Data and Biospecimen Use
and
Publications
Committees

GUIDELINES FOR THE USE OF DATA AND BIOLOGIC SPECIMENS, PERMISSION TO CONTACT STUDY PARTICIPANTS FOR ANCILLARY STUDIES, AND PUBLICATION OF STUDY RESULTS

Updated February 2020

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Summary

The Southern Community Cohort Study (SCCS) is a landmark study of disparities in cancer incidence and mortality, as well as of disparities in the occurrence of other chronic diseases such as diabetes, hypertension and heart disease. The data collected in this study are available for use by both SCCS Investigators and non-SCCS Investigators. As with all carefully conducted studies, quality control measures need to be applied regarding the use of raw data and stored biosamples in order to maintain the integrity of the study. In addition, the collection of ancillary data by recontacting study participants is an activity that is encouraged, but must be done in close coordination with primary SCCS operations to ensure the validity and success of such an ancillary study, and to minimize the burden on participants.

Two committees, a Data and Biospecimen Use Committee and a Publications Committee, have been assembled to ensure the protection of SCCS research subjects, the scientific validity of the results, and the scientific direction of the study, as well as proper use of data and biological samples collected in the SCCS. The Committees will carry out these responsibilities and respond to requests regarding data and biospecimen use and publications, as detailed on the following pages.

1. General guidelines for submitting a Request for Data and Biospecimen Use or for an ancillary study involving contact with study participants

Anyone requesting access to SCCS data or biospecimens, or permission to recontact participants, must submit a Request for Data and Biospecimen Use (hereafter referred to as the "Request"). This includes investigators whose goals are to:

- use existing SCCS data to perform analyses leading to a scientific manuscript or submission of a grant application
- have data analyses performed for them to support a grant application or a presentation
- use stored SCCS biospecimens
- recontact participants for the collection of new data/biospecimens (an *ancillary study*)

All Requests must be submitted through the SCCS online request system (ORS) at https://ors.southerncommunitystudy.org/, or by following the "Information for Researchers" link at the SCCS website (www.southerncommunitystudy.org). Any questions concerning the electronic submission and review process can be emailed to datause@southerncommunitystudy.org.

Individual Requests are submitted within "Application Concepts", which are containers designed to allow Applicants to organize multiple Requests related to the same research project. An Application Concept consists of a title, keywords, and co-investigators, if applicable. Requests with similar aims/hypotheses (e.g., a Data Access Request and the resulting Manuscript) should be submitted within the same Application Concept.

All Applicants must create an account in the online system using their email address, and communication regarding the Request will be via email.

A Request may be submitted at any time. It is recommended that non-SCCS Investigator Applicants have an SCCS Investigator listed on their Application Concept as a Co-Applicant that can assist with understanding the SCCS resources and processes. The applicant must upload an NIH formatted biosketch at the time of account creation.

Requests upon receipt will be referred to the Data and Biospecimen Use Committee (the "DBU Committee") for review. In addition to DBU Committee members, the Request may also be sent for review to outside scientific consultants if necessary. The Applicant may suggest consultants to participate in the review process.

The DBU Committee will judge whether the research duplicates or overlaps existing or planned SCCS research, whether it is feasible, whether the impact of the proposed research on SCCS operations and resources is justified by its scientific merit, and whether it is in line with the goals of the SCCS. As a general rule, Requests that are focused on one or two hypotheses or require a limited dataset will have a greater chance of being accepted than those that have broader objectives and/or seek to utilize large portions of the SCCS dataset, biospecimens or population. In addition, Requests that require the unique resources of the SCCS will be given priority, whereas Requests for studies that could be conducted just as well in other populations will have lower priority. Under no circumstance shall subjects' confidential data be disclosed.

