MACS/WIHS Combined Cohort Study (MWCCS)

Concept Sheet Guidelines for Investigators

Developed by Catalina Ramirez, MPH, MHA, CCRP, Susan Holman, RN, MS, and the MWCCS Data Analysis & Coordination Center (DACC)

Useful Acronyms

Acronym	Term
COI	Conflict of Interest
CS	Concept Sheet
CRS	Clinical Research Site
DACC	Data Analysis and Coordination Center
DACCTrack	Web-Based Project Submission & Tracking System
DM	Data Manager
EC	Executive Committee
F&A	Facilities and Administrative (also called Indirect Costs)
HIPAA	Health Insurance Portability and Accountability Act
IRB	Institutional Review Board
LOI	Letter of Intent
LOS	Letter of Support

Acronym	Term
MACS	Multicenter AIDS Cohort Study
MWCCS	MACS/WIHS Combined Cohort Study
NOA	Notice of Award
PD	Project Director
PI	Principal Investigator
RFA	Request for Applications
RFP	Request for Proposals
SF424	Standard Form 424
SOW	Statement of Work
sIRB	Single IRB
WIHS	Women's Interagency HIV Study
WG	Working Group

Table of Contents

OVERVIEW

Welcome!

The MACS/WIHS Combined Cohort Study (MWCCS) welcomes scientific proposals from a diverse group of investigators. The MWCCS process for proposing research in the MWCCS is explained on the study website in the "MWCCS Concept Sheet and Publication Policies and Procedures" document. This document provides additional guidance on roles and responsibilities, processes, tips, and resources to help external investigators successfully develop and submit a research concept sheet (CS) to utilize MWCCS data and/or resources.

1.1 Introduction to MWCCS

The Multicenter AIDS Cohort Study (MACS) / Women's Interagency HIV Study (WIHS) Combined Cohort Study (MWCCS) is a collaborative research effort that aims to understand and reduce the impact of chronic health conditions that affect people living with HIV. The MWCCS builds on previous scientific and clinical research from the WIHS and the MACS, which were the longest-running research cohorts of women and men, respectively, with or at risk for HIV infection in the U.S.

Since 1984, more than 12,000 people have participated in the WIHS and the MACS. These participants' contributions have provided investigators with rich data to pursue a multitude of research questions, yielding more than 3,000 publications and over 85 currently active linked NIH grants. The newly consolidated study includes WIHS and MACS participants who agreed to participate in the MWCCS, as well as newly recruited participants from groups that were underrepresented in previous studies, including African American and Hispanic populations and residents of Southern states.

Investigators can learn more about the cohort, and ongoing research, by utilizing the following resources:

Resource	Description
National MWCCS Website http://mwccs.org/	• Description of data collection instruments and protocols • Searchable database of publications • Searchable database of approved concept sheets (inclusive of all historic WIHS and MACS concepts sheets) • Study Acknowledgement • Relevant policies
Historical MACS & WIHS forms https://statepi.jhsph.edu/mwccs/data-collection-forms/	• Links to view historical MACS & WIHS data collection instruments and protocols **Note:** Use of historical MACS & WIHS data or specimens will still require submission of a MWCCS Concept Sheet

QUICK TIP: Check out the **Work With Us** page on the MWCCS website for easy to follow, step-by-step instructions on how to submit concept sheets, manuscripts, abstracts, and more.

