MACS/WIHS COMBINED COHORT STUDY (MWCCS)
CONCEPT SHEET AND PUBLICATION POLICIES AND PROCEDURES

Updated October 17, 2025

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

Contents

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 MWCCS concept sheets (CS) are ultimately under the purview of the MWCCS Executive Committee (EC). If an investigator disagrees with a decision regarding the CS, they can appeal for the concept sheet to be reviewed by the EC (see procedure below). Additionally, the EC can review and overrule the initial decision and has final authority regarding concept sheet decisions.

Specimens and data provided by the MWCCS 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 MWCCS 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 MWCCS central repositories.

New data generation from externally funded grants: New data from MWCCS protocols or measurement of MWCCS biological specimens must be submitted to the Data Analysis and Coordination 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 MWCCS liaison in the development of a draft concept sheet. The MWCCS recommends that the study liaison be a PI of a MWCCS site or a Working Group (WG) chair.

All external investigators should have a study liaison. The role of a study liaison is to:

- Ensure the investigator follows the MWCCS Publication Policy, especially policies concerning 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 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 MWCCS liaison, contact the DACC (MWCCS@jhu.edu) for assistance with identifying one.

Investigators should consider, and address, the following questions in their proposal:

1. What are the specific aims of this investigation?
2. Is there overlap with any existing concept sheets? Prior to submitting a concept sheet, investigators should check for overlap. If you are an external investigator, please consult with your MWCCS study liaison regarding overlap review.
3. What is the study design, measures to be used, number of participants, and analytic plan?
4. 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?
        - 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 their site's PI (for internal investigators) or with a MWCCS 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, investigator(s) must also:

- Review the proposed research with the Project Director (PD) from all sites that are being asked to participate.
- Contact the relevant sites through their site PD or MWCCS liaison and 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).

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.*

Once the site PI/PD/MWCCS liaison has reviewed the concept sheet and deemed it appropriate, the investigator(s) may submit the final version to the DACC via the online Concept Sheet Submission Form. If the proposed research includes the collection of new data or specimens, the 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 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

You will receive an automated email following submission confirming that your concept sheet submission has been received. 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 MWCCS 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 submission form. An email about the concept sheet will be distributed via the DACCTrack system to all members of the selected WGs. If more than one WG is assigned and the WG reviews do not agree a Scientific Reviewer (SR) will be assigned to review the CS and adjudicate the WG reviews. SRs will include PIs, WG chairs, and other key investigators identified by the MWCCS EC.

1. FOR ALL CONCEPT SHEETS

All concept sheets will be made available for EC review and feedback, PIs, WG chairs, and PDs will receive a weekly digest specifying concept sheets that are under review. 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.

All concept sheets involving three or more sites will be assigned to the relevant Working Groups for review based upon a concept sheet's topics and/or scope. Working Groups have a goal of **10 business days** to submit their reviews through DACCTrack; however, reviews may take longer and investigators submitting CS should know that it may take up to 8 weeks for the initial review (and each time subsequent revisions are requested). Please make sure you use the current version of the research plan template (on website in "Submit a Concept Sheet" section: https://statepi.jhsph.edu/mwccs/work-with-us/) and complete *all* sections to prevent a revision request for missing information.

