MACS/WIHS CCS
CONCEPT SHEET AND PUBLICATION POLICIES AND PROCEDURES

Updated January 15, 2019

All investigators who wish to use data and specimens from MACS/WIHS Combined Cohort Study (CCS) **MUST** agree to follow CCS policies and procedures.

I. CONCEPT SHEET POLICIES

Submission of a concept sheet research plan is required for all proposed investigations involving analyses using existing data sets, the collection of new data (questionnaires, clinical, and physical measures), and/or use or collection of laboratory specimens.

All decisions regarding CCS concept sheets (CS) are ultimately under the purview of the CCS Executive Committee (EC). If an investigator disagrees with the Scientific Reviewers' (SRs) decision regarding approval of the CS, they can appeal for the concept sheet to be reviewed by the EC (see procedure below). Additionally, any EC member can request that a concept sheet be reviewed by the full EC after the SRs' decision. The EC can overrule the SRs and has final authority regarding concept sheet approval.

Specimens and data provided by the CCS are intended for the express purpose of performing EC-approved research. These specimens and data must not be provided to other investigators or used for additional projects without the explicit written consent of the CCS EC. Failure to follow these guidelines may result in the withdrawal of approval of the study concept sheet. Unauthorized use of data and/or specimens for work not specifically described in the aims of an approved concept sheet will be considered a breach of professional ethics and could result in such actions as withdrawal of abstracts or publications, as well as the prohibition of the future use of cohort data and specimens.

Use of Specimens: Leftover material cannot be returned to the CCS central repositories.

New data generation from externally funded grants: New data from CCS protocols or measurement of CCS biological specimens must be submitted to the Data Analysis and Coordinating Center (DACC) once data generation/testing is complete. Data will not be released until the original aims of the funded study are complete, and/or PI approval is given.

II. PROCEDURES FOR CONCEPT SHEET SUBMISSION, REVIEW, AND APPROVAL

A. CONCEPT SHEET DEVELOPMENT

Investigator(s) should work closely with their site Principal Investigator (PI) or CCS liaison in the development of a draft concept sheet. The CCS recommends that the study liaison be a PI of a CCS site or a Working Group (WG) chair.

All investigators (who are not PIs) should have a study liaison. The role of a study liaison is to:

- ensure the investigator follows the CCS Publication Policy, especially with regard to abstract and manuscript submission.
- ensure that the investigator is aware of any cohort data/specimen limitations, i.e., what data and specimens are available, and will contribute as needed to study design.
- ensure that persons with the appropriate scientific expertise have provided input. If appropriate expertise in a certain area is found to be lacking, the site PI or CCS liaison can consult the relevant WG chair to identify an investigator who may be able to provide the missing expertise.

NOTE: If you are an external investigator and do not have a CCS liaison, contact the DACC (MWCCS@jhu.edu) for assistance with identifying one.

Investigators should consider, and address, the following questions in their concept sheet proposal.

- What are the specific aims of this investigation?
  - Is there overlap with any existing concept sheets?
- Have persons with all relevant expertise provided input to the concept sheet?
- What is the study design, measures that will be used, number of participants, and analytic plan?
- What data/specimens will be used or collected?
  - What sites and participants will be eligible?
  - If additional data or specimens are to be collected:
    - At what point in the study visit will the additional data collection take place?
    - What tests/analyses will be performed?
    - How will specimens be tested, and by whom?
    - Will the results be provided to participants?
    - How long will data/specimen collection take? Will a separate visit be needed?
    - What training or equipment/supplies will be needed to implement the protocol?
    - Who will provide training or equipment/supplies?
    - Will sites or participants be reimbursed for the additional effort? If so, what mechanism will be used to reimburse sites (e.g., fee for service, contract)?
- What are the logistical considerations?

- Is this concept sheet part of a grant submission? If so, what is the timeline for submission?
- Has the local IRB approved this study? Will new IRB approval or IRB amendments be needed from other sites?

B. PRE-SUBMISSION REVIEW

Investigator(s) must review the proposed research with either his/her site's PI (for internal investigators) or with a CCS liaison (for external investigators) before submitting the concept sheet for EC review.

Concept sheets that include additional data or specimen collection:

If the concept sheet includes collection of new data or specimens then these additional policies apply. Investigator(s) must also review the proposed research with the local site's Project Director (PD), as well as the PDs from all sites that are being asked to participate. Investigator(s) should contact the relevant sites through his/her site PD or CCS liaison and should provide each site with: (1) the draft concept sheet, (2) any new forms or questionnaires proposed for administration, and (3) an associated budget (if applicable). (add link to directory of MACS/WIHS CCS PDs)

The PDs will review the concept sheet and provide the investigator(s) with feedback regarding the feasibility of the concept sheet, as well as an assessment of the potential site burden. PDs will work with the investigator(s) to develop a budget based on standardized rates for data collection, administrative/staff effort, and protocol implementation.