1.2 Roles and Responsibilities

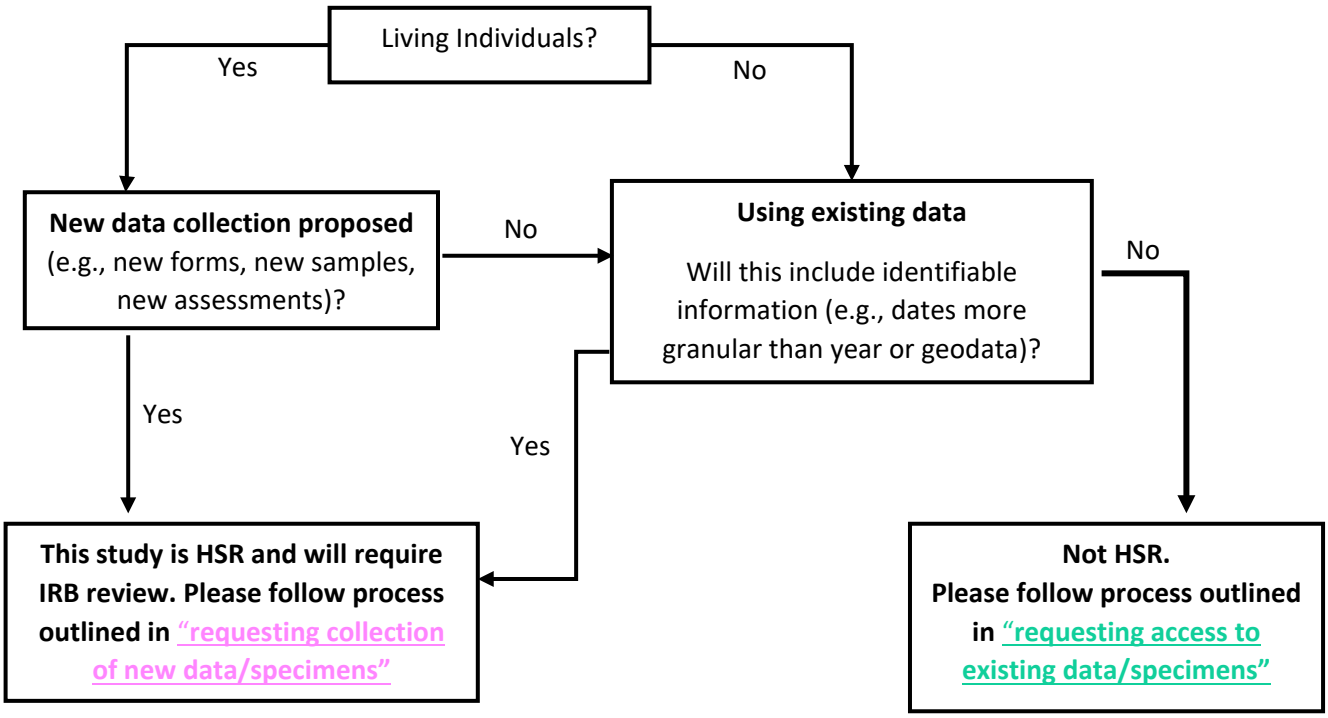
Investigator • Engage local MWCCS site PI prior to CS development. Investigators from external institutions will need to work with a liaison (a MWCCs Investigator who will sponsor your concept sheet). If you do not have a study liaison, you may contact the DACC at mwccs@jhu.edu for assistance in finding a liaison. • Provide CS to site PI or liaison for approval **prior to** formal submission. • Once approved, complete required annual online Productivity Update Form. *If additional specimens/data collection is required:* • Using the MWCCS directory, contact the PI and PD at the desired participating MWCCS sites to develop scope of work and budget prior to CS submission • Provide grant-related materials to sites with enough time (at least 8 weeks) to meet site-specific deadlines • Develop regulatory plan	**Local MWCCS Site PI/ MWCCS Liaison** • Assist Investigator in determining technical feasibility of concept sheet (e.g., availability of data/specimens, logistical assessments of new data/specimen collection, and potential overlap) *If additional specimens/data collection is required:* • Refer Investigator to site PD or PD Working Group Chair (as appropriate) to assist with initial logistical review • Connect Investigator with PI/PDs at participating sites to begin a discussion regarding the scope of work, budget, and regulatory oversight
DACC • Assign MWCCS liaison (if needed) • Assign reviewers for CS, as appropriate • Provide reviewer responses and instructions for CS revisions to investigator • Once CS approved, initiate data use agreement (DUA) if data requested and materials transfer agreement (MTA) if samples requested • Communicate with Investigator regarding changes in study-related processes	**Participating MWCCS Sites** • Participate in all study-start up activities per scope of work (e.g., local IRB submissions, staff hiring/training) • Provide timely response to Investigators regarding study implementation and data collection • Collect specimens/data per protocol • Communicate with Investigator (as needed) regarding any potential impacts to study activities

1.3 Overview of Concept Sheet (CS) Development Process

All proposals to use existing data/specimens from the MWCCS must first be submitted using a CS submission form (see https://statepi.jhsph.edu/mwccs/work-with-us/). The process for developing a CS differs based on whether you are using already collected data/samples or you are proposing to collect new data/samples (which involves **'human subjects research' (HSR)** in a multi-site study).