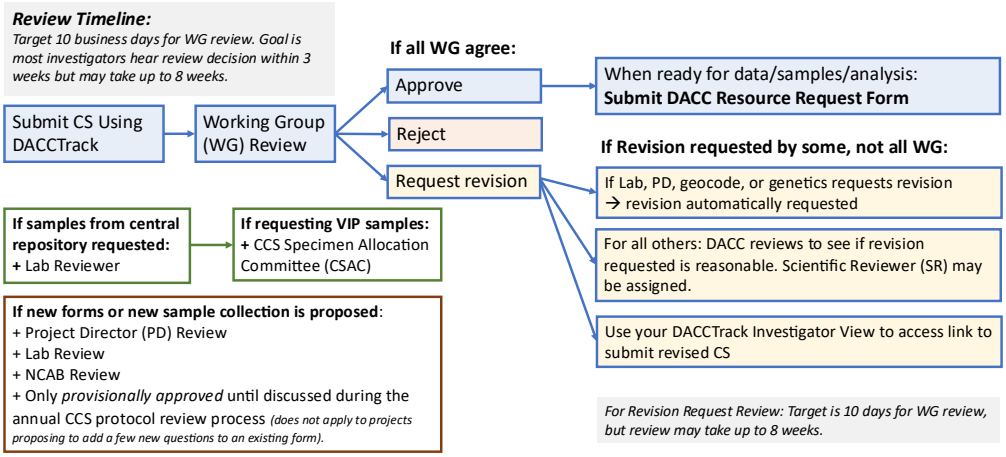
The following reviewers are also assigned when relevant. These reviews also have a goal of submission within **10 business days**, but may take longer:

- Lab Reviewer (LR) if the withdrawal of specimens from the central repository is proposed or if new specimen collection is proposed
- Geocoding Reviewer (GeoR) if proposing to use census-linked datasets
- Project Director Reviewer (PDR) if proposing new protocol, new specimen collection, or significant changes to protocol that impact clinical site staff and/or participant burden
- NCAB Reviewer (NCAB) if proposing new protocol, new questionnaire, new specimen collection, or significant changes to protocol that impact participant burden
- Scientific Reviewer (SR) may be assigned to review when working group recommendations differ (i.e., some WGs approve, some WGs request revision)

Depending on the scope of the proposed concept sheet, there are three different types of review:

1) multi-site investigations that do not require new data collection
2) multi-site investigations that propose new data, sample collection, or request specimens from the central repository
3) single-site investigations (1-2 sites included)

Quick Glance Summary: CCS Concept Sheet Review Process*



* This process applies to multi-site concept sheets and single-site concept sheets that will request specimens from the central repository. Single-site investigations that propose to utilize and/or collect data/specimens from **1-2** CCS sites require review by the PI and PD from that specific site and relevant WG chairs.

Steps required for each of these different types of review are described on the next page:

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

Multi-site concept sheets with three or more sites included, that require no additional data collection (i.e., seek to analyze existing data), will be reviewed by the appropriate Working Groups (WGs).

3. MULTI-SITE INVESTIGATIONS THAT PROPOSE NEW FORMS, SPECIMEN COLLECTION, or REQUEST SPECIMENS FROM THE CENTRAL REPOSITORY

Multi-site concept sheets with three or more sites included that require new forms, specimen collection, or request specimens from the central repository will be reviewed by:

1. Appropriate WGs
2. Project Director Reviewer (PDR)
3. NCAB Reviewer (NCAB)
4. Lab Reviewer (LR) if requesting specimens
5. Scientific Review (SR) by Lab Working Group Chairs if proposing new specimen collection
6. Executive Committee (EC)

If there are no concerns, the concept sheet will be *provisionally approved.*

In addition to the reviews outlined above, concept sheets that require new forms or procedures to be added to the MWCCS visit **require full EC discussion and approval during the bi-annual MWCCS protocol review process**. This process consists of the review and discussion of protocol amendments and additions. There are two protocol review discussions per year (in January and June), 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 MWCCS protocol review deadline. It is recommended that investigators also present their provisionally approved concept to the NCAB prior to the EC discussion to ensure participant feedback is incorporated into the final new forms and/or procedures. Note: This does not apply to concept sheets including only 1 or 2 sites

The "completion visit" is the preferred time for ancillary studies to be performed. Note, 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 bi-annual MWCCS protocol review process, an implementation timeline can be developed. Given the length of the core MWCCS interview and the administrative activities required to implement a protocol at each site (e.g., IRB submission, contract approval, staff training), 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.

4. 1-2 SITE INVESTIGATIONS

All concept sheets that propose to utilize and/or collect data/specimens from only 1-2 sites will be reviewed by a PI from the specific site(s). The site PI review will ensure that there is no scientific overlap with other ongoing projects.