NOTE: *Budget negotiations must be completed before the concept sheet may be approved. Investigator(s) must contact the PD co-chairs (or relevant local site PDs) as early as possible in the concept sheet process to ensure that a budget is finalized before any grant submission deadlines. PD contacts are listed here* ***<website***-will add link>.

Once the site PI/PD/CCS liaison has reviewed the concept sheet and deemed it appropriate, the investigator(s) may submit the final version to DACC via the online submission form. If the proposed research includes the collection of new data or specimens, investigator(s) must also submit the data collection instrument and a draft budget (if applicable) as an attachment to the concept sheet.

Concept sheets that are submitted to the CCS before receiving approval from either the corresponding site PI or the CCS liaison will not be reviewed by the CCS EC and will be returned to the investigator without review.

Concept sheets that are led by a student:

If the concept sheet to be submitted is related to a student dissertation or thesis, the student must upload a letter of support from their advisor/faculty mentor stating that the advisor will assist the student with the proposed project.

C. CONCEPT SHEET REVIEW

Once the concept sheet has been submitted to the DACC, it will be reviewed by DACC staff for completeness. If the concept sheet is found to be incomplete, it will be returned to the investigator for further work before distribution for CCS review.

If the concept sheet is found to be complete, the DACC will assign a README number for tracking purposes. This number will be used in all ensuing communication throughout the life of the project. The concept sheet will then be assigned to the appropriate Working Group(s) for review based on the scientific topic(s) that the investigator indicates on the concept sheet. The concept sheet will also be assigned Scientific Reviewers (SRs) based on expertise. SRs will include PIs, WG chairs, and other key investigators identified by the CCS EC. Once reviewers are assigned, the concept sheet will be distributed via the DACCTrack system to all reviewers and all members of the selected WGs.

Depending on the scope of the proposed concept sheet, there are three different types of review including: 1) multi-site investigations that propose new data collection, 2) multi-site investigations that require no new data collection, and 3) single site investigations.

1. MULTI-SITE INVESTIGATIONS THAT PROPOSE NEW FORMS OR SPECIMEN COLLECTION

Multi-site concept sheets requiring new forms or specimen collection will be reviewed by:

- Appropriate WGs
- Project Director Reviewer (PDR)
- Scientific Reviewers (SRs; one MACS and one WIHS if the proposal includes both MACS and WIHS sites)

In addition, if appropriate there will also be review by :

- a Lab Reviewer (LR), if the collection of new specimens, or withdrawal of specimens from the central repository, is proposed
- a Genetics Reviewer (GR), for all genomics studies
- a Geocoding Reviewer (GeoR), for all studies proposing to use census-linked datasets

All concept sheets will be made available for EC comments and feedback.

Once a concept sheet has been distributed, all reviewers other than the SRs are required to submit their reviews within a two-week (10 business day) window. The SRs will be allotted two extra business days so they can take into account other reviews and any EC comments/feedback before completing their final

reviews. Reviewer comments will be available in DACCTrack and a link to access those reviews will be provided to the concept sheet investigator along with their approval/revision/rejection letter.

- **Scientific Reviewers (SRs),** from among the site PIs, WG chairs, and other key investigators as identified by the CCS EC, will be asked to review each concept sheet in detail. Assignments will be made on a rotating basis based on the area of expertise. The SRs will review the concept sheet for scientific merit, feasibility, and potential overlap with other approved CCS concept sheets. The SRs should review all comments from other reviewers before giving a final determination for a concept sheet of **approve, reject,** or **request revision**.

  NOTE: The SRs will also review the concept sheet for any potential conflicts of interest**.** Investigators are responsible for identifying financial interests that may create conflicts of interest or give the appearance of conflicts of interest. An investigator may hold a conflict of interest if they have **significant** financial or property interest in the outcomes of the CCS research concept sheet. This could include:

  - Investigators involved with developing or marketing a product or treatment that will be studied.
  - Investigators involved with developing or marketing a competing product or treatment.

  Investigators are required to disclose any potential conflicts of interest on the concept sheet submission form.

- The **Project Director Reviewer (PDR)** will review the feasibility and participant/site staff burden of the proposed research activities. Investigator(s) should carefully address each of these issues within the concept sheet. In addition, the PDR will review the costs associated with the proposed research. All sub-studies that require data collection will need to ensure adequate CCS site funding for activities proposed in the concept sheet (e.g., administrative/personnel effort, protocol administration, data management, participant reimbursement, etc.). DACC assigns the PDR on a rotating basis across the sites.

- A **Lab Reviewer (LR)** will be assigned to review a concept sheet if any new specimens will be collected from participants, or if specimens will be withdrawn from any CCS central repository. To protect the most valuable and irreplaceable specimens in the CCS, central repository requests for specimens from certain groups of CCS participants (HIV-seroconverter, ART-naïve HAART initiator, long-term non-progressor, elite non-progressor, rapid progressor, fast progressor, incident cancer case, etc.) will receive additional review by the CCS Specimen Allocation Committee (CSAC). All **approved** concept sheets that request these VIP specimens will undergo a

final review by the CSAC before sending samples to the indicated lab. The mandate of the LR is a targeted review to ensure the appropriate assays and specimens are being used and the proposed science justifies specimen use.

