**Atlanta MWCCS Concept Sheet Submission Form**

Note that, although this form is similar to the CCS online submission form, it is not identical. The online CCS submission form must be filled after this form is approved by the Atlanta team.

**A. GENERAL INFORMATION**

**Lead Investigator(s):** Click here to enter text.

Institution: Click here to enter text.

Address: Click here to enter text.

Telephone Number: Click here to enter text.

Email: Click here to enter text.

**Co-Investigators:** Click here to enter text.

/*Please, include Atlanta MWCCS point person as a co-investigator/*

[ ]  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)?

[ ]  Is the lead investigator an early stage investigator as defined by the NIH

(https: grants.nih.gov/policy/early-investigators/index.htm)?

 If “Yes”:

 Name of MWCCS liaison or mentor? Click here to enter text.

 [ ]  I confirm that my MWCCS liaison or mentor has reviewed and approved this concept

 sheet proposal prior to this submission?

Concept sheet title: Click here to enter text.

Submission type:

[ ]  Initial

[ ]  Revision

[ ]  Addendum

If revision, please, provide summary of changes: Click here to enter text.

[ ]  Is this existing submission related to an existing, approved concept sheet?

 If “Yes,” enter concept sheet readme number Click here to enter text.

[ ]  Is this submission related to a student dissertation or thesis?

**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

[ ]  Other cohorts (specify) Click here to enter text.

**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

[ ]  Is this a multi-cohort proposal?

 If “Yes,” which cohorts?

 [ ]  NA-ACCORD

 [ ]  ALIVE

 [ ]  ACTG

 [ ]  Other Click here to enter text.

**2. Does this project involve additional participant burden?**

[ ]  Yes *(check all that apply below)* [ ]  No /skip to Item 3/

[ ]  New specimen collection needed

[ ]  New questionnaire administered

[ ]  New procedure (e.g., MRI, biopsy)

[ ]  New or additional consent needed

[ ]  Additional visit required

 [ ]  Other Click here to enter text.

If “Yes”:

Will results of any tests or procedures performed be returned to the participants?

[ ]  Yes [ ]  No [ ]  N/A

Please, indicate type of specimen, procedure, or questionnaire to be added: Click here to enter text.

Detail any anticipated additional MWCCS participant burden (in terms of amount of time

required, additional visit(s), amount and type of specimens to be collected, types of procedures or questionnaires to be added, etc.) and reimbursement to be provided. Click here to enter text.

**3. Does this project involve additional MWCCS site staff burden** (e.g., IRB submission, coordination of participant visits, administration of forms, data management, training etc.)?

[ ]  Yes [ ]  No

If “Yes” detail any anticipated additional MWCCS staff burden (in terms of amount of time required, additional visits, specimens to be collected, etc.). Click here to enter text.

**4. Lay Language Summary**

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: <https://www.online-utility.org/english/readability_test_and_improve.jsp>

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": <https://www.proedit.com/how-to-write-for-an-eighth-grade-reading-level/>

Click here to enter text.

**5. Topic** *(please select up to three from the following topics)***:**

[ ]  Aging [ ]  Metabolic

[ ]  Behavioral and Psychosocial [ ]  Microbiome

[ ]  Biomarkers [ ]  Neuropsychology

[ ]  Cardiovascular [ ]  Oral/Dental

[ ]  Clinical Outcomes/Epidemiology [ ]  Pathogenesis/Immunology/Virology

[ ]  Data Analysis/Methods [ ]  Pharmacology

[ ]  Genetics/Genomics [ ]  Pregnancy

[ ]  Geography (census-linked data) [ ]  Pulmonary

[ ]  Gynecology [ ]  Renal

[ ]  HPV [ ]  Sleep

[ ]  Liver [ ]  Sociocultural

[ ]  Laboratory/Specimens [ ]  Substance Use

[ ]  Malignancy [ ]  Other (specify) Click here to enter text.

[ ]  Mental Health

**Note that, based on your topic selection, your CS will be assigned to all relevant working groups for review. Where feasible, we suggest to select one primary topic.**

**6. Grant Information:**

a. Proposed study is related to an existing grant?

[ ]  Yes (*please indicate the sponsor and, if NIH-supported, indicate the grant number*)

i. NIH Sponsor: Click here to enter text. Grant Number: Click here to enter text.

ii. Other sponsor (*please specify*): Click here to enter text.

[ ]  No

b. Proposed study is related to a future or a pending grant submission?