1-2 site concept sheets will be assigned to WG chairs from 1 relevant WG for scientific review. WG chairs will only request revisions to these CS if they have strong objections to the proposal or have overlap concerns with cohort-wide activities.

If additional data or specimens are to be collected, the site PD(s) must also approve. If the concept sheet proposes the use of existing specimens or new specimen collection, a lab reviewer will be assigned to review the CS. If the concept sheet proposes new specimen collection, the Lab Working Group Chairs will be assigned as Scientific Reviewers of the CS.

Once the reviews are complete, the project may proceed.

5. NA-ACCORD INVESTIGATIONS

NA-ACCORD concept sheets are assigned to WG chairs from 1-2 relevant WGs for scientific review. These concept sheets are not sent to all WG members to review.

The assigned WG chairs review to "approve" or "disapprove" MWCCS participation in the NA-ACCORD study, with "default approval" if no objections are raised.

If overlap with an approved MWCCS concept sheet is identified during NA-ACCORD concept sheet review:

- The WG chairs will notify the lead investigator of the MWCCS concept sheet to ensure there is no objection to approval.
- If the lead of the MWCCS CS is an internal investigator, they will be assigned as a co-author on the NA-ACCORD concept sheet if approved.

If a new MWCCS concept sheet is submitted that overlaps with an existing NA-ACCORD concept sheet:

- This does not prevent the MWCCS CS from proceeding and being approved. Participation in an NA-ACCORD topic does **not** prevent MWCCS investigation of those topics.
- Assigned reviewer(s) should note the overlapping topics in the comments section of their review, but addressing this potential overlap is <u>not</u> a required revision.

6. Enrolling MWCCS Participants in Non-MWCCS Studies/Investigations

Researchers who plan to recruit participants from a MWCCS clinic into a study separate from MWCCS and who do not plan to use any MWCCS data or specimens, do not need to submit a concept sheet but will need approval from the PIs of those sites to approach their participants. Researchers enrolling MWCCS participants into a separate study who will request any MWCCS data/covariates for participants they recruit do need to submit a concept sheet clearly stating what MWCCS data they will request.

D. EXPLANATION OF REVIEWER ROLES

1. WORKING GROUP (WG)

<u>Working Group</u> (WG) reviews will be completed concurrently. The DACC will send notification of a new concept sheet to all members of the appropriate WG(s). WG review can take place via email; concept sheets do not need to be discussed on a WG call. The

WG chair (or designee) will compile WG member comments and submit a recommendation on behalf of the WG via DACCTrack. If a WG review is not submitted within two weeks (10 business days), the DACC can proceed based on the other reviews received (if only one WG is assigned, the DACC will wait for the review).

The WG should review the concept sheet for:

1. **Scientific merit**
    - Are there any grievous concerns about the science proposed?
    - WG reviews of concept sheets should not have the same rigor as a grant or manuscript review. Investigators are not required to make modifications for preferred approaches. WG CS review is to check for and identify any concerning issues/approaches that would require revision.
    - Other optional suggestions can be given under approved CS status as recommendations or suggestions but don't require revision
2. **Feasibility**
    - Are the data, samples, or participant type needed available in MWCCS?
3. **Potential overlap with other approved, active MWCCS concept sheets**

    If there is overlap with existing projects:

    - The WGs should indicate if the project should be combined with other related projects or revised to avoid overlap
    - The WG Chair (or designee) should contact the investigator to work out the best way to proceed. For example, removing one of three aims that overlaps another CS, combining with an approach in an existing CS, or revising the CS aim or approach. The WG may ask the DACC to talk to the investigator on their behalf if desired.

NOTE: 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 MWCCS 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.

2. SCIENTIFIC REVIEWER (SR)

Scientific Reviewers (SRs) from among the site PIs, WG chairs, and other key investigators as identified by the MWCCS EC, may be asked to review concept sheets when the working group recommendations differ.