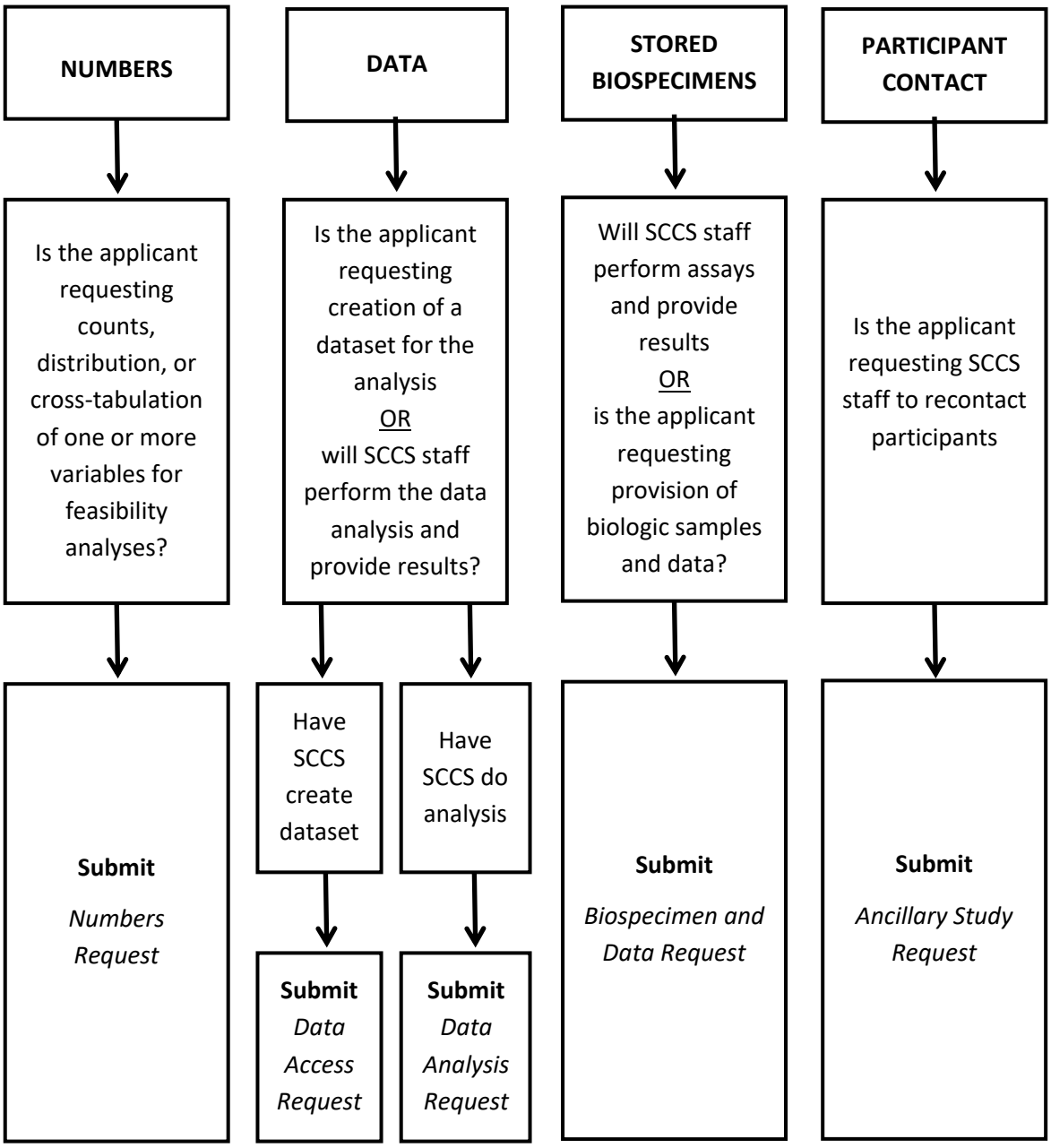
The DBU Committee will review Requests on the first Tuesday of every month. Requests must be submitted through the SCCS online system no later than 15 days prior to this meeting to be eligible for review. See the link on the SCCS ORS home page to get the current meeting and submission deadline schedule.

The Applicant will typically receive notification of the DBU Committee's decision within one week of the DBU Committee's review. If the Request is approved, additional time will be required for the provision of data sets, data analyses, biospecimen samples, and/or biospecimen assays, as described in Sections 2-4.

Incomplete or incorrectly completed Requests will be returned to the Applicant for corrections prior to review.

The Applicant should have funds to cover SCCS personnel effort (and other costs) associated with preparing data sets, conducting data analyses, accessing biologic specimens, preparing aliquots with specific amounts of blood or other biologic materials, extracting DNA, and performing molecular and genetic assays in the SCCS laboratory or shipping the samples to qualified labs. It is highly recommended, prior to submitting the Request, that the Applicant contact datause@southerncommunitystudy.org to obtain preliminary estimates of the anticipated cost needed to complete a Request. If 10 or more hours are required to complete the Request, the Applicant must reimburse the SCCS for time and expense. For VUMC Applicants, this will be accomplished by the provision of a Cost Center Number. For non-VUMC Applicants, this will require a subcontract with VUMC for services performed. The costs for requisitioning and assaying the biospecimens are based upon the type of sample and type of assay. (Please click here for SCCS laboratory costs)

REQUESTING SCCS DATA, BIOSPECIMENS OR PARTICIPANT CONTACT



2. Requesting SCCS datasets (e.g., for analyses leading to the preparation of scientific manuscript(s) or a grant application)

As prompted in the online request process, Applicants who request to use existing SCCS data must submit a **Data Access Request**. All relevant sections of the Request must be completed. Incomplete Requests will be returned to the Applicant without Committee review. Investigators/personnel who will be involved in the analysis of the data, the interpretation of data results, and/or the writing of the resulting scientific manuscript(s) should be added to the Application Concept as co-applicants. An ORS account will be required for all co-applicants. It is recommended that one of the listed investigators be an SCCS Investigator. If the Request is for data to include in a cohort consortium or pooled analysis, it is recommended that one of the listed investigators be a VUMC Principal Investigator.

