MWCCS Concept Sheet (CS) Submission Form

MACS/WIHS COMBINED COHORT STUDY

Multicenter AIDS Cohort Study (MACS) & Women's Interagency HIV Study (WIHS) Combined Cohort Study (MWCCS)

The MACS/WIHS Combined Cohort Study (MWCCS) welcomes proposals from internal or external investigators for the use of study data or specimens and new instruments and protocols. All investigators are required to submit their concept sheet using this form to be reviewed by the MWCCS Executive Committee (EC). As part of this proposal, investigators are asked to complete a Research Plan that provides details regarding their proposal.

Prior to concept sheet submission, investigators must review the Concept Sheet and Publication Policies and Procedures that guide the use of data and specimens from the MWCCS. Further, they must solicit approval for their concept sheet from either their site's PI (for internal investigators) or a MWCCS liaison (for external investigators). External investigators may request a liaison from the MACS/WIHS MWCCS Data Analysis and Coordination Center (DACC) at MWCCS@jhu.edu.

Should you have any questions regarding the concept sheet submission process, please contact us at MWCCS@jhu.edu.

The online form includes:

1. Collection of administrative information related to the concept sheet.

2. A link to upload a required Word document (Research Plan) summarizing the proposed research and analysis plan.

3. Two conditional links for additional documentation if applicable (description of revisions in response to prior reviews and advisor's letter of support for student projects).

Click here to download the Research Plan template. Note: please use the following file naming system when uploading your Research Plan: RP_LastName_MMDDYY

Study Resources Requested

- ☐ Data
- ☐ Specimens
- ☐ DACC-led analysis

1. Lead Investigator Name *

2. Lead Investigator Email *

3. Institution: *

4. Telephone Number: *

5. Main contact (if different from lead investigator):
First Name Last Name

5a. Additional Contact Email #1:
example@example.com

6. Additional Investigators (Maximum 15)

Additional Investigator #1
First Name Last Name

7. Is the lead investigator currently a MWCCS-supported investigator (i.e., receiving salary or research support from one of the core MACS/WIHS CCS grants)? *

Yes No

8. Is the lead investigator an early stage investigator as defined by the NIH (https:/ grants.nih.gov/policy/early-investigators/index.htm)? *

Yes No

8a. Name of MWCCS liaison or mentor *
First Name Last Name

8b. I confirm that my MWCCS liaison or mentor has reviewed and approved this concept sheet proposal prior to this submission

Yes

All investigators (who are not PIs) should have a study liaison. The role of a study liaison is to make sure the investigator follows the MWCCS Publication Policy, especially with regard to abstract and manuscript submission. In addition, the liaison will 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. The site PI or MWCCS liaison who is assisting in the development of the concept sheet should 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 MWCCS liaison can consult the relevant working group chair to identify an investigator who may be able to provide the missing expertise.

External investigators may request a liaison from the MACS/WIHS CCS DACC via email MWCCS@jhu.edu.

9. Concept Title: *

Submission Types

- **Initial**: New submission
- **Revision:** A *requested* revision in response to reviewers
- **Addendum:** For significant changes to a previously approved concept sheet. Minor administrative changes can be done via email at MWCCS@jhu.edu. **NOTE: If the concept sheet proposes new aims, substantially different data elements to be collected and/or analyzed, a significantly expanded scope, sub-studies, or will result in the publication of an additional manuscript a new concept sheet must be submitted. The new concept sheet can reference the previously approved concept sheet.**

10. Submission type: *

Initial

Revision

Addendum

10a. Summary of changes *

10b. Is this new submission related to an existing, approved concept sheet?

Yes No

10c. Readme Number (or historic MACS Concept ID) *

11. Is this submission related to a student dissertation or thesis? *

Yes

No

B. Concept Information

1. Proposal includes: *

All MWCCS sites

Select MWCCS sites

One MWCCS site (local study only)

1a. What time period and cohort(s) will your proposal include? Check all that apply

- ☐ **Historic MACS (pre-2020 merger)**
- ☐ **Historic WIHS (pre-2020 merger)**
- ☐ **MWCCS (2020+)**

1b. Sites included in proposal, indicate centers (select all that apply). This site participation information will be used to assign co-authors for this concept.
Please note, some sites began enrolling men in 2021, those sites are marked with an asterisk.