- A **Genetics Reviewer (GR**) will be assigned to review a concept sheet if any of the following apply:
  - DNA is being requested from one of the CCS DNA Repositories
  - Specimens will be used by the investigator to create his/her own genetic materials for study
  - GWAS data will be used
  - Any genetics analysis is to be done as part of the concept sheet

  For genetic data generated before 2019: If MACS genetics data is to be used a MACS GR will be assigned, and if WIHS genetics data is to be used a WIHS GR will be assigned.

  Genetic data generated during the CCS (≥ 2019) will have one GR assigned.

- A **Geocoding Reviewer (GeoR**) will be assigned to review the feasibility of the proposed research activities if the concept sheet is requesting contextual data from the CCS Geocoding Core.
- **Working Group (WG)** reviews will be completed concurrently with the other concept sheet reviews. The DACC will send notification of a new concept sheet to all members of the appropriate WGs. WG review can take place via email; concept sheets do not need to be discussed on a WG call. The WG chair will compile WG member comments and submit a recommendation via DACCTrack. If a WG review is not submitted within two weeks (10 business days), the SRs can proceed without WG review.

The CCS EC will be notified at the time of concept sheet submission if a concept requests new data or specimen collection. The EC will be encouraged to comment on these concept sheets, and a reminder email will be sent to PIs in a weekly digest indicating which concept sheets are under review. PIs will be given one additional week (7 days) to review concept sheets requesting new data or specimen collection after WG reviews have been received. Any issues/concerns regarding the data/specimen collection will be discussed on an EC call. If there are no concerns, the concept sheet will not be discussed on a call, and the concept sheet will be approved.

In addition to the reviews outlined above, concept sheets that require new forms to be added to the CCS visit will require full EC approval and will only receive *provisional approval* until they are discussed during the semiannual CCS protocol review process. This does not apply to concept sheets adding only a few questions to an existing form – they can receive full approval. This process consists of the review and discussion of protocol amendments and additions and takes place

three months before the start of the visit window (i.e., July for the October visit, or January for the April visit). There are only two protocol review discussions per year, so investigators must plan accordingly and submit concept sheets and forms with adequate time for review and revision so that they do not miss the CCS protocol review deadlines.

Note that no one sub-study can take precedence over another. Once a concept sheet and any related protocol/forms are approved by the EC during the semi-annual CCS protocol review process, an implementation timeline can be developed. Given the length of the core CCS interview and the administrative activities required to implement a protocol at each site (e.g., IRB submission, contract approval, staff training) study concept sheets usually cannot be implemented during the visit window immediately following approval. In addition, once a study is approved, it will queue up behind other approved concept sheets for implementation at future visits.

2. **MULTI-SITE INVESTIGATIONS THAT REQUIRE NO ADDITIONAL DATA COLLECTION**

   Multi-site concept sheets that require no additional data collection (i.e., seek to analyze existing data or specimens) will be reviewed by:

   - Appropriate WGs
   - Scientific Reviewers (SRs; one each from former MACS and WIHS sites). If a concept sheet proposes to use only MACS or only WIHS historical data, then a SR from that cohort only will be assigned to review the CS, along with WG/LR/GR/GeoR, as appropriate.

   If relevant the following are also assigned: a Lab Reviewer (LR) if withdrawal of specimens from the central repository is proposed; a Genetics Reviewer (GR) if DNA is being requested from the CCS DNA Repositories or if any genetics analysis is to be done as part of the concept sheet; and/or a Geocoding Reviewer (GeoR) if proposing to use census-linked datasets.

3. **SINGLE-SITE INVESTIGATIONS**

   Single-site investigations are those that propose to utilize and/or collect data/specimens from one CCS site only. All site-specific concept sheets will be reviewed by the PI from that specific site. The site PI review will ensure that there is no scientific overlap with other ongoing projects. If additional data or specimens are to be collected, the site PD must also approve. Once the reviews are complete, the project may proceed. However, if the single-site concept sheet proposes the withdrawal of specimens from any of the CCS central repositories, then it will receive a full review, as in #2 above.

D. CONCEPT SHEET REVIEW PROCESS AND TIMELINE

Each concept sheet will have an initial two-week (10 business day) review period. During this period, all EC members will have the opportunity to submit comments about the concept sheet, and the WGs and PDR/LR/GR/GeoR will submit their reviews

to DACCTrack. At the end of this two-week period, the SRs will have two additional business days to submit the final review along with their ultimate recommendation for approval or rejection. SRs should consider comments made by EC members, the WG and PD/LR/GR/GeoR reviews, the significance of the proposed investigation, whether the project overlaps with other ongoing or submitted proposals, and whether the science is relevant to the CCS. If there is overlap with existing projects, the SRs must indicate if the project should be combined with other related projects or revised to avoid overlap.