This Request will include the following sections:

1. Request Title
2. A list of all investigators/personnel who will be involved in the analysis of the data (include qualifications of the person(s) performing the statistical analysis)
3. Purpose of the Request, i.e., is this a Request to support an abstract, manuscript, and/or grant?
4. Plan for funding, including grant number and project period, if applicable
5. Date due to funding institution, if applicable
6. Timeline for work completion
7. Proposal abstract, a summary of the aims of the Request (100 words or less)
8. Keywords (no more than 5-7). These do not need to be the same as the Application Concept keywords
9. Background (scientific justification for the proposed analysis)
10. Hypothesis(es) to be tested
11. Number of participants involved and details of sample selection
12. Detailed analytic/statistical plan (four paragraphs maximum; include power calculations)
13. Listing of exact variable names (from the current SCCS Codebooks) requested in the dataset. If a derived variable is requested (e.g., "incident COPD"), it is the sole responsibility of the Applicant to specify the data source(s), codes, and/or algorithm required. An example of a sufficient Request is as follows:

    Incident COPD identified through linkage to Medicare and Medicaid and defined according to the following algorithm:

    a. One inpatient hospitalization or one emergency room encounter with a COPD diagnosis (Codes = 491.x; 492.x; 496) listed in any position as a discharge diagnosis, OR
    b. Two professional claims with different dates of service, with a COPD diagnosis (same as above) listed in any position as a discharge diagnosis, OR
    c. Surgical procedure codes (ICD-9 CM, CPT, HCPCS) for lung volume reduction surgery, lung bullectomy, or lung transplantation:
       (32) Excision of lung and bronchus
       (32.0) Local excision or destruction of lesion or tissue of bronchus
       (32.1) Other excision of bronchus
       (32.2) Local excision or destruction of lesion or tissue of lung
       (32.3) Segmental resection of lung
       (32.4) Lobectomy of lung
       (32.5) Complete pneumonectomy
       (32.6) Radical dissection of thoracic structures
       (32.9) Other excision of lung
14. References

All sections of the Request are required. If a section does not apply to your request, type "N/A". The entire **Data Access Request**, excluding the Abstract, Keywords, Variable Names, and References, should be less than **3,000** words combined. Incomplete requests, or requests that are too long, will returned to the Applicant prior to DBU Committee review.

The Applicant shall notify the DBU Committee Chair of any grant funding obtained to support the work described in the Request, including the grant number and project period. Only SCCS data managers shall have access to participants' confidential identifying information and are not permitted to release identifying information

If the details provided are not sufficient for an SCCS data manager to fulfill the Request, including insufficient instructions for the derivation of variables, the Request will be rejected and will need to be resubmitted.

If an Applicant's Request for data use is approved, the SCCS data manager will contact the Applicant, determine that he/she is ready to begin the research employing the SCCS data requested (e.g., if grant funding is necessary to conduct the research), and make arrangements for the preparation of the appropriate analytic dataset. The native format for SCCS datasets will be SAS. Analytic datasets will be de-identified for the purposes of confidentiality. Prior to receiving SCCS data, the Applicant and all Co-applicants must agree in writing not to share the data with individuals other than those listed on the approved Request, nor to use the data for unapproved purposes. Note: Datasets that comprise the entire cohort or a large portion of the cohort will typically not be provided; if approved analyses require all or most of the cohort, these analyses will be done as an in-house data analysis request by SCCS biostatisticians with no datasets released (see #3 Data analyses requests below).

The SCCS data are derived from questionnaires administered as computer-assisted personal interview (CAPI) or telephone interview (CATI), self-administered and optically scanned questionnaires, mortality, hospital discharge, Medicare, Medicaid, and cancer registry linkages, completed assays of various molecular and genetic markers and other sources. The dataset thus is large and complex, and requires solid familiarity with both the data collection instruments and the coding of the final data in order to avoid serious mistakes in statistical analysis and interpretation. For these reasons, Applicants seeking to use SCCS data should work closely with SCCS investigators and staff and may, at the Chair's discretion, need to meet in person with SCCS analytic and/or laboratory staff in order to receive training on use of the dataset. The expenses associated with travel to Nashville, Tennessee and/or Rockville, Maryland for this purpose will be the responsibility of the Applicant.

The DBU Committee Chair may recommend the involvement of additional SCCS Investigators with expertise in the subject area prior to Request approval.

Analyses intended to be included within the body of a grant application are typically simple tabulations or simple preliminary analyses. Unless the Applicant has a compelling reason to request the raw data (and gains permission from the DBU Committee), these types of analyses will be performed by an SCCS data manager, with the results supplied to the Applicant. The Applicant should follow the instructions shown in Sections 3 (Data Analysis Request) or 4 (Requesting Numbers for Feasibility Analyses).

3. Requesting data analyses to be performed and results supplied (e.g., for preliminary or exploratory analyses, to support a grant application, or for other purposes)

As prompted in the online request process, Applicants who request analyses of SCCS data will be asked to submit a **Data Analysis Request**. Incomplete Requests will be returned to the Applicant without Committee review. Investigators/personnel who will be involved in the interpretation of data results, and/or the writing of the resulting scientific manuscript(s) should be added to the Application Concept as co-applicants. An ORS

account will be required for all co-applicants. It is recommended that one of the listed investigators be an SCCS Investigator.