All sites with men participants
All sites with women participants
Atlanta (men* and women)
Birmingham/Jackson (men* and women)
Bronx (men* and women)
Brooklyn (women only)
Baltimore/District of Columbia (Whitman Walker) (men only)
Chapel Hill (men* and women)
Chicago- Northwestern (former MACS) (men only)
Chicago- Cook County (former WIHS) (women only)
District of Columbia (Georgetown) (women only)
Los Angeles (UCLA) (men only)
Miami (men* and women)
Pittsburgh/Columbus (men only)
San Francisco (includes USC as of 2019) (men* and women)

1b. Is this a multi-cohort proposal? *

Yes

No

1c. Which cohorts? *

NA-ACCORD

ALIVE

ACTG

ACSR

Other

Approval of new instruments, changes to instruments, new specimen collection, and other data collection changes to the core protocol is conditional at the time of concept sheet review, except in unusual circumstances. An example of unusual circumstances is a public health crisis, like a pandemic leading to the development of a new questionnaire during a visit cycle. **Final protocol changes are reviewed and approved by the EC on an annual basis.**

For more information regarding the review and approval process for protocol changes, please see our Guidelines for Investigators.

2. Does this project involve any additional participant burden (select all that apply)? *

No new/additional participant burden

Additional specimen collection(s)

New questionnaire(s)

New procedure(s) (e.g. ECG)

2a. Will this require an additional visit? *

Yes

No

2b. Will results of any tests or procedures performed be returned to the participants? *

Yes

No

N/A

2c. Please indicate type of specimen, procedure, or questionnaire to be added: *

3. Does this project involve additional MWCCS site staff burden (select all that apply)? *

No new/additional site staff burden

Provide/coordinate participant incentives

Additional specimen collection/new questionnaire/procedure

Development of site budget

Staff training

3a. How are you planning on obtaining IRB approval for this project? Note: MWCCS has obtained a sIRB waiver (aka, exception) for our core protocol only. If approved in the MWCCS review, the MWCCS leadership will provide a Letter of Support from MWCCS that may be used by the investigator to petition the NIH to waive the sIRB application requirement. Projects that are outside the scope of the current protocol or are more intensive need a separate sIRB oversight. It should be noted that, even if the MWCCS supports the sIRB exception for a proposed study, the NIH (sIRB Exceptions Committee at the Office of Extramural Research) may decide to reject the petition for an sIRB waiver and sIRB oversight may be required.

Requesting sIRB waiver: the MWCCS will support the investigator with incorporation of the proposed specimen collection/questionnaire/procedure into the MWCCS core protocol when the grant is funded

Separate sIRB/IRB application: Specimen collection/questionnaire/procedure will be done through an independent IRB protocol (sIRB required if proposal includes 2+ sites)

Please provide a lay language summary for this project. This summary should be written at an 8th grade education level and is not the same as an abstract. These summaries are provided to study participants so they can understand the study and the impact it may have on them. Please keep the language simple, short, and clear. Include any burden the study will have on participants. Participant burden includes: new specimen collections, new study questionnaires, requiring the participant to do a new exam or procedure, requiring the participant to come in for a separate visit, etc.

4. Lay Language Summary *

Maximum 150 words in lay language; include impact on participants0/150

5. To assist in assigning reviewers, please choose between 1 to 3 of the following topics (incomplete topic selection can delay concept sheet review): *

Aging

Behavioral and Psychosocial

Biomarkers

Cardiovascular

Clinical Outcomes/Epidemiology

COVID-19

Data Analysis/Methods

Dental/Oral Health

Genetics/Genomics

Geocode/Geography (census-linked data)

Gynecology

HPV
Liver
Laboratory/Specimens
Malignancy
Mental Health
Metabolic
Microbiome
Neuropsychology
Pathogenesis/Immunology/Virology
Pharmacology
Pregnancy
Pulmonary
Renal
Sleep
Sociocultu
ral
Substance
Use

6. Funding source(s) *

Existing Core MWCCS grants
Other already funded grants or contracts
Concept sheet will be part of a new funding application
Not applicable

6a. Current Sponsor(s): *
Please indicate the sponsor

6b. Grant number(s): *
Please indicate the grant number

6c. Future Sponsor(s): *
Please indicate the sponsor

6d. NIH or other Solicitation Number: *
Please specify solicitation number

6e. Is a letter of support from the MWCCS needed? *

Yes No

6f. Submission deadline: *

6g. Submission title: *

7. Will this collaboration involve individuals, institutions, and/or companies that are not located in the United States? *