The SRs will determine if the concept sheet requires revision and repeat SR review, if the investigator must respond to questions/comments in the review before approval, and finally, the overall approval status of the concept sheet. If, after review, the SRs think additional discussion is necessary for a given concept sheet, the project will be discussed during the next scheduled EC conference call.

This additional review may be scientific (e.g., questions related to whether the science is relevant to the CCS, or what priority the project should be given, etc.), or operational (e.g., questions regarding implementation, overlap, etc.) in nature. As previously mentioned, if new data will be collected as part of the proposal, the concept sheet will only be *provisionally approved* until the semi-annual CCS protocol discussion, at which time it may receive final approval.

If there is disagreement among the SRs as to whether a concept sheet should be approved, the SRs should coordinate with each other to resolve and make a joint decision. If they cannot come to an agreement, the final decision will be made by the EC.

Once a final decision is made, the DACC, on behalf of the EC Chair, will send a letter of approval or rejection to the lead investigator and will include the review feedback. For concept sheets related to grant applications, a letter of support will be provided by the DACC on behalf of the EC Chair.

NOTE: *If a concept sheet is submitted as part of a grant application, it will receive a full scientific and administrative review by the CCS before approval.*

Investigator(s) who are submitting the concept sheet as part of a grant application may request a Letter of Support (LOS) from the EC through the concept sheet submission form, and the letter will be provided when the concept sheet has received approval. If the grant deadline is before the concept sheet has been approved, the EC can review and decide to provide a conditional LOS.

If a study is using data or specimens collected CCS-wide, co-authors will be identified from each site, and the DACC after the concept sheet is approved. If a study is using data or specimens from only a subset of sites, co-authors will be identified and assigned from only those sites contributing data (and the DACC when centrally managed data is used). Site PIs will have two weeks (14 days) to recommend co-authors from their sites. These co-authors should be listed on any abstracts and manuscripts that are submitted as part of the aims outlined in the

concept sheet.

E. CONCEPT SHEET REVISIONS AND AMENDMENTS

In cases where a concept sheet requires revisions before approval, investigator(s) will be provided a link to submit his/her revision through a pre-filled form. They should provide a summary of changes, and highlight or track all changes in the concept sheet research plan form to offset them from the original language. Additionally, a point-by-point response to any SR comments/questions should be attached and uploaded with the revised concept sheet research plan.

Investigators who wish to amend an already-approved concept sheet (e.g., to request additional specimens and/or data) should revise the original concept sheet research plan taking care to highlight any changes and upload it using the online concept sheet submission form.

Revised concept sheets will retain the same README number assigned upon submission. Amendments requesting additional resources (e.g., data or specimens) will retain the same README number assigned to the initial project.

If an amendment proposes the addition of aims or substantially different data elements to be collected and/or analyzed, that will result in publication of an additional manuscript, or if it will significantly expand the scope of the concept sheet, it must be submitted as a new, initial concept sheet and will receive a new README number.

F. CCS DATA AGREEMENTS

All investigators who are requesting DNA from the CCS DNA Repositories, or are requesting GWAS data, or are proposing any genetics analysis, are required to submit a signed **Genetics Data Use Certification Agreement**. This agreement will be coordinated by a MACS representative for the use of MACS genetic data and by a WIHS representative for the use of WIHS genetic data.

Additionally, all investigators who are requesting data from the CCS Geocoding Core will be required to agree to the **Instructions for the use of Contextual Datasets** and have a signed Data Use Agreement (DUA) with UNC in place before the transfer of contextual data.

Investigators may not initiate any research activities until the requisite documents are received by the managing institution.

G. EXPIRATION AND DEACTIVATION OF CONCEPT SHEETS

The lead investigator for each approved concept sheet must submit a **progress report** to the DACC annually, using the link in their DACCTrack Investigator View. If no progress report is received after two email reminders, approval for the concept sheet will expire. If a completed progress report indicates that no activity is occurring on the project, the project will be declared inactive.

H. REQUESTS FOR DATA, SPECIMENS, AND ANALYTIC SUPPORT

Once a project is approved, requests for data, specimens, and or analytic support for the project should be made to the DACC as outlined below. If the analysis is to be performed by the DACC, the lead investigator should communicate with the DACC to begin collaboration on study design, the creation of analytical datasets, and selection of repository specimens and data analysis.

1. DATA REQUESTS

Data requests will be fulfilled both by the DACC and by site investigators. All CCS investigators have direct access to the CCS dataset, which is distributed semiannually on DVD to all site Data Managers. Data requests not filled at the local level should be submitted to DACC through DACCTrack using the CCS Resource Request Form. The form should include the README number, a list of CCS variable names and the corresponding form number needed for the dataset, as well as the visit number(s) and/or calendar dates for which data are needed. Variable names can be obtained from the CCS codebooks and the master variable list [will add link]. Codebooks are distributed with data freezes to the Data Managers at each site and are also located on the *CCS Admin Website* [will add link]. A DACC programmer will be assigned to the project once a data request is made.