The SRs should review all comments from other reviewers before giving a final determination of approve, reject, or request revision. It is possible that an assigned SR for a concept sheet may also be a member of a working group that has been assigned to complete a Working Group review. **If this is the case, please note that the SR is not the same as the WG review**. **The SR takes into consideration all WG and/or EC comments before making the final decision**.

3. ADDITIONAL SPECIALIZED REVIEWS FOR SELECT CONCEPTS

There are several additional types of reviewers that are not working group reviews, but are important parts of the review process for select concept sheets.

a. Lab Reviewer (LR)

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 MWCCS central repository. 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.

To protect the most valuable and irreplaceable specimens in the MWCCS, central repository requests for specimens from certain groups of MWCCS participants (see the full list of VIP specimens on page 14) will receive additional review by the MWCCS **Specimen Allocation Committee (CSAC).** All *approved* concept sheets that request these VIP specimens will undergo a final review by the CSAC once a resource request has been submitted. Once these samples have been approved by the CSAC, the samples will be sent to the indicated lab.

b. Project Director Reviewer (PDR)

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 and/or specimen collection will need to ensure adequate MWCCS 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.

c. NCAB Reviewer (NCAB)

The **NCAB Reviewer (NCAB)** will review the participant burden of the proposed research activities and the acceptability of questionnaires and other new procedures. The NCAB review will also provide overall feedback on whether the NCAB supports or does not support the proposal.

d. Geocoding Reviewer (GeoR)

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 MWCCS Geocoding Core.

E. CONFLICT OF INTEREST IN CONCEPT SHEET REVIEW

In the MWCCS, we aim to reduce bias and conflicts of interest when it comes to scientific review of concept sheets (CS). If for any reason a reviewer feels they have a 'conflict' with a particular CS that would bias their evaluation, they should recuse themselves from any discussion or review of the CS.

An investigator or reviewer (including WG chairs and PIs) cannot submit reviews for any CS where they are designated as a lead investigator or an additional investigator.

F. CONCEPT SHEET REVIEW PROCESS AND TIMELINE

Each concept sheet has an initial two-week (10 business day) goal for working group review, but review may take up to 8 weeks for initial review (and each time revisions are requested).

If all WGs approve the concept sheet, it is considered approved. In cases where the WG recommendations differ (i.e., one WG suggests revision while another WG suggests approval) the DACC may assign a Scientific Reviewer (SR) to determine whether or not the revisions suggested by the WG are appropriate or if the CS can be approved.

- If the revisions proposed were deemed appropriate by the SR, the CS is sent back to the investigator requesting revisions, with comments from all WGs.
- If the revisions proposed were deemed inappropriate by the SR (SR approves CS) the CS is considered approved.
- If after review, the SR thinks additional discussion is necessary, the SR can ask that the project be discussed during the next scheduled EC conference call.

The MWCCS EC can be asked by the investigator to re-review if the investigator feels the revision requested is unreasonable. Once a final decision is made, the DACC, on behalf of the EC Chairs, 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.

NOTE: *If a concept sheet is submitted as part of a grant application, it will receive a full scientific and administrative review by the MWCCS 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 **only** be provided when the concept sheet has received approval.*

Concept sheets proposing new data or new specimen collection as part of a grant application will not be provided a provisional LOS. MWCCS encourages submission of concept in advance of grant deadlines to allow for full scientific and administrative review.

If a study is using data or specimens collected MWCCS-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. Any concept sheet with three or more participating sites will have a DACC coauthor assigned to it.

Site PIs will have two weeks (10 business 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. A reminder email will be sent to PIs who do not assign coauthors, and if there is no reply after another five business days, the PI will be assigned as the coauthor for that site. 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).

G. CONCEPT SHEET REVISIONS AND ADDENDUMS

In cases where a concept sheet requires revisions before approval, the investigator(s) will be provided a link to submit their 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 document to offset them from the original language. Additionally, a point-by-point response to any comments/questions should be uploaded with the revised concept sheet research plan. **Reviewers are given ten business days to review a revised concept sheet**, however, reviews may take longer and investigators submitting CS should know that it may take up to 8 weeks for each review to be completed.

