formally submitted (by clicking “Submit Request”), the only available options are to “View” the PDF or “Withdraw” the Request. Requests should only be withdrawn when you no longer wish to proceed on the project; the appropriate committee will be notified of the withdrawal. No further action may be taken on a withdrawn Request.
- If the Request is to be reviewed by the DBU Committee, once the Request has been screened the assigned meeting date will be emailed to you and can be viewed by selecting the “View” PDF option. Meeting dates are determined by the date and time the Request is submitted.
- If the Request is approved, available options are to “View” the PDF, “Amend” (submit an Amendment to the appropriate committee), or “Withdraw”.
- If the Request is rejected, available options are to “View” or “Resubmit” the Request.

Viewing a Request

Once a Request has been saved, clicking “View” will generate a PDF of the Request. It will contain the Application Concept information, Request information, and Administrative information like links to the associated files. After submission to the appropriate committee, the PDF will also include any updates to the Approval status as of the date and time you click “View”. Please download and save a copy or copies of this PDF for your records.

Ancillary Study Request Details

Administrative Notes

Status: Approved **Complete?** Yes **Completed:** 2/3/2016

Files (co-applicants may only download 'Applicant' files):

Filename	Source	Added On	
125-Ancillary-24_DUA.pdf	Admin	7/23/2018 10:41 AM	Download
125-Ancillary-24_polypill_analysis_07252018.zip	Admin	7/26/2018 10:47 AM	Download

Parent Application Concept

App ID: 125 **Created:** 1/21/2014 12:00 AM

Title

Cardiovascular disease and cancer prevention among underserved populations: the SCCS polypill pilot trial

Keywords

Cardiovascular Prevention, Hypertension, Hyperlipidemia, Cancer Prevention, Aspirin

Applicant/Co-applicants:

Title	First	Last	Email	Affiliation	SCCS Investigator?
	Thomas	Wang		Vanderbilt University	Yes
	Jen	Sirko		Other (specify)	Yes
Dr.	Joseph	McLaughlin		International Epidemiology Institute	No
Dr	William	Blot		Vanderbilt University	Yes
Dr	Debra	Friedman		Vanderbilt University	Yes
Dr	Wei	Zheng		Vanderbilt University	Yes

Request ID: 24 **Submitted:** 1/21/2014

Request title

Cardiovascular disease and cancer prevention among underserved populations: the SCCS polypill pilot trial

Submitting an Amendment to an Approved Request

Once a Request has been approved, the Applicant has the option to submit an amendment to this approved Request. To do so, navigate to the Request under the appropriate Application Concept and click “Amend”. A pre-filled form will appear with the information for the original Request. Please make the desired changes in the appropriate fields and upload a cover letter to the appropriate committee explaining the changes and the reasoning behind the changes.

Please note that documents uploaded in support of the original Request will need to be uploaded again.

Amendments submitted to the DBU Committee are subject to the same deadlines for review as novel Requests.

Submitting a Revision to a Rejected Request

If a Request has been rejected by the SCCS Data Managers, the SCCS DBU Committee, or the SCCS Publications Committee, you have the option to submit a revised Request. Click “Resubmit”. A pre-filled form will appear with the information from the original Request. Please make the desired changes in the appropriate fields and upload a cover letter to the appropriate committee explaining the changes and the reasoning behind the changes.

Please note that documents uploaded in support of the original Request will need to be uploaded again.

Revisions submitted to the DBU Committee are subject to the same deadlines for review as novel Requests.

Withdrawing a Request

To withdraw a submitted Request, click “Withdraw” and confirm your desire to withdraw the Request. Once a Request has been withdrawn, even if it has been approved, no further action can be taken on this Request.

Viewing Co-Applicant Requests

Applicants can view submitted Requests on which they are listed as a Co-Applicant. Using the Requests menu bar link, select the sub item “[Co-Application Concepts](#)” to view these Requests.

