**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 (Maximum 400 words)**
3. **Background (Maximum 400 words, not including references)**
4. **Specific Aims & Hypotheses (Maximum 200 words, not including references)**
5. **Approach**Please include a summarized study design(s), inclusion/exclusion criteria, analytical methods, & sample size calculations.
6. **Description of Participant or Site Staff Burden (Maximum 400 words)**For participant burden please provide details if your project will require additional specimen collection, a new questionnaire, new procedures, new informed consent, and/or if your project will require an additional visit. For CCS staff burden please provide details if your project will require IRB submission, staff training, and/or coordinating/consenting /providing participant incentives.

*\*Note: For more information regarding the approval process for protocol changes that include additional participant and/or staff burden, please see our* [*Guidelines for Investigators*](https://statepi.jhsph.edu/mwccs/wp-content/uploads/2020/11/MWCCS_Guidelines-for-Investigators_112420.pdf)*.*

1. **Specimen Characteristics and Laboratory Methods**For projects that will use participant specimens, describe the criteria for selecting specimens, the lab testing methods, and the procedures for QA/QC.
2. **References**