This Request will include the following sections:

1. Request Title
2. Purpose of the Request, i.e., is this Request exploratory, or to support an abstract, manuscript, and/or grant?
3. Plan for funding, including grant number and project period, if applicable. If 10 or more hours are required to complete the Request, the Applicant must reimburse the SCCS for time and expense. For VUMC Applicants, this will be accomplished by the provision of a Cost Center Number. For non-VUMC Applicants, this will require a subcontract with VUMC for services performed.
4. Date due to funding institution, if applicable
5. Timeline for work completion
6. Date analysis results are needed
7. Proposal abstract, a summary of the aims of the Request (100 words or less)
8. Keywords (no more than 5-7). These do not need to be the same as the Application Concept keywords
9. Background (scientific justification for the proposed analysis)
10. Hypothesis(es) to be tested
11. Number of participants involved and details of sample selection
12. Detailed analytic/statistical plan (four paragraphs maximum; include power calculations)
    a. Utilize standard statistical terminology (e.g., the *mean age*, the age-adjusted *odds ratio*)
    b. Specify preference for the use of specific statistical methods (e.g., conditional logistic regression). Clearly specify any analyses that will be requested and are not included in the skeleton tables (e.g ., for presentation in the text of a manuscript only)
13. Listing of exact variable names (from the current SCCS Codebooks) to be used in the analysis. If a derived variable is requested (e.g., "incident COPD"), it is the sole responsibility of the Applicant to specify the data source(s), codes, and/or algorithm required (see example in 2.13)
    a. For covariates included in statistical models, specify the form of each in the model (e.g., adjust for age in categories as follows: 40-49, 50-59, 60-69, 70+)
14. References
15. Upload skeleton tables showing clearly the analytic results you are seeking and how you would like them presented

All sections of the Request are required. If a section does not apply to your request, type "N/A". The entire **Data Analysis Request**, excluding the Abstract, Keywords, Variable Names, and References, should be less than **3,000** words combined. Please check the length of your Request prior to submission. Incomplete Requests, or Requests that are too long, will be returned to the Applicant prior to DBU Committee Review.

The Applicant shall notify the DBU Committee Chair of any grant funding obtained to support the work described in the Request, including the grant number and project period.

If the details provided are not sufficient for an SCCS data manager to fulfill the Request, including insufficient instructions for the derivation of variables, the Request will be rejected and will need to be resubmitted.

If the analyses are being requested to support a grant application, analyses should be requested well in advance of the deadline to submit the grant application. We suggest at least two months in advance. Requests submitted with less time are not guaranteed to be processed in time for grant submission.

4. Requesting numbers for feasibility analyses

As prompted in the online request process, Applicants may submit a **Numbers Request** for the counts, distribution, or cross-tabulation of one or more variables. The Request will be reviewed by SCCS data managers and will not require DBU Committee approval.

Incomplete Requests will be returned to the Applicant. This Request will include the following sections:

1. Request Title
2. Keywords (no more than 5-7). These do not need to be the same as the Application Concept keywords
3. Date the results are needed. We suggest submission of the Request at least two weeks in advance
4. Purpose of the Request, i.e., is this Request exploratory, or to support an abstract, manuscript, and/or grant? Provide a brief description of the motivation for the Request and how the results will be used
5. Number of participants involved and details of sample selection
6. Listing of exact variable names (from the current SCCS Codebooks) to be used in the Request. If a derived variable is requested (e.g., "incident COPD"), it is the sole responsibility of the Applicant to specify the data source(s), codes, and/or algorithm required (see example in 2.13)
    a. Specify the form of each variable to be included in the tabulation (e.g., provide the frequency by age categories as follows: 40-49, 50-59, 60-69, 70+)
    b. Utilize standard statistical terminology (e.g., the *frequency* of self-reported hypertension at baseline, the *mean* BMI)
7. Upload skeleton tables showing clearly the analytic results you are seeking and how you would like them presented

If the details provided are not sufficient for an SCCS data manager to fulfill the Request, including insufficient instructions for the derivation of variables, the Request will be rejected and will need to be resubmitted.

In general, analyses to determine the association between an exposure and an outcome are not appropriate for Numbers Requests. If a more detailed analysis than a count, distribution, or cross-tabulation is requested, the Request will be rejected and will need to be resubmitted as a Data Analysis Request and reviewed by the DBU Committee.

5. Requesting use of stored SCCS biospecimens and data

As prompted in the online request process, Applicants who request use of stored SCCS biospecimens, e.g., for analyses leading to the preparation of scientific manuscript(s), the generation of preliminary data to support new projects or grant applications, or the submission of new grant applications, must submit a **Biospecimen and Data Request**. Descriptions of the types of biospecimens available and how they were processed and are stored can be found in a separate document, "Types of SCCS biospecimens available including collection, processing and storage details." Incomplete Requests will be returned to the Applicant without Committee review. Investigators/personnel who will be involved in the interpretation of data results, and/or the writing of the resulting scientific manuscript(s) should be added to the Application Concept as co-applicants. An ORS account will be required for all co-applicants. It is recommended that one of the listed investigators be a VUMC Principal Investigator.

The Applicant will be invited to present his/her Request during the monthly DBU Committee meeting, in person or by telephone. Committee members will have the opportunity to ask questions, obtain clarification, and/or make suggestions to the Request.