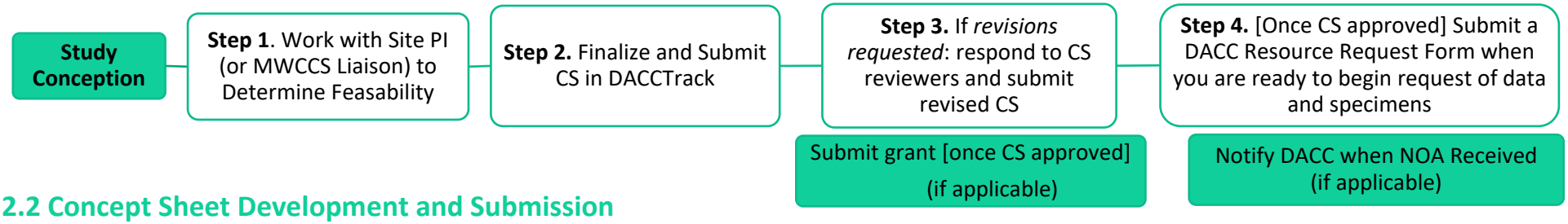
Investigators should utilize the decision tree below to determine what portion of this guide is relevant to their proposed research CS. Figure 1.

Note: Use of the public datasets for MACS and WIHS do not require a CS. Visit this page to request access to the public datasets.



SPECIFIC GUIDANCE TO INVESTIGATORS WHO ARE REQUESTING ACCESS TO EXISTING DATA AND/OR SPECIMENS

2.1 Process Map



2.2 Concept Sheet Development and Submission

The MWCCS website provides detailed guidance on the process for developing and submitting a CS on the Work With Us page. Concept sheets are evaluated for relevance to MWCCS core aims and hypotheses and to determine if there is overlap with existing initiatives. A clear, detailed proposal is necessary for the Working Groups and EC to adequately evaluate the scientific merit and feasibility of a proposed CS.

Investigators should receive approval from their MWCCS site PI or MWCCS liaison (if applicable) prior to submitting the research plan to the MWCCS.

2.3 Regulatory Oversight

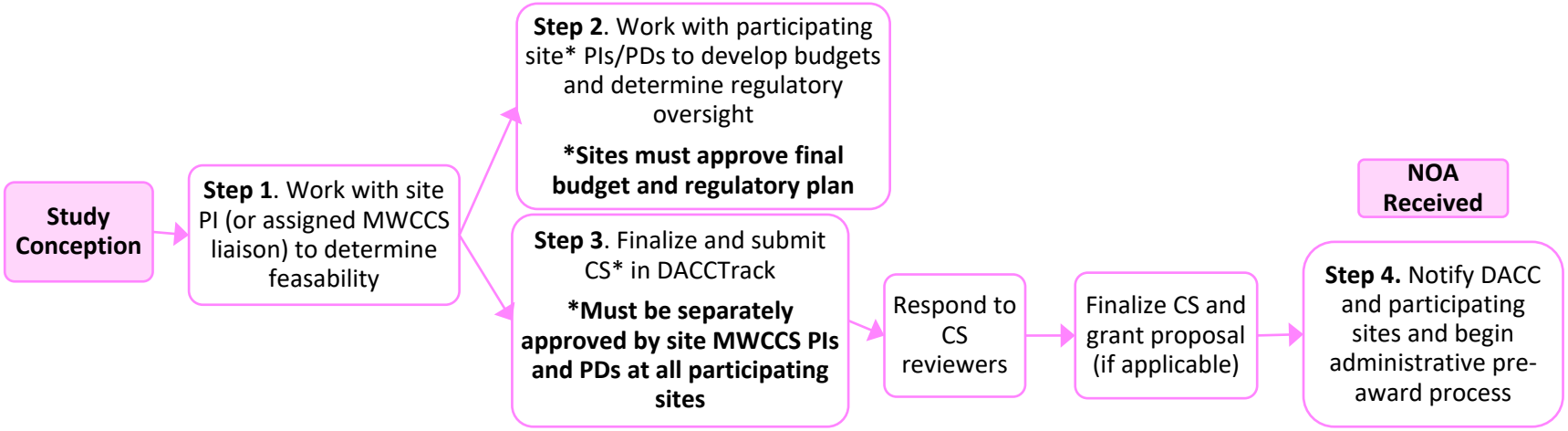
Research studies that use existing specimens/data and will not have access to any PHI (per **Figure 1**) are exempt from the human subject regulations (do not meet the definition of human subjects research). In most cases, these proposed studies will be considered "exempt" under Category 4.

All Investigators at external institutions (e.g., institutions that are not MWCCS data collection sites or already parties to the MWCCS master DUA) will need to complete a Data Use Agreement (DUA) prior to getting data and a Material Transfer Agreement (MTA) prior to getting samples (if applicable).