2. SPECIMEN REQUESTS

All specimen requests should be submitted to the DACC through DACCTrack using the **CCS Resource Request Form**.

Selection of Specimens

If an investigator has already determined the appropriate ID/visits to a request for an approved project, an Excel spreadsheet of IDs, visits, and visit dates should be attached to the CCS Resource Request Form. If the investigator has not yet determined appropriate ID/visits, the assigned DACC coauthor and a DACC data manager will be assigned to work with the investigator to select appropriate ID/visits based on the selection criteria in the approved concept sheet. Investigators can email the DACC at MWCCS@jhu.edu to ask about specimen availability during concept sheet development if needed.

a. CCS Specimen Allocation Committee Review (CSAC)

The CCS Specimen Allocation Committee (CSAC) is charged by the CCS EC to assist in the allocation of high-value repository specimens. The CSAC reviews all requests for the release of samples from individuals who contribute significant or unique outcomes to overall CCS research aims and will determine whether or not the restricted samples should be released to the requesting investigator. When necessary, the CSAC may be asked to review concept sheets that request the use of high-value samples.

Restricted specimens include those from:

- *HIV seroconverters:* restrict samples from last three negative visits, plus all positive visits
- *Pre-HAART deaths:* restrict samples from all visits for participants who died on or before September 30, 1997, with at least two years of follow up
- *HAART initiators* (i.e., ART-naïve participants who initiated HAART): restrict samples from one visit before HAART initiation, plus first three visits after HAART initiation (i.e., first reported HAART visit, plus the two visits after initiation)
- *Long-term non-progressors:* restrict all samples
- *Elite non-progressors:* restrict all samples
- *Rapid progressors* (i.e., <3 years between seroconverting and first AIDS diagnosis): restrict all samples
- *Fast progressors* (i.e., 3-5 years between seroconverting and first AIDS diagnosis): restrict all samples
- *Incident cancers:* restrict samples for up to four pre-cancer visits, plus the visit at which the cancer is reported
- *Incident MI and stroke:* restrict samples for up to four pre-MI or stroke visits, plus the visit at which the MI or stroke is reported

Review by the CSAC occurs after the concept sheet has been approved and ID/visits have been identified for a particular request. Investigators may elect to drop restricted ID/visits and proceed without these samples. Alternatively, investigators may ask for a CSAC review of their request to use these specimens. The CSAC will determine whether the scientific value of the concept sheet merits inclusion of the restricted specimens in the request.

The DACC will facilitate this process by tracking requests in a database and sending an email notification including the following information:

- Investigator name, the title of concept sheet, README number, and links to the concept sheet and reviews
- A summary of the request: selection criteria, specimen type, aliquot number and total volume needed for testing, tests to be performed, expected ID/visits, expected number of samples
- Summary of restricted ID/visits: percent restricted ID/visits in request, if alternate ID/visits are possible, summary of reasons for requesting the restricted ID/visits as they relate to the aims/hypotheses of the concept sheet, number of specimens currently available and how the request would deplete the ID/visits

available

- Other extenuating circumstances known by the coordinator

Once they have received the notification, CSAC members have one week (7 days) to respond as to whether or not they approve the use of restricted samples. The DACC will communicate the final decision of the CSAC to the requesting investigator. If the CSAC does not approve the use of restricted specimens, the requesting investigator can appeal to the EC.

3. ANALYTIC REQUESTS

If the lead investigator is requesting that the analysis be performed by the DACC, they should indicate that request in DAACTrack during concept sheet submission. The DAAC will support requested analyses for core investigations (studies using data generated as part of the principal CCS collaborative agreements) whenever possible. Analytic support for multi-site or single-site studies may also be provided, pending programmer availability and study project priority.

All projects requesting analytic support will undergo an additional methodology review (MR) to assure the study design and analytic plan are feasible and appropriate for the study question. This review will be done within 7 days of submission of the analytic specifications via the **CCS Resource Request Form**. Investigators will be told whether DACC can provide support:

- "Yes" Perform analysis and have the needed details to begin
- "Pending" Perform the analysis, but only once more details are provided and/or issues clarified
- "No" Cannot support the analysis

4. REQUESTS FOR CONFERENCE ABSTRACT AND PRESENTATION ANALYSIS

Requests to DACC for analysis of approved concept sheets must be given at least 6 weeks prior to the deadline.

> **NOTE:** For complex study designs or analyses, longer times may be needed. DACC analysts or investigators may, at their discretion, determine that requested analyses cannot be done within the 6-week timeframe to a 'good science' standard. Investigators are encouraged to talk to DACC as early as possible if deadline-driven analyses will be needed.

DACC encourages conference abstract submission and supports as many analyses as possible. Active communication between the investigator and biostatistician from concept sheet approval to the completion of the manuscript is strongly encouraged.

