***Data Plan***

**MACS/WIHS Combined Cohort Study (MWCCS)** **MWCCS@jhu.edu**

Please provide the requested information 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 reading center data submission plan as part of Section A.

1. **Background**

*Please describe the reading center process and overview of operations.*

1. **Study Design***Please describe the study design, inclusion/exclusion criteria, and number to be tested.*
2. **Testing to be done by reading center**

*Please explain the exact testing to be performed by the reading center.*

1. **Data/Output to be produced by reading center**

*Please describe the reading center data/output that will be generated. Please include names of assays, measurement types, and relevant units. Include what summarized/interpreted data metrics will be produced.*

1. **Description of Participant and/or Site Staff Burden***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 MWCCS staff burden please provide details if your project will require IRB submission, staff training, and/or coordinating/consenting /providing participant incentives.*
2. **Quality Assurance**

*Please explain what checks and edits will be done by the reading center prior to data transfer to the DACC.*

1. **Returning Participant Results**

*Please explain plans to give results back to participant here and upload a copy of the participant letter with this submission if applicable. Or if results will not be given back, please explain why here.*