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 them using the online concept sheet submission form.

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

NOTE: *If an addendum 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.*

H. MWCCS POLICY FOR NIH DATA SHARING AND MANAGEMENT PLANS

1. A MWCCS Data Sharing and Management Template is available on our website under the Investigators tab.

2. MWCCS utilizes a plan for controlled release data management and sharing. In summary, all data (including any new data collected–or generated– as part of an ancillary grant) must be shared through the consortium-established concept sheet submission process. Concept sheets submitted to the MWCCS will include appropriate details as to how proposing investigators will be responsible for either: 1) depositing their analytic dataset directly to the Data Analysis and Coordination Center (DACC) for controlled release (this dataset will need to be given to the DACC at or before the time of manuscript submission to the Executive Committee), or 2) providing secure, long-term storage for their analytic dataset and submitting a data access plan to the DACC that details how data will be shared for approved research concepts.

I. MWCCS DATA AGREEMENTS

1. Master Data Use Agreement (mDUA)

The MWCCS Executive Committee has executed a master Data Use Agreement (mDUA) governing the sharing of data amongst all MWCCS Clinical Research Sites (CRS) and the DACC. All grant supported investigators and external investigators affiliated with a CRS' institution are covered by this agreement.

2. Data Use Agreement (DUA) for third parties

The 3rd Party DUA is used for investigators at external institutions. This agreement will need to be executed by anyone requesting data who is not already covered by the master DUA.

3. Master Material Transfer Agreement (mMTA)

The MWCCS Executive Committee has executed a master Material Transfer Agreement (mMTA) governing the sharing of specimens amongst all MWCCS Clinical Research Sites (CRS) and the DACC. All investigators affiliated with a CRS' institution are covered by this agreement.

4. Material Transfer Agreement (MTA) for third parties

The 3rd Party MTA for investigators will need to be executed by external investigators and anyone requesting specimens who is not already covered by the master MTA.

5. Genomics Data User Certification Agreement

All investigators who are requesting DNA from the MWCCS DNA Repositories, requesting GWAS data, or are proposing any genetics analysis, are required to submit a signed Genomics Data User Certification Agreement.

Additionally, all investigators who are requesting data from the MWCCS 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.

J. EXPIRATION AND DEACTIVATION OF CONCEPT SHEETS

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

Concept sheets are conferred an eight year lifespan upon approval. **All CS will be closed 8 years after their initial approval.** If work on a given CS is not completed within that time period, a new CS containing current aims and analysis must be submitted, reviewed, and approved.

The EC maintains the right to periodically review and adjust the status of open concept sheets.

If you need to request your unique Investigator View link, please click here and complete the Investigator View Look Up Form.

III. 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.

A. DATA REQUESTS

Data requests will be fulfilled both by the DACC and by site investigators. All MWCCS investigators have direct access to the MWCCS dataset, which is distributed annually to all site Data Managers. Data requests not filled at the local level should be submitted to DACC through DACCTrack using the MWCCS Resource Request Form. The form should include the README number, a list of MWCCS 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 MWCCS codebooks and the master variable list. Codebooks are distributed with data freezes to the Data Managers at each site and are also located on the *MWCCS Admin Website*. A DACC programmer will be assigned to the project once a data request is made.

B. SPECIMEN REQUESTS

All specimen requests should be submitted to the DACC through DACCTrack using the MWCCS Resource Request Form (*link to form can be found in your unique Investigator View*).

If you need to request your unique Investigator View link, please click here and complete the Investigator View Look Up Form.

1. 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 MWCCS DACC 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.

2. MWCCS Specimen Allocation Committee Review (CSAC)

The MWCCS Specimen Allocation Committee (CSAC) is charged by the MWCCS EC to assist in the allocation of high-value repository specimens, i.e., those specimens contributed by MWCCS participants who experienced significant or unique outcomes pertinent to overall MWCCS research aims or associated NIH-funded grants. The CSAC reviews all requests for the release of such high-value samples and determines whether or not the restricted samples should be released to the requesting investigator. When appropriate, the CSAC may be asked to review concept sheets that request the use of high-value samples.