However, based on competing cohort demands DACC reserves the right to adjust the prioritization of requests. DACC will always provide datasets when analyses cannot be done by DACC analysts in a timeframe that is acceptable to the investigator.

III. PUBLICATION AND PUBLICITY POLICIES

All abstracts and manuscripts resulting from approved concept sheets MUST be approved by all co-authors and submitted to the CCS EC before submission for presentation or publication. Final revisions also must be approved by co-authors and submitted to the CCS EC before resubmission.

Failure to comply with this policy may lead to such actions as withdrawal of abstracts/publications or prohibited future use of cohort data and specimens.

A. CREDIT, AUTHORSHIP, AND WRITING COMMITTEES

The following categories specify how credit and authorship are apportioned for most CCS projects. The lead investigator listed on the concept sheet should include any investigators and analysts (CCS or external) that make substantial contributions to the project. The CCS adheres to criteria for authorship promulgated by the International Committee of Medical Journal Editors. Special requests regarding authorship (e.g., number of assigned authors) are discussed and voted upon by the CCS EC.

a. SINGLE-SITE INVESTIGATIONS

A single-site investigation is one using data collected from one site only and funded through that site's CCS collaborative agreement or external sources (e.g., RO1, unobligated funds, etc.). These data may be collected as part of a pilot study, the core CCS protocol, a local sub-study, or be generated from local specimens collected during CCS or additional visits. In general, single-site investigations should be rare; investigators are encouraged to utilize the entire CCS cohort for most projects.

Publications resulting from single-site investigations will include co-authors at the discretion of the lead investigator from the local site. Co-authors will not be assigned by the DACC. Manuscripts should be approved by the site Principal Investigator before submission to the CCS EC.

b. MULTI-SITE INVESTIGATIONS

A multi-site investigation is one wherein analyses utilize data from at least two, but not all, CCS clinical sites. For these investigations, site representation will be solicited by the DACC only from the sites contributing data, specimens, and/or analytic support. Each site contributing data, specimens, and/or analytic support will be allowed to name one co-author.

c. CORE INVESTIGATIONS

A core investigation is one using data generated as part of the principal CCS collaborative agreements (i.e., all clinical sites and the DACC). These data may be part of the core CCS protocol, a sub-study, or generated from specimens collected as part of CCS visits.

Core investigations require that each of the CCS sites (including the DACC, even if the analysis is conducted elsewhere) be offered co-author representation in recognition of the substantial amount of operational work performed by each site for cohort recruitment, retention, data collection, and data management.

The lead investigator of a core investigation does not necessarily need to be supported by the CCS (i.e. can be an "external" investigator). However, the CCS reserves the right to assign a new lead author to a project if an external investigator does not wish to write up the study results, but agrees that a publication is worthwhile.

While the DACC performs the analyses for many core investigations, data analyses may be conducted elsewhere for both core and external projects. In these cases, the lead investigator should arrange for the DACC to receive data sets and programs that relate to the tables and figures in the manuscript upon publication.

NOTE: *If a site's sole contribution to a project will be the provision of data, then the site will be allowed to name only one co-author. Additional co-authors from a site may be added at the discretion of the lead author and would need to be based on individual contribution to the project.*

d. **MULTI-COHORT COLLABORATIVE INVESTIGATIONS**

Proposed studies that involve pooled data from the CCS and other cohorts should include authors from each of the partner organizations involved. It is recognized that multi-cohort collaborations can result in an unwieldy number of co-authors. Hence, in general, a subset of CCS representatives (1 to 2) will be assigned to multi-cohort collaborations, in addition to the project investigators. The DACC will contact the CCS WG chair with expertise in the area of investigation for help in selecting a CCS co-author(s) for these projects.

B. PROCEDURES FOR REVIEW AND APPROVAL OF CCS PUBLICATIONS

Writing Groups: Upon approval of a concept sheet, the DACC will send a request to specified CCS sites (as determined below by investigation type) requesting the appointment of a co-author from their site. PIs will have two weeks to reply to the DACC with their site's co-author appointment or else one of the site PIs will be assigned to be the co-author by the DACC. If investigators from a site are named as already involved in the concept sheet when submitted, they will be automatically assigned by the DACC as the representative from that site (i.e. additional co-authors will only be solicited for sites not already represented in the study team as

submitted in the concept sheet).

1. MANUSCRIPT REVIEW BY CO-AUTHORS

Co-author(s) must be given the opportunity to participate in the writing and/or review process of manuscripts promptly. Co-authors should be given at least two weeks (14 days) review a manuscript and provide revisions/suggestions. If, after the two-week review period has concluded, the lead investigator has not heard back from a co-author, he/she should adhere to the following process:

1. Send a reminder email to the co-author. The co-author should be given three business days to provide revisions/suggestions.
2. If the co-author does not respond within three business days, send a second reminder email to the co-author. The co-author should be given an additional three business days to provide revisions/suggestions. This email should include the reminder that co-authors who do not respond to a second reminder email for manuscript feedback are removed from authorship (see below).