This Request will include the following sections:

1. Request Title

2. A list of all investigators/personnel who will be involved in the analysis of the data (include qualifications of the person(s) performing the statistical analysis)
3. Purpose of the Request, i.e., is this a Request to support an abstract, manuscript, and/or grant?
4. Plan for funding, including grant number and project period, if applicable. Explicitly state how you will cover costs to access stored SCCS biospecimens
5. Date due to funding institution, if applicable
6. Timeline for work completion
7. Proposal abstract, a summary of the aims of the Request (100 words or less)
8. Keywords (no more than 5-7). These do not need to be the same as the Application Concept keywords
9. Background (scientific justification for the proposed use of biospecimens and data)
10. Hypothesis(es) to be tested
11. Number of participants involved and details of sample selection
12. Types and amounts of biospecimens to be retrieved
13. Details of laboratory methods proposed and selection of laboratories, including the specimen amount required for each laboratory test
14. Detailed analytic/statistical plan (four paragraphs maximum; include power calculations)
15. Exact variable names (from the current SCCS Codebooks) for data on the participants whose biologic samples are requested. If a derived variable is requested (e.g., "incident COPD"), it is the sole responsibility of the Applicant to specify the data source(s), codes, and/or algorithm required (see example in 2.13)
16. References

All sections of the Request are required. If a section does not apply to your request, type "N/A". The entire **Biospecimen and Data Request**, excluding the Abstract, Keywords, Variable Names, and References, should be less than **3,500** words combined. Please check the length of your Request prior to submission. Incomplete Requests, or Requests that are too long, will be returned to the Applicant prior to DBU Committee Review.

The following issues should be addressed in the Biospecimen and Data Access Request.

Applicants should bear in mind that each SCCS participant has a finite amount of biospecimen stored for the study, thus they are encouraged to identify the laboratory method that uses the smallest amount of biospecimen for the biomarker under investigation. Applicants should provide information regarding the validity and reliability of the proposed assay and compare the pros and cons of alternative laboratory methods if more than one laboratory method is available for the biomarker under investigation.

Typically, one study/analysis may not use up an entire aliquot of sample, and thawing and re-freezing samples could degrade some biomarkers. It would therefore be helpful for the Applicant to provide data regarding the effect of thawing and re-freezing on the biomarker under investigation. In order to minimize the number of thawing/re-freezing cycles for SCCS biospecimens, the staff at the SCCS Biospecimen Repository will coordinate the assays of several studies, and sometimes several assays will need to be conducted in the same laboratory at about the same time. Thus, the timing of a project may be affected and the laboratory selected by the Applicant may not be the one where the assays will be eventually performed.

Only a very small amount of DNA is generally needed for genotyping assays, and the aliquoting of a small amount of DNA into multiple tubes causes some attrition (and thus waste). Also, it is likely that DNA produced using the whole genome amplification method may be used in future genotyping assays, so native DNA would be saved for other assays where native DNA is absolutely needed. Some quality control procedures will need to be

implemented when amplified DNA samples are used in genotyping assays. The Applicant will need to describe the proposed genotyping method and the amount of DNA needed in the Request. The Applicant could suggest a laboratory for the proposed genotyping assays. The staff at the SCCC Biospecimen Repository will work with the Applicant to identify a suitable laboratory, keeping in mind that in order to efficiently use DNA, some coordination may be required so that genotyping assays from several studies could be conducted at the same time in the same laboratory.

If the concept of an Applicant's Request for biospecimen use is approved, SCCS Biospecimen Repository personnel will contact the Applicant, determine that he/she is ready to begin the research employing the biospecimens (e.g., if grant funding is necessary to conduct the research), and will coordinate either the transfer of the necessary biospecimens or the conduct of the necessary biospecimen analyses on-site or at a collaborating laboratory. Please note that the timing of the biospecimen use may be affected by other (unrelated) projects seeking to use biospecimens and that, for example, access to the biospecimens may be delayed to await multiple projects that can make use of the entire contents of a frozen aliquot to avoid sample waste. Furthermore, in some circumstances where assay batch effects are anticipated, biospecimens may be held to reduce the numbers of batches to be assayed.

All biospecimens will be de-identified for the purposes of confidentiality prior to assay. Prior to receiving SCCS biospecimens, the Applicant and all co-applicants must agree in writing not to share the biospecimens or the resulting data with individuals other than those listed on the approved Request, not to use the biospecimens or the resulting data for unapproved purposes, and not to retain excess sample material that should be returned to the SCCS biospecimen repository. The Applicant must ensure that appropriate protocols for sample handling are utilized to preserve the integrity of any remaining biological samples for future studies.

It is expected that, no more than six months after the completion of the laboratory work, original results of all assays performed on the SCCS biospecimens will be provided to be entered into the SCCS database and made available for general use by approved SCCS Investigators. Documentation regarding the assay design and methods, as well as details regarding data formatting, must also be provided. The Applicant will have the priority to use these data for the approved project during the approved project period. The Applicant will be prevented from applying for or using SCCS data until the results of the laboratory work have been provided. Individual-level data are typically not provided to non-SCCS investigators, and given the complexity of using SCCS biospecimens for molecular epidemiologic studies, Applicants seeking to use the biospecimens shall work closely with SCCS investigators and staff at VUMC for protocol development as well as data analysis, interpretation, and publication. The Data and Biospecimen Use Committee reserves the right to suggest the involvement of additional SCCS Investigators with expertise in the subject area prior to Request approval.