Restricted specimens include those from:

- *Visit 101 samples (October 2020-September 2021)*
- *Visit 102 samples (October 2021-September 2022)*
- *Baseline visit for new enrollees*
- *HIV seroconverters*
- *Deaths*
- *HAART initiators:* participants who initiated HAART
- *Long-term non-progressors (LTNP):* participants who keep a CD4 T-cell count >500 while not on ART for at least 5 years
- *Elite non-progressors:* participants who maintain an HIV viral load <= 80 copies/mL while not on ART for at least 1.5 years
- *Rapid progressors:* <3 years between seroconverting and first AIDS diagnosis

- *Fast progressors:* 3-5 years between seroconverting and first AIDS diagnosis
- *Incident cancers*
- *Incident MI and stroke*
- *Incident hepatitis C virus (HCV) infection*
- *Spontaneous HCV clearance*
- *HCV treatment*
- *Incident hepatitis B virus (HBV) infection*
- *Resolution of HBV infection with treatment*
- *COVID-19 hospitalizations*
- *Last vial for any participant at any visit*

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 high-value 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: 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 DACC coordinator
- For requests including last vials, there is additional information required for investigators to provide to the CSAC relating to how their research aligns with the MWCCS aims and justifying use of these last vials. The DACC coordinator will work with the investigator to provide the form template and will include the completed form in the CSAC review submission.

Once they have received the notification, CSAC members have **seven business days** to respond as to whether or not they approve the use of restricted samples, or if they approve release of some but not all of the requested 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.

C. ANALYTIC REQUESTS

If the lead investigator is requesting that the analysis be performed by the DACC, they should indicate that request in DACCTrack during concept sheet submission. The DACC will support requested analyses for core investigations (studies using data generated as part of the principal MWCCS 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 seven business days of submission of the analytic specifications via the MWCCS **DACC Resource Request Form**. Investigators will be told whether DACC can provide support:

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

1. REQUESTS FOR CONFERENCE ABSTRACT AND PRESENTATION ANALYSIS

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

> **NOTE:** For complex study designs or analyses, more time 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.

IV. PUBLICATION AND PUBLICITY POLICIES

All abstracts and manuscripts resulting from approved concept sheets MUST be approved by all co-authors and submitted to the MWCCS EC before submission for presentation or publication. 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.

MWCCS strongly encourages the use of non-stigmatizing language in all MWCCS-related documentation, communications, and publications. Please review all Concept Sheets and resulting abstracts, manuscripts, and presentations to ensure you are using non-stigmatizing language.

A. CREDIT, AUTHORSHIP, AND WRITING COMMITTEES

The following categories specify how credit and authorship are apportioned for most MWCCS projects. The lead investigator listed on the concept sheet should include any investigators and analysts (MWCCS or external) that make substantial contributions to the project. The MWCCS 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 MWCCS EC.

1. 1-2 SITE INVESTIGATIONS

This section outlines publication policies for investigations using data collected from 1-2 sites only and funded through that site's MWCCS collaborative agreement or external sources (e.g., RO1, unobligated funds, etc.). These data may be collected as part of a pilot study, the core MWCCS protocol, a local sub-study, or be generated from local specimens collected during MWCCS or additional visits. In general, these investigations should be rare; investigators are encouraged to utilize the entire MWCCS cohort for most projects.

Publications resulting from investigations involving 1-2 sites will include co-authors at the discretion of the lead investigator from the local site(s). Co-authors will not be assigned by the DACC. Manuscripts should be approved by the site Principal Investigator before submission DACCTrack. These manuscripts do not require MWCCS EC review, but will be tracked for reporting purposes.