If the lead investigator does not hear back from a co-author after sending two reminder emails, the expectation is that lead author will remove the non-responsive co-author(s) from the manuscript and **notify the co-author, the co-author's site Principal Investigator, and the DACC of this authorship change.** If the co-author is external to the CCS, the lead investigator must notify the EC.

It is also the responsibility of co-authors to sign journal copyright forms promptly (within one week; 7 days), once the manuscript is submitted. If a co-author does not sign the copyright form promptly, the lead investigator can exclude that co-author from the current and subsequent manuscripts related to the approved concept sheet.

2. COAUTHOR APPROVAL OF MANUSCRIPTS

Approval of all co-authors is required before submitting a manuscript to the EC or to a journal (barring co-author non-response as covered above). Co-author edits and suggestions should be considered and incorporated where appropriate and a revised manuscript circulated to Co-authors.

Study lead is responsible for documenting the approval from all Co-authors (via email or other written records) and keeping this approval for reference if needed.

If a co-author disagrees with the main findings or methods of a manuscript or finds the data or analysis misleading, he/she must attempt to resolve these issues with the writing group/co-authors before the manuscript is submitted to the EC. If a co-author still finds fault with the version submitted to the EC, he or she should address these concerns with the lead investigator. If one or more of the co-authors still disagree with the lead author regarding analyses in the paper, he or she may wish to be removed as a co-author. This should be done before submission for EC review. If

the co-author does not want to be removed from the paper, and if the disagreement over the main findings or methods of a manuscript cannot be resolved, the manuscript should be submitted to the EC with a description of the issues/ disagreement by each party involved and the manuscript will have a formal review by the EC to determine how to proceed.

3. SUBMISSION OF MANUSCRIPT TO THE EC AFTER CO-AUTHOR APPROVAL

Once the manuscript is approved by all co-authors, the lead investigator should submit it electronically to the EC via DACCTrack using the **Manuscript Submission Form.** Manuscripts submitted without assigned co-author inclusion/approval or without the appropriate CCS acknowledgement will be returned to the lead author for correction before posting.

The submitted manuscript will be accessible via DACCTrack, and the DACC will notify EC members via email about submitted papers; however, there will be no centralized EC review of manuscripts. If the lead investigator is not contacted about any concerns with the manuscript within one week (7 days) of submitting to the EC, they may proceed and submit the paper to a journal.

3a. CHANGES TO CO-AUTHORS

If a PI wants to make a change to the assigned co-author for a given concept sheet or paper, they should notify the DACC (after speaking to the currently assigned co-author) who will notify the study lead about the change.

If the lead investigator wants to request a co-author change (for example, because an assigned co-author has moved or no longer has time to be involved, or if a new investigator has joined the site and is now more involved in the research) they should either discuss directly with the PI of that site or discuss with the DACC who will coordinate with the site PI about the possible change.

Any changes to an assigned co-author should be made before the manuscript is submitted to the EC, so the new co-author has the opportunity to contribute.

4. ABSTRACT & PRESENTATION REVIEW

Final abstracts and presentations must adhere to the following guidelines:

- Abstracts must be associated with an EC-approved concept sheet.
- Co-authors should be the same as the ones assigned for the EC-approved concept sheet. All co-authors must review and approve the final EC-approved abstract before submission to the EC for review.
- CCS-wide abstracts require co-authors from each CCS clinical site, as well as the DACC. CCS collaborations (multi-cohort projects) require at least one co-author representative from the CCS.

- Abstracts must be provided to co-authors before the abstract is submitted to the DACC for EC review. Co-authors must be given at least three business days to review and approve the abstract before it is submitted to the DACC. The submitting investigator should indicate upon submission to the DACC that co-authors were provided three business days to review and approve.
- If a co-author does not respond within the three business day period, the submitting investigator can assume approval and proceed with submission to the DACC. If a co-author wishes to be removed from the abstract, the submitting investigator should indicate this upon submission to the DACC.
- Abstracts must be submitted to the DACC (with co-author approval) using the **Abstract Submission Form** at least three complete business days prior to the scientific meeting/conference submission deadline, e.g., if the conference deadline is on a Thursday, the abstract must be submitted to the DACC before 4:00 pm ET Monday, so that the abstract can be posted Monday, and reviewed by the EC Tuesday through Thursday. Abstract submission deadlines are below:

DACC SUBMISSION DEADLINE (BEFORE 4:00 pm ET)	CONFERENCE DEADLINE
Wednesday before conference submission deadline	Monday
Thursday before conference submission deadline	Tuesday
Friday before conference submission deadline	Wednesday
Monday before conference submission deadline	Thursday
Tuesday before conference submission deadline	Friday

- DACC will communicate any concerns by email or phone. If no issues are identified, the abstract will be considered approved after three full business days.