GUIDELINES FOR RESEARCH CONCEPT SHEETS REQUESTING NEW COLLECTION OF DATA AND/OR SPECIMENS

Research studies that propose the collection of new data and specimens require significant engagement with participating MWCCS sites **PRIOR** to the submission of a grant proposal (or associated CS). In most cases, these studies will require funding to support research costs at participating sites. Additionally, research proposals that include more than one data collection site may be subject to the NIH's sIRB policy. As of 2021, MWCCS sites have an exemption to the sIRB requirement for the MWCCS core protocol, so each participating site has its own local IRB of the core protocol. Data and specimen collection changes are coordinated and submitted twice per year. The following sections provide detailed guidance to help you successfully collaborate with the MWCCS.

3.1 Concept Sheet Development and Submission



Engagement with your sites' MWCCS PI and PD should begin as early as possible in advance of grant-funding deadlines. Collection of additional data and/or specimens will require funding to support operational and administrative costs and participant expenses at each participating site. Your site PI and PD will help to guide you through the process of engaging MWCCS sites, finalizing your CS, and (if funded), implementing your proposed study.

Step 1: Work with Local PI/PD to Determine Feasibility

The contact information for MWCCS PIs and PDs can be found in the study directory.

NOTE: If you are NOT associated with a MWCCS site or are not familiar with any of the site PIs, please contact the DACC (mwccs@jhu.edu) who will help link you with an MWCCS Liaison.

The site PI/PD (or liaison) will work with the Investigator to determine the feasibility of data/specimen collection and to assist the Investigator with determining the timeline for CS submission. As part of this process the Investigator and the local MWCCS team (or liaison) will need to consider:

What data/specimens will be used or collected?	• What sites and participants will be eligible? • At what point in the study visit will the additional data collection take place? • What test/analysis will be performed? • How will specimens be tested, and by whom? • Will the results be provided to participants?
What are the logistical considerations?	• Is this CS part of a grant submission? If so, what is the timeline for submission? How long do sites need in order to compile grant-related materials and budgets? • Will this study require an sIRB?
What would be needed at the sites to participate in this protocol?	• How long will data/specimen collection take? Will a separate visit be needed? • What training or equipment/supplies will be needed in order to implement the protocol? • Who will provide training or equipment/supplies? • Will sites or participants be reimbursed for the additional effort? If so, what mechanism will be used to reimburse sites (i.e., sub-award)? • Will the site be required to set up outside contracts with additional organizations such as Quest, LabCorp, etc?

TIP
Detailed guidance on regulatory and budgetary planning can be found in Sections 3.2 and 3.3

Step 2. Work with participating site PIs/PDs to develop budgets and determine regulatory oversight

Prior to submission of a CS, Investigators will need to work with participating sites to finalize scope of work, budgets, and develop a regulatory oversight plan. Detailed guidance on regulatory and budgetary planning can be found **in Sections 3.2 and 3.3 of this document,** respectively. **This process may include working with a local site for single-site studies or working with all MWCCS sites if you are proposing a MWCCS-wide study.**

If you are proposing new data or sample collection the concept sheet should NOT be submitted without approval from all participating sites. Investigators should plan to engage all participating site PIs and PDs early to allow sufficient time for all pre-submission activities (i.e., at least eight weeks prior to grant

submission). Many of the MWCCS sites are part of research consortia that include more than one institution and may require additional time to review and finalize sub-award documents; please plan accordingly and allow at least eight weeks for this process.

Step 3. Finalize and Submit CS in DACCTrack

After the Investigator has finalized the technical portion of the CS, and received approval from all participating sites, the local site PI (or liaison) must review and approve the document. Following approval, the Investigator may submit the CS to the MWCCS EC for review. **Concept sheets that are submitted to MWCCS prior to receiving approval from the local PI/liaison will not be reviewed until initial approval is granted.**

The MWCCS website provides detailed guidance on the process for developing and submitting a concept sheet on the Work With Us page. Submitted concept sheets are evaluated for relevance to MWCCS core aims and hypotheses and to determine if there is duplication with existing initiatives.

The MWCCS website also provides detailed guidance on the timeline for CS review.

Concept sheets will simultaneously be assigned to the following reviewers:

- 1-2 scientific Working Groups (WG)
- Project Director (if requesting new data collection or specimen collection)
- Other relevant groups (e.g., laboratory, geocoding)

All reviewers will have ten business days to submit an initial review. Investigators must review and revise the CS (if requested), making sure to address any substantive issues, prior to re-submission. Each round of revisions, until approval is granted, can take up to ten business days.