Yes No

7a. Name of non-US institution and investigator(s): *

8. Do any of the investigators have any financial conflicts of interest to disclose? *

Yes No

8a. Please disclose potential financial conflicts of interest. *

C. Concept Sheet Research Plan

1. Abstract *

2. Specific Aims (please omit hypotheses)

3. Research Plan Upload. Note: Please use the following file naming system when uploading your Research Plan: RP_lastname_MMDDYY

4. Letter to the MWCCS Executive Committee addressing changes. Note: Please use the following file naming system when uploading your EC letter: EC_LastName_ReadMe_MMDDYY

D.Sample Specifications

1. Specimen Time Period and Cohort Requested (select all that apply) *

MWCCS samples (2020+)
MACS samples (< 2020)
WIHS samples (< 2020)

1a. Check all MWCCS sample types that apply *

Serum
EDTA plasma
CPT plasma (former WIHS sites only)
Sodium heparin plasma (former MACS sites only)
CPT dry cell pellet (former WIHS sites only)
Sodium heparin dry cell pellet (former MACS sites only)
CPT viable cells (PBMC; former WIHS sites only)
Sodium heparin viable cells (PBMC; former MACS sites only)
Urine (first void)
Urine (supernatant)
Cervicovaginal lavage (CVL; whole)
Cervical swab
Vaginal swab
Hair
Host DNA
Saliva (unstimulated)
Oral rinse
Oral rinse (pellet)

1b. Check all historical MACS sample types that apply *

Serum
EDTA plasma

Sodium heparin plasma
Sodium heparin viable cells (PBMC)
Sodium heparin dry cell pellet
B-cells (pellets)
Urine (clean void)
Stool
Anal swab
Throat wash
Semen

1c. Check all historical WIHS sample types that apply *

Serum
EDTA plasma (limited before V48)
CPT plasma
CPT viable cells (PMBC)
CPT dry cell pellet
Sodium Fluoride/Potassium Oxalate Plasma
Urine (clean void)
Urine (supernatant)
Urine (pellet)
Cervicovaginal lavage (CVL; whole)
Cervical swab
Hair
Host DNA
Saliva (stimulated)

*Please note, not all specimens are available at all visits or from all participants. Please email MWCCS@jhu.edu for more information.

2. Sample Type & Quantity (NOTE: for PBMC please list the optimal and minimal acceptable numbers of viable PBMCs requested. For dry cell pellets, please list the optimal and minimal number of PBMCs in the pellet):**:**

3. Indicate if, and which, high-value samples will be requested *

Visit 101 samples (October 2020 - September 2021)
Visit 102 samples (October 2021-September 2022)
Baseline visit for new enrollees
HIV seroconverters
Deaths

HAART initiators
Long-term non-progressors
Elite non-progressors
Rapid progressors
Fast progressors
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
SARS-COV-2/COVID-19
Not requesting high value samples

4. Expected number of person-visits to be requested?

NOTE: This is the total number of participant-visits you are requesting specimens from. For example, if you plan to request specimens from 10 participants, and you want specimens from two visits each, this response would be 20.

E. MWCCS Data Transfer and Use Agreement

Provider: Johns Hopkins University on behalf of its Bloomberg School of Public Health's Data Analysis and Coordination Center ("DACC")

Data Type *

De-identified Dataset (default option)

Limited Dataset

For the MWCCS, Limited Dataset includes requests for geo-code data, exact dates (instead of year), etc.

TERMS AND CONDITIONS

1) Provider shall provide the data set described in the resources requested per the submitted Concept Sheet (the "Data") to Recipient for the research purpose set forth as the Concept Title as listed in the Concept Sheet (the "Project"). Recipient does not obtain any rights in the Data other than as set forth herein.

2) Recipient shall not use the Data except as authorized under this Agreement. The Data will be used

solely to conduct the Project and solely by Recipient Scientist and Recipient's faculty, employees, fellows, students, agents, contractors, and subcontractors ("Recipient Personnel") that have a need to use, or provide a service in respect of, the Data in connection with the Project and whose obligations of use are consistent with the terms of this Agreement (collectively, "Authorized Persons"). Recipient will ensure that any agent, contractor, or subcontractor to whom Data is disclosed agrees to the same restrictions and conditions that apply to Recipient under this Agreement.

