The MACS/WIHS Combined Cohort Study (CCS) Concept Sheet Submission Form

NOTE: All CCS DACC Concept Sheet Submission Forms must be submitted online using DACCTrack. This PDF has been provided to show the questions asked in the online form.

The MACS/WIHS Combined Cohort Study (CCS) 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 CCS 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 CCS. Further, they must solicit approval for their concept sheet from either their site’s PI (for internal investigators) or a CCS liaison (for external investigators). External investigators may request a liaison from the MACS/WIHS CCS Data and Analysis 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.

Study Resources Requested

- Are you requesting data?
- Are you requesting either a new specimen collection or specimens from the repository?
- Are you requesting analytic support?

(please check all that apply): *

- [ ] Data
- [ ] Specimens
- [ ] DACC-led Analysis
A. General Information

1. Lead Investigator *

   Prefix [ ] First Name [ ] Middle Initial [ ] Last Name

   Preferred First Name [ ]
   If different from your legal first name

2. Lead Investigator Email *

   example@example.com

3. Institution: *

4. Telephone Number: *

   - Area Code Phone Number

5. Main contact (if different from lead investigator): [ ]

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

6. Additional Investigators #1-#15 (Maximum 15)

   First Name [ ] Last Name

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

   C Yes  C No

7a. Name of MACS/WIHS CCS co-investigator liaison *

   First Name [ ] Last Name

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 CCS 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 CCS 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 CCS 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.

8. 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.

9. Submission type: *

- Initial
- Revision
- Addendum

9a. Summary of changes *

Please re-upload your research plan with highlighted or tracked changes/additions.

9b. Is this new submission related to an existing, approved concept sheet?

- Yes
- No

9c. Readme Number (or historic MACS Concept ID) *

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

- Yes
- No

10a. Upload a letter of support from advisor *
B. Concept Information

1. Proposal includes: *
   - All CCS sites
   - Select CCS sites
   - One CCS site (local study only)
   - All historic MACS Sites
   - All historic WIHS Sites including LA WIHS
   - All historic WIHS sites excluding LA WIHS

1a. Sites included in proposal, indicate centers (select all that apply): *
   - Atlanta
   - Birmingham/Jackson
   - Bronx
   - Brooklyn
   - Baltimore/District of Columbia (Whitman Walker)
   - Chapel Hill
   - Chicago (MACS-Cook County/Northwestern)
   - Chicago (WIHS-Cook County/Rush)
   - District of Columbia (Georgetown)
   - Los Angeles (UCLA)
   - Los Angeles (USC WIHS-closed after V37)
   - Miami
   - Pittsburgh/Columbus
   - San Francisco

Approval of meritorious proposals for changes to instruments, specimens, and other data collection during the core protocol is made only conditionally at the time of the concept sheet review, except in unusual situations. Final protocol changes are reviewed and approved by the EC on a semi-annual basis.

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 CCS site staff burden (select all that apply)? *
   - No new/additional site staff burden ☐
   - IRB submission ☐
   - Staff training ☐
   - Providing/coordinating participant incentives ☐

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.

Click here to utilize a Readability Calculator. You can copy and paste your LLS into the readability calculator and it will give you the grade level using different literacy scales. As long as one scale is between 8-10 the LLS is sufficient.

Click here to read an article "How to Write for an Eighth-Grade Reading Level".

This is an example of an appropriate lay language summary.
Medicines used to treat people living with HIV help them to live longer and healthier lives. Sometimes people on HIV medicines still have problems with memory and concentration. We want to understand how HIV affects the brain and leads to these problems. We will do brain scans and ask questions about memory and concentration on women and men with HIV. We plan to look at 150 people. Some of these people will have HIV and some will not. 50 of the 150 people will also get another type of brain scan to look at inflammation in the brain. Inflammation is your body’s response to things that are trying to harm it.
4. Lay Language Summary *

Maximum 150 words in lay language; include impact on participants 0/150

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

- Aging
- Behavioral and Psychosocial
- Biomarkers
- Cardiovascular
- Clinical Outcomes/Epidemiology
- Data Analysis/Methods
- Genetics/Genomics
- Geography (census-linked data)
- Gynecology
- HPV
- Liver
- Laboratory/Specimens
- Malignancy
- Mental Health
- Metabolic
- Microbiome
- Neuropsychology
- Oral/Dental
- Pathogenesis/Immunology/Virology
- Pharmacology
- Pregnancy
- Pulmonary
- Renal
- Sleep
- Sociocultural
- Substance Use
6. Funding source(s) *

☐ Existing Core CCS 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 CCS needed? *

☐ Yes ☐ No

6f. Submission deadline: *


Please indicate your grant submission deadline

6g. Submission title: *


Please indicate the title of the funding submission

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

Please submit your research plan using the following template: CCS Concept Sheet Research Plan Form. Once complete, upload the form as a single PDF file to your online concept sheet submission using "LastName_Date" as the file's nomenclature.

1. Abstract *

2. Specific Aims (please omit hypotheses) *

Maximum 200 words.

3. Research Plan Upload *

Please Upload your Research Plan and any other relevant documents in a single file.

4. Letter to the CCS Executive Committee addressing changes *

Please Upload your letter here.
D. Sample Specifications

1. Sample Type (check all that apply): *
   - [ ] Anal Swabs (MACS only)
   - [ ] B-cells (pellets)
   - [ ] Cervical Swabs (WIHS only)
   - [ ] Cervical Vaginal Lavage (WIHS only)
   - [ ] Citrate Plasma (WIHS only)
   - [ ] CPT Plasma (WIHS only)
   - [ ] Dry Cell Pellet (CPT;WIHS only)
   - [ ] Dry Cell Pellet (heparinized;MACS only)
   - [ ] EDTA Plasma
   - [ ] Hair
   - [ ] Host DNA
   - [ ] Oral Rinse
   - [ ] PBMC (viable;CPT;WIHS only)
   - [ ] PBMC (viable;heparinized;MACS only)
   - [ ] Plasma (heparinized;MACS only)
   - [ ] Saliva
   - [ ] Semen (MACS only)
   - [ ] Serum
   - [ ] Stool
   - [ ] Urine (clean void)
   - [ ] Urine (pellet)
   - [ ] Urine (supernatant)
   - [ ] Vaginal Swabs (WIHS only)

Please list specimen type and quantity for every sample type being requested (mL or cells/vials)

2. Sample Quantity:

[Blank Table]
3. Indicate if, and which, high-value samples will be requested (link to description) *

- Not requesting high-value samples
- HIV seroconverters
- Pre-HAART deaths
- HAART initiators
- Long-term non-progressors
- Elite non-progressors
- Rapid progressors
- Fast progressors
- Incident cancers
- Incident MI and stroke

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

[ ]
E. 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.
☐ 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 CCS Data Use Agreement (DUA) if this proposal receives approval and requires one.
☐ I will submit a CCS Material Transfer Agreement (MTA) if this proposal receives approval and requires one.
☐ Abstracts resulting from approved concepts MUST be submitted to the DACC for CCS EC prior to submission to a conference. Manuscripts must be submitted to the DACC to be shared with the CCS EC prior to submission to a journal.
☐ Under no circumstances will I make any CCS 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 * [Date]

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

Additional Concept Information