2. MULTI-SITE INVESTIGATIONS

A multi-site investigation is one wherein analyses utilize data from at least three, but not all, MWCCS 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 have the opportunity to name one co-author.*

3. CORE INVESTIGATIONS

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

Core investigations require that each of the MWCCS 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 MWCCS (i.e., can be an "external" investigator). However, the MWCCS 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.*

4. MULTI-COHORT COLLABORATIVE INVESTIGATIONS

Proposed studies that involve pooled data from the MWCCS 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 MWCCS representatives (1 to 2) will be assigned to multi-cohort collaborations, in addition to the project investigators. The DACC will contact the MWCCS WG chair with expertise in the area of investigation for help in selecting a MWCCS co-author(s) for these projects.

B. PROCEDURES FOR REVIEW AND APPROVAL OF MWCCS PUBLICATIONS

Writing Groups: Upon approval of a concept sheet, the DACC will send a request to specified MWCCS sites (as determined below by investigation type) requesting the appointment of a co-author from their site. PIs will have 10 business days to reply to the DACC with their site's co-author appointment. When only two sites are contributing data a DACC co-author does not need to be assigned. Any concept sheet with three or more participating sites will have a DACC coauthor assigned to it. A reminder email will be sent to PIs who do not assign coauthors, and if there is no reply after another five business days, the PI will be assigned as the coauthor for that site. 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).

NOTE: *When a journal has a limit on the number of allowed coauthors, the lead author can email coauthors to let them know that there are author limits in a journal of interest and **ask** if anyone volunteers to be removed from the paper. If there are no volunteers, then the lead author must find another journal to submit to.*

1. MANUSCRIPT REVIEW BY CO-AUTHORS

Co-author(s) must be allowed to participate in the writing and/or review process of manuscripts promptly. Co-authors should be given at least two weeks (10 business days)

to 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 the 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 MWCCS, the lead investigator must notify the EC.

It is also the responsibility of co-authors to sign journal copyright forms promptly (within seven business 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

Coauthor review and approval (10 business days): **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

Posting and EC Review (7 business days): 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 must be submitted to the DACC (with co-author approval) at least **7 business days** prior to submission to the journal. **This allows for one business day to process and six business days for EC review. You will receive an automated email following submission confirming that your manuscript submission has been received.** Manuscripts submitted without assigned co-author inclusion/approval or without the appropriate MWCCS acknowledgment will be returned to the lead author for correction before the manuscript is circulated to the EC.

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. The lead investigator will receive an email from the DACC once their manuscript has been processed for review with a date they may submit their manuscript to the journal. If there are EC concerns about the manuscript, DACC will communicate them to the lead investigator within the seven business day review window. The lead investigator will receive an email on the day EC review ends alerting them to move forward with submission to the journal.

4. 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.

5. ABSTRACT & PRESENTATION REVIEW

Final abstracts and presentations must adhere to the following guidelines:

- Abstracts must be associated with an EC-approved concept sheet.
- MWCCS-wide abstracts require co-authors from each MWCCS clinical research site that contributed data to the project, as well as the DACC. MWCCS collaborations (multi-cohort projects) require at least one co-author representative from the MWCCS. Co-authors included on the abstract should be the same as those assigned for the EC-approved concept sheet.

Note*: When a conference has a limit on the number of allowed coauthors (e.g., CROI) the CS lead author can remove some coauthors as needed, with the*

suggestion that the first removed coauthors are site PIs (since they are more senior members). If you are still over the coauthor limit, consult with your liaison (if external to study) or site PI (if internal to study) to determine which additional coauthors to remove to reach the allowed number for the conference. Lead author must email authors to let them know that there were limits on the coauthors so some authors were removed (specify which) and that all assigned coauthors will be included in the manuscript.

MWCCS recommends circulating your abstract draft to co-authors **at least 10 business days prior to conference deadline** to allow sufficient time for any needed rounds of coauthor editing prior to finalizing and approving the abstract.