6. Submitting a grant application for an ancillary study that proposes to contact SCCS participants

Ancillary studies involving contact with SCCS study participants have the potential to enrich the SCCS resource and are encouraged. Priority will be given to studies that:

- require the unique characteristics and resources of the SCCS cohort
- have the highest scientific merit
- place the least burden on SCCS participants
- have objectives in accord with those of the SCCS
- do not interfere with or duplicate SCCS research objectives
- have minimal negative impact on future studies/analyses using the SCCS cohort

Applicants considering undertaking an ancillary study should coordinate closely with a VUMC Principal Investigator to explore interest in the concept. Applicants must then submit an **Ancillary Study Request** for review by the DBU Committee. Incomplete Requests will be returned to the Applicant without Committee review. Investigators/personnel who will be involved in the interpretation of data results, and/or the writing of the resulting scientific manuscript(s) should be added to the Application Concept as co-applicants. An ORS account

will be required for all co-applicants. It is recommended that one of the listed investigators be a VUMC Principal Investigator.

The Applicant will be invited to present his/her Request during the monthly DBU Committee meeting, in person or by telephone. Committee members will have the opportunity to ask questions, obtain clarification, and/or make suggestions to the Request.

This Request will include the following sections:

1. Proposed Study Title
2. A list of all investigators/personnel who will be involved in the analysis of the data (include qualifications of the person(s) performing the statistical analysis)
3. Target funding institution where grant application would likely be submitted and grant type, including grant number and project period, if applicable
4. Date due to funding institution
5. Timeline for work completion
6. Proposal abstract, a summary of the aims of the Request (100 words or less)
7. Keywords (no more than 5-7). These do not need to be the same as the Application Concept keywords
8. Background (scientific justification for the proposed ancillary study)
9. Overall hypothesis(es) and Specific Aims
10. Justification for why the ancillary study would best be conducted within the SCCS
11. Number of participants to be contacted and details of sample selection
12. Detailed Study Design and Methods
13. Detailed Analytic/statistical plan (four paragraphs maximum; include power calculations)
14. If SCCS data will be requested as part of the Ancillary Study, list the exact variable names (from the current SCCS Codebooks) requested. If a derived variable is requested (e.g., "incident COPD"), it is the sole responsibility of the Applicant to specify the data source(s), codes, and/or algorithm required (see example in 2.13)
15. If stored SCCS biospecimens will be requested, include the types and amounts of biospecimens to be retrieved and details of laboratory methods proposed and selection of laboratories (see Section 5.13), including the specimen amount required for each laboratory test
16. References

All sections of the Request are required. If a section does not apply to your request, type "N/A". The entire **Ancillary Study Request**, excluding the Abstract, Keywords, Variable Names, and References, should be less than **4,000** words combined. Please check the length of your Request prior to submission. Incomplete Requests, or Requests that are too long, will be returned to the Applicant prior to DBU Committee Review.

For an approved **Ancillary Study Request**, the Applicant must submit to the DBU Committee Chair (at the time they are available) the following documents:

- A copy of the <u>final</u> grant proposal submitted to the funding agency. As it pertains to the use of SCCS data or participants, the final submitted grant proposal should match the original Request in its scope and content; if it does not, then an amendment to the Request must be submitted.
- The IRB application(s)
- The final IRB approval letter(s)
- The final IRB-approved consent forms

Contact of potential subjects for ancillary studies shall be made only by staff at VUMC or the SCCS Study Field Operations Center. Final approval from all relevant IRBs will be necessary before work begins on the ancillary study.

Applicants shall promptly update the DBU Committee Chair with the review results (e.g., merit score and percentile) of the submitted grant proposal and send to the DBU Committee a copy of the summary statement of grant review.

Every Ancillary Study Request must provide funds for SCCS data managers, SCCS Biospecimen Repository personnel and/or other relevant staff, whose time will be needed to coordinate between the main and ancillary study, perform field work, prepare data or biospecimens, review and confirm final analyses, etc. The Applicant must coordinate closely with SCCS Investigators prior to submitting a Request, so that appropriate coverage of SCCS personnel effort (and other associated costs) is incorporated into the proposal.

If an ancillary study grant proposal is awarded funding, the Principal Investigator of the ancillary study must notify the DBU Committee Chair in writing, and the DBU Committee will consider this ancillary study to be active.

For active ancillary studies, the Principal Investigator of the ancillary study must submit a one-page progress report to the DBU Committee Chair every six months. This report shall include the status of study funding, any changes to the timeline, the general status of study work (i.e., the number of ancillary study participants enrolled and the progress of field work, data collection, etc.), and any unanticipated problems.

Consent forms used for ancillary studies shall clearly identify the ancillary study as one being performed in addition to the main study, and inform subjects that their participation in the ancillary study is not necessary for them to continue in the SCCS. A copy of the consent form signed by every SCCS participant in the ancillary study must be given to the SCCS for permanent storage.