Abstracts will be available in DACCTrack and the CCS EC members will be notified of their availability via e-mail. The CCS EC will have three business days to comment on the abstract, and recommend acceptance, acceptance with revisions, or rejection.

If no revisions or objections are received within three business days, the abstract will be approved. If there is a question regarding whether requested revision is reasonable, the Scientific Leadership Committee (SLC) will review and decide. DACC will notify the author if there is a concern, otherwise they can submit to the conference after three business days.

If the abstract is the result of a **site-specific study**, the abstract still has to be submitted to DACCTrack and EC members will be notified of the posting via e-mail. However, site-specific abstracts only require the approval of the site PI before submission to a meeting/conference and need not be posted three business days before conference submission.

If the guidelines above are not met, the following policy will take effect:

- If an abstract is submitted to the DACC without co-author approval, the abstract will be returned to the lead investigator for circulation to all co-authors for review and approval.
- If three business days are not provided to co-authors to review and approve the abstract before the scientific meeting/conference submission deadline, the abstract will not be EC-approved and cannot be submitted to the scientific meeting/conference.
- If an abstract is submitted to the DACC with co-author approval, but three business days are not provided for the EC to review, the abstract will not be EC-approved and cannot be submitted to the scientific meeting/conference.

If the abstract is being submitted to a conference that limits the number of abstracts that can be submitted from any one cohort, the following abstract submission policy will take effect:

- All abstracts must be submitted to co-authors for review and approval three business days before submitting for EC review.
- All co-author approved abstracts must be submitted for EC review at least three business days before the abstract submission deadline.
- Abstracts that are submitted without three full business days remaining before the abstract submission deadline will not be approved for submission.
- After all compliant abstracts have been received, they will be distributed to EC members and members will be asked to apply a forced ranking system to rank the top six (or the number set by the conference) abstracts.
- Investigators from the top abstracts will be notified that they can submit to the conference. All others will be informed that their abstract was not approved for submission.
- All other abstract submission guidelines apply.

5. **JOURNAL SUBMISSION**

Please remember that presentations or manuscript submissions that do not have prior approval are inconsistent with the spirit of collaborative research. Disregard of this policy may result in future denial of access to CCS data and cessation of collaborative support.

Publications and presentations shall comply with the rules and procedures of the disclosure outlined in the Privacy Act. The confidential or proprietary information shall not be disclosed without the prior written consent of the individual or institution. Privacy Act compliance and documentation of written disclosure consents are the responsibility of each institution involved in the paper/presentation.

If a manuscript is accepted for publication, lead authors are responsible for submitting a PDF version of the final published article to the DACC using the **Publication Submission Form**.

6. NIH PUBLIC ACCESS POLICY

NIH requires all CCS investigators who are participating in this study, which is funded by NIH, to make their peer-reviewed final manuscripts available to other researchers and the public at the National Library of Medicine's (NLM) PubMed Central (PMC) within 12 months of the publication date. NIH expects investigators to submit an electronic copy of the final version of the manuscript accepted for publication. A separate submission is not necessary if the manuscript has been accepted by a journal that permits free access to PDFs within 12 months of publication. Click here for a list of these journals. To submit PDFs of articles, please visit the NIHMS system website.

IV. Acknowledgments

All investigators must acknowledge that CCS specimens and data are the property of CCS. Investigators are responsible for reviewing and agreeing to the CCS Publication Policy, ensuring that the samples and data are used in the manner outlined in the concept sheet, and disseminating results to assigned CCS collaborators/co-authors promptly.

All CCS manuscripts must acknowledge that the data were collected through the MACS/WIHS Combined Cohort Study (CCS). They must also credit participating institutions (CCS clinical sites, the DACC, and the supporting NIH agencies) and grant numbers. Appendix A contains an example of the suggested format for CCS acknowledgments.

APPENDIX A – SUGGESTED MANUSCRIPT LANGUAGE

SUGGESTED CCS ACKNOWLEDGMENT

Data in this manuscript were collected by the MACS/WIHS Combined Cohort Study (CCS). The contents of this publication are solely the responsibility of the authors and do not represent the official views of the National Institutes of Health (NIH). CCS (Principal Investigators):

Will list all CCS clinical sites and DACC with principal investigators and grant numbers.

Please add the following paragraph to the acknowledgments when publishing a cancer-related manuscript:

We would like to acknowledge the National Program of Cancer Registries of the Centers for Disease Control and Prevention (CDC) for the funds that helped support the collection and availability of the cancer registry data and thank the following state cancer registries for their help: AL, CA, FL, GA, IL, MD, MS, NY, NC, PA, and VA. The authors assume full responsibility for analyses and interpretations of these data.

SUGGESTED DATA AVAILABILITY STATEMENT IF REQUESTED BY THE JOURNAL:

Access to individual level data from the MACS/WIHS Combined Cohort Study Data (CCS) may be obtained upon review and approval of a CCS concept sheet. Links and instructions for online concept sheet submission are on the study website (https://mwccs.org/).