- *Coauthor review: Coauthor comments should be requested early and incorporated. Remember to check DACCTrack to see the correct list of assigned coauthors and include all coauthors on the abstract authorship list and review process.*
- *Coauthor approval (3 business days):* At a minimum, all co-authors must be given **at least three business days** to review and approve the final version of the abstract before submission to the DACC EC for review.
    - Abstracts submitted to coauthors without this three day review period may not be submitted unless coauthors agree in writing to the shortened review period and that they approve the version to be submitted.
    - If a co-author does not respond within the three business day review 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.
- *Posting and EC Review (3 business days):* Abstracts must be submitted to the DACC (with co-author approval) using the **Abstract Submission Form** at least **three business days** prior to the scientific meeting/conference submission deadline. **This allows for one business day to process, one business day for EC review , and one business day to address any potential issues or updates**Abstracts will be available in DACCTrack and MWCCS EC members will be notified of their availability via email. DACC will communicate any EC concerns to the lead author by email.
    - Example: If the conference deadline is on a Thursday, the abstract must be submitted to the DACC before 4:00 pm ET on Monday. Abstract submission deadlines are below:

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

- The lead author will receive an automated email specifying the date that they can move forward with submitting the abstract to the conference. The lead author will receive an email alerting them to move forward with submission to the conference after the 3 business day period has ended.

If the following special circumstances apply, then the abstract should be submitted to the DACC at least **one business day** before conference submission. **Approval of the co-authors is still required before submission.** The EC does not formally review these abstracts, but EC members will be notified of their posting via email:

If the abstract is

- a **site-specific study**
- a **multi-cohort study** (e.g. NA ACCORD)
- abstracts and presentations for **internal groups** (e.g., cohort or other group meeting where abstracts are not made public externally)
- an **invited presentation** of work

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 abstract is submitted to the DACC for EC review, the abstract will not be circulated to the EC for review and it 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 processing (to ensure all required coauthors are included) and EC review, the abstract will not be circulated to the EC for review and it cannot be submitted to the scientific meeting/conference.
- If an abstract is submitted to a conference without co-author and/or EC review, the lead author may be asked to withdraw the abstract.

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 submission to the DACC for EC review.
- All co-author approved abstracts must be submitted to the DACC for EC review **at least eight business days** before the abstract submission deadline.
- Abstracts that are submitted without eight full business days remaining before the abstract submission deadline will not be approved for submission.

- After all compliant abstracts have been received, if there are more abstracts than allowed from one cohort for the conference, the abstracts will be distributed to the SC and they 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.

C. 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 MWCCS 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.

When a manuscript is accepted for publication, lead authors are responsible for submitting the final reference (citation) for the published article to the DACC. This can be submitted by 1. Email to mwccs@jhu.edu (please reference which CS the paper is related to and provide the README#) or 2. Submitted using the Productivity Update Form link in your Investigator View in DACCTrack.

If you need to request your unique Investigator View link, please click here and complete the Investigator View Look Up Form.

D. NIH PUBLIC ACCESS POLICY

NIH requires all MWCCS investigators participating in this study, which is funded by NIH, to make their peer-reviewed or author accepted manuscripts (AAMs) available to other researchers and the public at the National Library of Medicine's (NLM) PubMed Central (PMC) by the date of the manuscript's publication. NIH expects investigators to submit an electronic copy of the author's accepted manuscript (AAM) immediately to PubMed Central upon acceptance for publication. A PubMed Central reference number (PMCID) is required to demonstrate policy compliance. Failure to provide evidence of compliance with the policy in an application, proposal or report is a violation of the terms and conditions of the NIH award. To submit an applicable paper to PubMed Central (PMC) in compliance with the NIH Public Access Policy, please visit the NIHMS system website.

E. ACKNOWLEDGMENTS

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

All MWCCS manuscripts must acknowledge that the data were collected through the MACS/WIHS Combined Cohort Study (MWCCS). They must also credit participating institutions (MWCCS clinical sites, the DACC, and the supporting NIH agencies) and grant numbers. The most current and suggested format for MWCCS acknowledgments can be found on our website at mwccs.org.

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, OH, 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 (MWCCS) may be obtained upon review and approval of a MWCCS concept sheet. Links and instructions for online concept sheet submission are on the study website (http://mwccs.org/).