If an ancillary study involves the collection of any new data from SCCS participants, these data must be shared with the SCCS in their entirety and in a format jointly agreed upon with the SCCS data managers. It is expected that these data be received by the SCCS no later than six months after the data are collected or within 2 years after the initiation of data collection, whichever is earlier. The Applicant shall have the priority to use these newly collected data within the first 2 years of data collection. In addition to the raw data, the ancillary study investigators must provide the SCCS data managers with an appropriate codebook for the data. Also, while the ancillary study investigators may retain the newly collected analytic data for their analyses, they will delete (and confirm in writing that they have deleted) any identifying information used for the collection of these data (including, but not limited to, name, address, social security number) from all of their datasets and/or databases (including back-ups). They must retain, however, the study ID numbers (that are linked to SCCSID numbers) on their datasets, so that coordination with SCCS data managers is possible.

Often there is a finite amount of sample (e.g., blood or tumor tissue) available from each ancillary study subject, and it may not be feasible to include the same subject in multiple ancillary studies for sample collection. Thus, the collection of certain biological samples in an ancillary study might prevent future studies from collecting additional samples. For this reason, the Applicant must agree to share biospecimens collected from their ancillary study with the SCCS. The Applicant who seeks to collect new biological samples should work closely SCCS Biorepository staff at VUMC for protocol development and biospecimen collection activities. Except in unusual circumstances, all biological samples should be processed and stored in the SCCS Biorepository at VUMC according standard protocols, with sample aliquots subsequently sent to the Applicants for relevant bioassays proposed for the ancillary study. Any remaining samples at the end of the proposed bioassays should be returned to the SCCS Biorepository at VUMC for long-term storage for future studies. The investigators who collected the biospecimens would need to apply for the use of these biospecimens should they need additional material.

Requests dealing with ancillary study grant proposals should be submitted well in advance of the deadline to submit the grant application. We suggest at least three months in advance for submission. Review of a full Request must be completed prior to submission of the proposal to a funding agency. Requests submitted with less time are not guaranteed to be processed by the time of grant submission.

Applicants should not submit a proposal to a funding agency before they receive approval from the DBU Committee regarding the use of SCCS resources. This could disqualify the Applicant from utilizing SCCS resources and also from applying for future collaboration with the SCCS.

7. Approval of manuscripts prior to publication

The development of potential manuscripts generated from any SCCS data (interview data and/or biospecimen data, including data collected in ancillary studies) must adhere to the guidelines below.

The lead author of the manuscript (the Applicant) must submit the manuscript for review to the SCCS Publications Committee. This must be accomplished through the SCCS online system (https://ors.southerncommunitystudy.org/). Any questions concerning the electronic submission and review process can be emailed to datause@southerncommunitystudy.org. At the time of submission, the manuscript shall be in finalized, ready-for-publication form, and have been approved by all co-authors. The manuscript should be submitted under the same Application Concept as the original Request supplying data for analysis. The manuscript should already be formatted for the intended journal, as further editing to the manuscript to fit a journal's format may necessitate another review of the final version. It is strongly advised that each submitted manuscript have as a co-author a biostatistician who substantially performed or reviewed the analyses presented in the manuscript and/or advised on appropriate statistical procedures to be applied to the data and hypothesis at hand.

In addition to the manuscript itself, the analyses that are presented in the manuscript must be verified prior to submission to a journal. The Publications Committee Chairs will arrange for an independent statistical review by SCCS biostatisticians. For this purpose, the Applicant must provide the programming code (preferably SAS) used to produce the results (including code used to clean the data and create analytic variables). It is therefore imperative that the statistical program is able to be run on the original dataset provided to the Applicant. The SAS code provided must be organized to match the order of results as presented in the manuscript, and clearly document which sections are used for data cleaning, which sections produce numbers in the manuscript, and which sections produce output for the manuscript tables and figures and any supplementary tables. Code that does not produce results should be deleted or commented out. To avoid a common error, when deriving new variables be sure to run cross tabulations between old and new variables to ensure they were derived correctly. A header (comment section) should begin each program and include the name of the program, programmer's name, date, a sentence describing the purpose of the program and indication of the order of the program if there are multiple submitted programs. A sample header would be as follows:

Program:	ESRD case-control matching.sas
Author:	Heather Munro
Created:	7/24/12
Updated:	7/26/12
Purpose:	To choose controls for incident ESRD cases for a nested case-control dataset. Program 1 of 2.

An analytic review conducted by an SCCS biostatistician will be included with the overall review of the Publications Committee and could be the basis for rejection of the manuscript. If the SCCS biostatistician recommends significant revisions to analyses that should have been accomplished prior to submitting the manuscript for review, it will be recommended that the SCCS biostatistician be added as a co-author on the manuscript.

Manuscripts upon receipt will be referred by the Publications Committee Chairs to two or more appropriate members of the Publications Committee for primary review, with a copy of the manuscript submitted

to the entire Publications Committee. At the discretion of the Chairs, the manuscript also may be sent for review to outside scientific consultants.

The Publications Committee will generally give written comments on the manuscript to the Applicant (lead author) within 4 weeks of receiving the manuscript. The Publications Committee will indicate whether:

a. They have approved the manuscript as is.
b. They have approved the manuscript contingent upon certain minor revisions being made to the manuscript.
c. They do not approve the manuscript, and require a revision and resubmission.