[ ]  Yes (*please indicate the sponsor and, if NIH-supported, the solicitation number*)

i. NIH Sponsor: Click here to enter text. Solicitation Number: Click here to enter text.

ii. Other sponsor (*please specify*): Click here to enter text.

iii. Grant submission deadline: Click here to enter text.

iv. Submission title: Click here to enter text.

v. Is a letter of support from the CCS needed? [ ]  Yes [ ]  No

[ ]  No

c. If you answered “No” to both 5a & 5b, please indicate the source of funding for this proposed study: Click here to enter text.

**7. International Collaborations**

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

If “Yes,” Name of non-US institution or investigators Click here to enter text.

**8. Conflict of interest**

[ ]  Do any of the investigators have any financial conflicts of interest to disclose?

Please, disclose potential conflicts of interest Click here to enter text.

**C. MACS/WIHS Combined Cohort Study (CCS) Concept Sheet *Research Plan* Form****MWCCS@jhu.edu**

Please collaborate with your co-investigators, site-PI, or CCS liaison in the construction of your Research Plan using the following template. You may insert relevant figures, tables or images into this template. Once completed, upload this document as a single file to your online concept submission form as part of Section C.

1. **Concept Sheet Title**
2. **Abstract**
3. **Background**
4. **Specific Aims & Hypotheses**
5. **Approach**
	1. Study design(s) (include study visits and/or time period)
	2. Inclusion/exclusion criteria
	3. Analytical methods
	4. Sample size calculations
6. **Description of Participant or Site Staff Burden (for proposals requesting new data or specimen collection only)**

*Please provide the details below, which are important when faculty, staff and the NCAB evaluate your proposal:*

* 1. Additional participant time
	2. Number of visits
	3. Visit location (please clarify if data/samples will be collected at CCS site or another location)
	4. Compensation (if any) for participation
	5. Mode of questionnaire implementation (electronic or paper survey; self-administered or part of interview)
	6. Details about any specimen collection or new procedures (including If test results will be returned to participants and how they will be returned to participants)
	7. Copy of instrument(s) or questionnaire(s)

*If changes are made to the above plans outlined in Section 6 during or after concept review, please send updated information to MWCCS@jhu.edu).*

1. **Specimen Characteristics and Laboratory Methods**

*If you will be requesting specimens from the central repository, please provide the details below, which allow reviewers to evaluate feasibility of your proposal:*

a. Visit numbers and time period(s) that will be requested

b. Specimen type(s) and volume(s) that will be requested

c. Minimum acceptable volume and justification for volume requested for each specimen type

d. Are pristine samples required? If yes, you must provide a scientific justification for why this is required

1. **References**

**D. SAMPLE SPECIFICATIONS**

1. Specimen time period and cohort requested (select all that apply):

[ ]  MWCCS samples (2020+)

[ ]  MACS samples (<2020)

[ ]  WIHS samples (<2020)

a. Sample type

[ ]  Anal Swabs (MACS only) [ ]  PBMC (viable;CPT;WIHS only)

[ ]  B-cells (pellets) [ ]  PBMC (viable;heparinized;MACS only)

[ ]  Cervical Swabs (WIHS only) [ ]  Plasma (heparinized;MACS only)

[ ]  Cervical Vaginal Lavage (WIHS only) [ ]  Saliva

[ ]  Citrate Plasma (WIHS only) [ ]  Semen (MACS only)

[ ]  CPT Plasma (WIHS only) [ ]  Serum

[ ]  Dry Cell Pellet (CPT;WIHS only) [ ]  Stool

[ ]  Dry Cell Pellet (heparinized;MACS only) [ ]  Urine (clean void)

[ ]  EDTA Plasma [ ]  Urine (pellet)

[ ]  Hair [ ]  Urine (supernatant)

[ ]  Host DNA [ ]  Vaginal Swabs (WIHS only)

[ ]  Oral Rinse [ ]  Other (specify) Click here to enter text.

b. Please list specimen type and quantity for every sample type being requested (mL or cells/vials) Click here to enter text.

c. Sample quantity: Click here to enter text.

d. Indicate if, and which, high-value samples will be requested (link to description)

[ ]  Not requesting high-value samples [ ]  Elite non-progressors

[ ]  HIV seroconverters [ ]  Rapid progressors

[ ]  Pre-HAART deaths [ ]  Fast progressors

[ ]  HAART initiators [ ]  Incident cancers

[ ]  Long-term non-progressors [ ]  Incident MI and stroke

e. Expected number of person-visits to be requested? Click here to enter text.