For projects that require additional data/specimen collection, the PD review period can be expedited by working with sites prior to submission as outlined in this guide. Concept sheets that are not approved by the PDs at the participating sites will not be approved by the MWCCS EC, leading to delays with grant submission.

Step 4. Study Implementation

Upon funding notification, sites should work with the administrative contact at each site to finalize sub-contracts and begin the regulatory process for multi-sites studies (if applicable).

3.2 Regulatory Oversight

Starting on January 25, 2018, all federally funded multi-site studies involving non-exempt human subjects research must use a single IRB (sIRB). In March 2021, MWCCS was given an exemption to this requirement for the core protocol, but your own award will likely require you to have sIRB for your own new data/specimen collection. Please see the MWCCS sIRB exemption notice here.

Due to new sIRB policies, all studies that seek to collect additional data or specimens must either submit their own sIRB application (if sIRB is required by NIH) or will be required to submit local IRB applications at all participating institutions. **Please note, NIH had indicated sIRB exemptions for any nested grants within MWCCSS will be extremely rare.**

Budgetary considerations for regulatory oversight of multi-site studies are outlined in section 3.3 (Budgetary Considerations).

Studies that using are existing data/specimens only and do not need any identifying information for participants do not need separate IRB review/approval as analysis of de-identified data does not constitute human subjects research as defined at 45 CFR 46.102.

3.2.1 Regulatory Oversight for projects that require sIRB

Although the sIRB mandate streamlines IRB review, it does not eliminate the participating institutions' many other responsibilities for oversight of human subjects' research. Each participating institution remains responsible for researcher training, conflict of interest disclosures, HIPAA, conducting ancillary reviews such as Institutional Biosafety Committee (IBC) or radiation safety, compliant research conduct, and maintaining oversight with respect to state and local laws and other institutional policies.

If your funding requires sIRB, you are responsible for overseeing this process. These steps usually include:

1. Selection of sIRB and development of sIRB plan (pre-award)
2. sIRB Initial Submission, including: protocol, template consent, and other study materials (post-award)
3. Local IRB submissions of sIRB approved documents and local context review; finalization of reliance agreements
4. sIRB review of local consent changes and any additional site documents

3.2.2 Regulatory Oversight for projects that do not need sIRB – i.e. those with non-NIH funding and single site studies

For all multi-site studies that are supported by organizations that do not require an sIRB, investigators will need to work with the participating sites to facilitate local IRB submission for the study. Investigators should provide local site contacts with the following documents to facilitate IRB submission:

- Study Protocol
- Draft Consent (to be adapted by sites)
- A copy of the application (excluding budget documents) from the prime institution that sites can use to help fill out sections of their local application

Please note that if a proposed study is transferring data or specimens to an organization that is outside of the MWCCS, organizations may also require a data use agreement (DUA) or materials transfer agreement (MTA). These agreements must be finalized prior to IRB approval.

Studies may be approved through a local amendment to the MWCCS IRB application at each participating site if sIRB is not required by the funding for this new project (and all necessary approvals have been received to add additional data/specimen collection to MWCCS). Please review our Publication Policies for all steps required for final approval of additional data/specimen collection at multiple sites.

3.3 Budgetary Considerations

The collection of additional specimens or data at sites will, in most cases, require additional resources at sites to cover study related costs, including:

Budget Category	Examples of Budget Related Line Items
Personnel effort **at local sites**	o PI effort required on a sub-award o PD effort for administrative oversight, IRB coordination, etc. o Research staff effort (depending on protocol)
Equipment at **local sites**	o New equipment or portion of maintenance fees for use of existing equipment
Travel at **local sites**	o Staff or Investigator travel for training, data collection or study meetings
Materials and Supplies at **local sites**	o Office and clinical supplies required to complete study
Other Research Costs at l**ocal sites**	o Specimen courier, processing, and shipping o Participant reimbursement and compensation o Facility costs (rent, communications fees) for sites with off-campus F&A rates
Analytic or administrative **DACC support**	o Assistance with study design/ concept development o Programming of data collection forms into GEMINI (MWCCS data collection system) o Analytic support

Appendix A provides budget estimates which can be used by Investigators to determine general CS feasibility. **The estimates are not approved budget figures and do not replace the need to work with sites as part of CS submission.** Investigators should use these estimates to help determine the scope of work which *may* be feasible with the proposed funding and then should work with their local MWCCS PI or PD to contact participating sites to request official budget information.