In the case of a contingent approval (scenario b), prior to submitting the manuscript to a journal, the Applicant must resubmit the final version of the manuscript, with the appropriate changes made or responses to the reviewer comments explaining why the changes were not made, to the Publications Committee Chairs for review. The Applicant will be notified when the Publications Committee Chairs have decided that the manuscript is suitable for submission for publication.

In the case of a manuscript rejection (scenario c), the lead author may resubmit a new version to the Committee for another review. The authors may not submit the manuscript to a journal before they receive approval from the Publications Committee. It may take several reviews before a manuscript is approved by the Publications Committee.

The lead author will agree to accept as additional co-authors SCCS Investigators who have expertise in the subject matter of the manuscript, have offered to participate in the writing or editing process, and whose participation is deemed significant enough by the Publications Committee Chairs to warrant inclusion as a co-author.

Once the manuscript is submitted for publication, the lead author is responsible for reporting to the Publications Committee Chairs on the manuscript's progress. This includes notification when a manuscript receives final approval from a journal, is rejected from a journal, or when it has been sent to another journal. Revised and resubmitted versions must be shared with the Publications Committee. When the manuscript is published, the lead author must provide an electronic reprint (pdf) to the Publications Committee Chairs and must take responsibility for assuring compliance with NIH's public access policy (either by submitting the final accepted version to PubMed Central or by coordinating with the journal to do so).

If a manuscript is submitted to a journal without final approval from the Publications Committee, the Applicant and/or the responsible author may be prevented from applying for or using SCCS data in the future.

8. Approval of abstracts

Abstracts generated from any SCCS data (interview, outcome and/or biospecimen data, including data collected in ancillary studies) must be submitted to the Publications Committee Chairs for review through the SCCS online system. The abstract should be submitted under the same Application Concept as the original Request supplying data for analysis.

If the abstract is reporting on the same data from a manuscript that has already been reviewed and approved by the Publications Committee, the abstract must be submitted to the Publications Committee Chairs through the online system, but the Applicant need not wait for a response from the Publications Committee Chairs prior to submitting it to the outside organization/conference/etc.

If the abstract is the first reporting of the data to the Publications Committee Chairs, it must be submitted at least two weeks prior to the deadline for the abstract's submission. All authors on the abstract shall have approved the final version before it is submitted to the Publications Committee Chairs. If an abstract is submitted

to an organization/conference/etc. without final approval from the Publications Committee Chairs, the Applicant and/or the responsible author may be prevented from applying for or using SCCS data in the future.

Abstracts generally do not undergo statistical review, and the SCCS online system will not prompt the Applicant to provide the statistical program that generated the abstract results.

9. Requesting amendments to a previously approved Request

Amendments to a previously approved Request can be submitted at any time through the online system by clicking "Amend" next to the approved Request. In addition to making any necessary changes to the original Request, the Applicant must upload a cover letter clearly describing the proposed amendment.

The changes proposed in the amendment may not be initiated until the DBU Committee has approved them in writing.

10. Submitting a progress report for an approved Data Access, Data Analysis, Biospecimen and Data, or Ancillary Study Request

Data Access, Data Analysis, Biospecimen and Data, and Ancillary Study Requests are approved by the SCCS DBU Committee for a fixed period of time. One year following initial DBU Committee Approval, the Applicant will receive an email requesting submission of a brief progress report for review by the DBU Committee Chair. The progress report will consist of the following questions:

1. Have the aims for the project changed?
    a. If so, briefly describe the changed aims.
2. Please provide brief highlights of your 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.
3. Have you submitted an abstract for a peer reviewed poster or oral presentation at national meetings?
    a. If yes, was the abstract accepted?
    b. If yes, list the name and date of presentations.
4. Have you submitted a manuscript for a peer reviewed publication?
    a. If yes, was the manuscript accepted? Will you resubmit the manuscript if it was not accepted?
    b. If yes, provide a brief manuscript summary.
5. Have you submitted a grant for additional research based on preliminary date from the SCCS?
    a. If yes, was the grant funded? Will you resubmit the grant if it was not funded?
    b. If yes, provide a brief grant summary.
6. Does your team need additional time to complete the original aims or to submit academic materials such as manuscripts and grants?
    a. If yes, provide a brief rationale for requesting additional time.
    b. If yes, provide the date you plan to complete all work.

Submission of an updated progress report will be required annually to maintain DBU Committee approval for continuing work. The Applicant will receive an email notification for each required submission. The estimated length of the original project period will be considered for each project. If the Applicant and the DBU Committee Chair determine the Request to be complete, no further progress reports will be required.

If the progress report is not submitted with one month of the initial emailed invitation, Applicants will receive a second invitation to complete the progress report. Six weeks following this second invitation, if the progress report still is not submitted, the Applicant will be prohibited from submitting any new requests of the SCCS (including requests for Numbers, Data Access, Data Analysis, Biospecimen & Data, Ancillary Study, Manuscript review, Abstract review) until the progress report is submitted.

11. Properly referencing your Request when corresponding with the Committee

Each Request will be assigned a permanent reference number consisting of an Application Concept ID and Request ID. When corresponding with the Committee for any reason (e.g., when submitting an amended Request or a progress report, or for any type of general correspondence), please reference these numbers.