**Concept Sheet *Research Plan* Form
MACS/WIHS Combined Cohort Study (CCS)****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. Data analysis plan
	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) that will be administered to participant OR case report-forms to be completed by study staff (e.g., survey questions to be collected concurrent to specimen collection)
	8. Data Sharing and Management Plan: Report relevant details as to how you will *either*:
* 1) Deposit your 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
* 2) (more rarely) You will provide secure, long-term storage and distribution of your analytic dataset. A data access plan must be included here that details how you will then share data for approved research concepts in compliance with NIH requirements

*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**

*For all projects that will use currently collected or stored participant specimens*

* 1. Describe the criteria for selecting specimens
	2. Describe the lab testing methods
	3. Describe the procedures for QA/QC

*For projects 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. **New Specimen Collection: Characteristics and Laboratory Methods**

*For all projects that will require the collection of new specimens*

* 1. Describe the samples to be collected including:
		1. Type of specimen(s)
		2. Minimum acceptable volume
		3. Frequency of specimen collection
		4. Specimen processing
		5. Specimen storage (i.e., MWCCS central repository vs. Investigator or commercial lab).

***Please note: if approved, an SOP for collection, processing and storage will be required and will require review by the Core Laboratory Working Group.***

* 1. Describe the laboratory testing methods
	2. Describe the procedures for QA/QC (if the results will be shared with participants, will the results be collected in a CLIA certified laboratory?)
1. **References**