3) Except as authorized under this Agreement or otherwise required by law, Recipient agrees to retain control over the Data and shall not disclose, release, sell, rent, lease, loan, or otherwise grant access to the Data to any third party, except Authorized Persons, without the prior written consent of Provider. Recipient agrees to establish appropriate administrative, technical, and physical safeguards to prevent unauthorized use of or access to the Data and comply with any other special requirements relating to safeguarding of the Data as may be set forth in the selected Attachment 2.

4) Recipient agrees to use the Data in compliance with all applicable laws, rules, and regulations, in accordance with the MACS/WIHS CCS Concept and Publication Policies and Procedures, as well as all professional standards applicable to such research.

5) Recipient agrees to recognize the contribution of the MACS/WIHS Combined Cohort Study (MWCCS) as the source of the Data in all written, visual, or oral public disclosures concerning Recipient's research using the Data, and cite the MWCCS acknowledgement on all resulting manuscripts as listed on mwccs.org.

6) Recipient Investigator agrees to promptly report to the Recipient and Provider any use or disclosure of the data not provided for by this Agreement of which it becomes aware. Unless terminated earlier in accordance with this section, this Agreement shall expire when the project becomes complete or deactivated as defined in the MWCCS Publication Policies and Procedures, whichever comes first. Either party may terminate this Agreement with thirty (30) days written notice to the other party's Authorized Official as set forth below. Upon expiration or early termination of this Agreement, Recipient shall cease use of the Data and follow the disposition instructions provided in the MWCCS policy documents found at https:/ mwccs.org/policies publications/ (if any) and pursuant to any Provider instructions. However, Recipient may retain one (1) copy of the Data for the sole purpose of record retention requirements, research integrity, and verification.

7) Except as provided below or prohibited by law, any Data delivered pursuant to this Agreement is understood to be provided "AS IS." PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE DATA WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Notwithstanding, Provider, to the best of its knowledge and belief, has the right and authority to provide the Data to Recipient for use in the Project.

8) Except to the extent prohibited by law, the Recipient assumes all liability for damages which may arise from its use, storage, disclosure, or disposal of the Data. The Provider will not be liable to the Recipient for any loss, claim, or demand made by the Recipient, or made against the Recipient by any other party, due to or arising from the use of the Data by the Recipient, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the Provider. No indemnification for any loss, claim, damage, or liability is intended or provided by either party under this Agreement.

9) Neither party shall use the other party's name, trademarks, or other logos in any publicity, advertising, or news release without the prior written approval of an authorized representative of that party. The parties agree that each party may disclose factual information regarding the existence and purpose of the relationship that is the subject of this Agreement for other purposes without written permission from the other party provided that any such statement shall accurately and appropriately describe the relationship of the parties and shall not in any manner imply endorsement by the other party whose name is being used.

10) Unless otherwise specified, this Agreement and the below listed Attachments embody the entire understanding between Provider and Recipient regarding the transfer of the Data to Recipient for the Project:

I. Attachment 1: (attached separately) Approved Concept Sheet

II. Attachment 2: Data-specific Terms and Conditions (for either de-identified or Limited Data Set as elected above)

11) No modification or waiver of this Agreement shall be valid unless in writing and executed by duly-authorized representatives of both parties.

12) The undersigned Authorized Officials of Provider and Recipient expressly represent and affirm that the contents of any statements made herein are truthful and accurate and that they are duly authorized to sign this Agreement on behalf of their institution.

13) This data transfer and use agreement becomes effective only after there is an approved MWCCS Concept Sheet.

Data-specific Terms and Conditions: De-identified Data about Human Subjects

Additional Terms and Conditions:

1. If the Data being provided is coded, the Provider will not release, and the Recipient will not request, the key to the code.

2. Recipient will not use the Data, either alone or in concert with any other information, to make any effort to identify or contact individuals who are or may be the sources of Data without specific written approval from Provider and appropriate Institutional Review Board (IRB) approval, if required pursuant to 45 CFR 46. Should Recipient inadvertently receive identifiable information or otherwise identify a subject, Recipient shall promptly notify Provider and follow Provider's reasonable written instructions, which may include return or destruction of the identifiable information.