Email Updates

The website will email confirmations and updates from the email address “admin@ors.southerncommunitystudy.org”. Co-Applicants will receive a confirmation email at the time an Application Concept is saved and when a Co-Applicant is removed from an Application Concept. To receive a confirmation email upon saving an Application Concept, click “Receive a copy of this application via e-mail”.

The Applicant and Co-Applicants will receive an email confirmation at the time a Request is submitted or withdrawn, and when action is taken on a Request by the SCCS Data Managers, the SCCS DBU Committee, or the SCCS Publications Committee.

admin@ors.southerncommunitystudy.org is an unmonitored mailbox. For questions regarding your Request, please email datause@southerncommunitystudy.org

Downloading Files for an Approved Request

The Applicant and Co-Applicants will receive an email confirmation at the time SCCS Data Managers upload files for an approved Request. These files are typically filled table shells or SAS datasets.

A link to download the file will be provided in the email confirmation sent to the Applicant and co-Applicants at the time of file upload. At the same time this email confirmation is sent, the link to download the file will be added to the PDF of the Request on the ORS site (see “Viewing a Request”). The link will only be accessible by the Applicant; Co-Applicants may not download files uploaded by SCCS Data Managers (indicated as “Admin” on the Request PDF).

Note that the file will be automatically downloaded according to the default settings for the Applicant’s internet browser.

Uploading Files to a Request

When a file has been successfully uploaded, the file name will appear in blue text to let you know the file has been successfully uploaded:

Uploaded file (please include skeleton tables showing clearly the results you are seeking and how you would like them presented)

Numbers Request Test.xlsx will replace any existing file when you save or submit this form

If you exit the request without saving, the document will also be lost.

If you wish to remove the document and replace it with a different document, you must first click “save for later”. Then, reopen the Request by clicking “Edit”. You will then have the option to delete the previously uploaded file and to upload a new file.

Submitting a Progress Report

DBU Committee Approval is valid for a fixed period of time. Approximately eleven months after obtaining DBU Committee approval of a Data Access, Data Analysis, Biospecimen & Data, or Ancillary Study Request, the Applicant and Co-Applicants will receive an email prompting the Applicant to submit a Progress Report. The email will provide a link to your Application Concepts, and “Report Progress” will be listed as an allowable action after you select the particular request:

Existing Requests - select a row to view allowable actions for that request (gray text = withdrawn)

Type	Id	Subtitle	Keywords	Submitted	Status	Complete?	Completed	PDF
Data Access	276	Example Data Access request	sample request keywords		Approved	No		View

[Edit/Submit](#) [Report Progress](#)

The Progress Report will consist of a short form with the following questions, with additional questions appearing as you enter data:

Progress Report

1 Files

Have the aims for the project changed?
 Yes No

Please provide brief highlights of progress to date (300 words or less). A bulleted summary is sufficient. Include a summary of the status of proposed analyses (data/specimens) and any challenges encountered.

Have you submitted an abstract for a peer reviewed poster or oral presentation at national meetings?
 Yes No

Have you submitted a manuscript for a peer reviewed publication?
 Yes No

Have you submitted a grant for additional research based on preliminary data from the SCCS?
 Yes No

Does your team need additional time to complete the original aims or to submit academic materials such as manuscripts and grants?
 Yes No

[Cancel](#) [Submit](#)

You may upload any supporting documents as attachments on the “Files” tab.

The Progress Report must be submitted by the one year anniversary of the DBU committee meeting that approved the Request.

Submitted Progress Reports will be reviewed by the DBU Committee. The DBU Committee will be provided with the date the analytic dataset and/or biospecimen assay data was provided to assist with reviewing the progress report. If an extension of approval has been requested and the DBU Committee grants the extension, the Request will be approved for an additional 6 months. Progress Reports will be required every 6 months after the first year to maintain DBU Committee approval, and the DBU Committee may vote to Expire Requests at any review. If work on the Request is deemed “Complete”, no further Progress Reports will be required. If you have further work to complete, it is paramount that you answer “Yes” to “Does your team need additional time . . .”, otherwise your request will likely be deemed complete and closed.

For questions, or to suggest additional functionality, please email datause@southerncommunitystudy.org.