3. By signing this Agreement, Recipient provides assurance that relevant institutional policies and applicable federal, state, or local laws and regulations (if any) have been followed, including the completion of any IRB or ethics review or approval that may be required.

4. Recipient shall promptly report to the Provider any use or disclosure of the Data not provided for by this Agreement of which it becomes aware.

Data-specific Terms and Conditions: Limited Data Set

Additional Terms and Conditions:

1. Nothing herein shall authorize the Recipient to use or further disclose the Data in a manner that

would violate the requirements of Provider under 45 CFR 164.514.

2. Recipient shall not use or further disclose the Data other than as permitted by this Agreement or as otherwise required by law.

3. Recipient shall report to the Provider any use or disclosure of the Data not provided for by this Agreement within 5 business days of when it becomes aware of such use or disclosure.

4. The Data will be a Limited Data Set as defined by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). In accordance with Section 164.514(e)(2) of the HIPAA Privacy Rule, the Data shall exclude the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

- (i) Names;
- (ii) Postal address information, other than town or city, State, and zip code;
- (iii) Telephone numbers;
- (iv) Fax numbers;
- (v) Electronic mail addresses;
- (vi) Social security numbers;
- (vii) Medical record numbers;
- (viii) Health plan beneficiary numbers;
- (ix) Account numbers;
- (x) Certificate/license numbers;
- (xi) Vehicle identifiers and serial numbers, including license plate numbers;
- (xii) Device identifiers and serial numbers;
- (xiii) Web Universal Resource Locators (URLs);
- (xiv) Internet Protocol (IP) address numbers;
- (xv) Biometric identifiers, including finger and voice prints; and
- (xvi) Full face photographic images and any comparable images.

If the Data being provided is coded, the Provider will not release, and the Recipient will not request, the key to the code.

5. Recipient will not use the Data, either alone or in concert with any other information, to make any effort to identify or contact individuals who are or may be the sources of Data without specific written approval from Provider and appropriate Institutional Review Board approval, if required pursuant to 45 CFR 46. Should Recipient inadvertently receive identifiable information or otherwise identify a subject, Recipient shall promptly notify Provider and follow Provider's reasonable written instructions, which may include return or destruction of the identifiable information.

6. By signing this Agreement, Recipient provides assurance that relevant institutional policies and applicable federal, state, or local laws and regulations (if any) have been followed, including the completion of any IRB or ethics review or approval that may be required.

7. The parties agree to take such action as is necessary to amend this Agreement, from time to time, in order for the Provider to remain in compliance with applicable law.

Please note: upon concept sheet approval the DACC will follow-up with any agreements requiring an institutional signature.

F. Statement of Agreement

Please review the MACS/WIHS CCS Concept Sheet and Publication Policies and Procedures prior to submitting the concept sheet.

Before submission, please review, acknowledge, and agree to the following: *

I have reviewed and agree to abide by the MACS/WIHS CCS Concept Sheet and Publication Policies and Procedures.

I have checked for overlap between my proposal and existing MWCCS projects using the Public View in the MWCCS project tracking database

All information that I provide in this concept sheet is complete and correct as submitted.

Use of specimens and/or data is restricted to the aims outlined in the Research Plan.

IRB approval has been, or will be, obtained before any data and/or specimens are received.

I will complete a MWCCS Data Use Agreement (DUA) if this proposal receives approval and requires one.

I will submit a MWCCS Material Transfer Agreement (MTA) if this proposal receives approval and requires one.

Abstracts resulting from approved concepts MUST be submitted to the DACC for MWCCS EC prior to submission to a conference. Manuscripts must be submitted to the DACC to be shared with the MWCCS EC prior to submission to a journal.

Under no circumstances will I make any MWCCS study subject ID number public in either documents or presentations, e.g., journal articles, abstracts, oral or poster presentations, or on any website.

The lead investigator for each approved concept sheet must submit an annual progress report. If no progress report is received after two email reminders approval for the concept sheet will expire.

My signature below indicates a complete review and acceptance of the guidelines for collaborations, publication, and acknowledgment as outlined in the “Statement of Agreement”.

I, *

Type full name

certify and agree to the above on *

Month Day Year

Please add any additional information you feel is important to the review of this concept sheet below.

Additional Concept Information