Appendix B provides budget guidance for DACC related support, including the integration of forms/questionnaires into the MWCCS data collection system.

COMPLIANCE

All investigators are required to comply with the "MWCCS Concept Sheet and Publication Policies and Procedures" and MWCCS code of conduct. Visit this page to access these policies on our website.

APPENDIX A. MWCCS Budget Estimates

DO NOT USE THESE ESTIMATES AS FINAL BUDGET FIGURES

The tables below provide budget items and **estimates** which Investigators can use to assess feasibility of research projects within the MWCCS. This is not an exhaustive list of budget items, nor is this standardized pricing that can be used in a grant application.

These tables are provided as a resource meant to help Investigators think through the potential budget implications of multi-site studies that may involve data or specimen collection at multiple sites.

Investigators should use this resource as a way to pull together "rough" estimates at the CS development stage, and to help better inform the number of sites (and participants) that they want to include in a proposed CS. As has been emphasized, Investigator should work with their local PI and PD to develop their research concept and liaise with potential collaborating sites.

The sections below are broken out by NIH 424 expense category:

1. Personnel
2. Equipment
3. Travel
4. Materials and Supplies
5. Other Research Costs

1. Personnel

Study investigators will need to provide funding to cover all staff effort related to their proposed protocol. Estimates of time required to complete common research activities are outlined below. Investigators will need to work with sites to develop a final personnel budget.

Principal Investigator

PI effort will depend on the scope of work at each participating site. Most organizations require a minimum of 2% effort/PI per year of a sub-award. Most MWCCS sites have more than one PI and this effort may be split amongst the MPIs or delegated to a single PI, depending on local site policies.

Project Director

ACTIVITY	DESCRIPTION	ESTIMATED # HOURS
IRB Modification (EXISTING)	Submission of IRB modifications to an existing protocol. May include: minor changes to study protocol, data collection form or consent, response to IRB stipulations/requests.	Average hours per modification: □ Addition of new procedures: 6 □ Revision to existing procedures: 1 - 3

New Local IRB Submission	Submission of a new IRB application for human subject's research includes: submission of protocol, development of study-specific consent form (if applicable), local IRB submission system upload, response to IRB stipulations/requests, coordination of local IRB related processes.	Average hours per initial submission: □ Clinical Protocol w/ more than minimal risk (some or all procedures conducted in hospital): 20 □ Clinical Protocol w/ more than minimal risk (all procedures conducted at MWCCS clinic): 12 □ Clinical Protocol w/minimal risk: 10 □ Non-clinical protocol w/ minimal risk: 8
New sIRB Submission [if needed] **(Lead Site and Local Site components)**	Submission of a new sIRB application for human subject's research includes: *Lead Site:* sIRB application, development of protocol-specific template consent forms, finalization of reliance agreements with all participating organizations, coordination of local IRB submissions *Local Site*: local coordination of reliance agreement process, local IRB submission, sIRB submission following local approval,	Local Site avg hours per initial submission: □ Clinical Protocol w/ more than minimal risk (some or all procedures conducted in hospital): 65 □ Clinical Protocol w/ more than minimal risk (all procedures conducted at MWCCS clinic): 40 □ Clinical Protocol w/minimal risk: 35 □ Non-clinical protocol w/ minimal risk: 20
Protocol Development & Training	Development and/or implementation of protocol training for local MWCCS staff. May include: development of site-specific protocol for data collection, clinical protocol, laboratory specimen processing, and logistics for all study visits. Development of study protocol related forms (e.g., specimen requisitions, specimen labels, clinical flow sheets, etc.).	Average hours per protocol: □ Clinical Protocol w/ more than minimal risk (some or all procedures conducted in hospital): 20 hours □ Clinical Protocol w/ more than minimal risk (all procedures conducted at MWCCS clinic): 15 hours □ Clinical Protocol w/minimal risk: 10 hours □ Non-clinical protocol w/ minimal risk: 6 hours
Administrative Oversight	Development of study invoices, tracking of study progress, serving as point of contact between PI and study clinic team.	Average hours per year: □ Clinical Protocol w/ more than minimal risk (some or all procedures conducted in hospital): 20 hours □ Clinical Protocol w/ more than minimal risk (all procedures conducted at MWCCS clinic): 15 hours □ Clinical Protocol w/minimal risk: 10 hours □ Non-clinical protocol w/ minimal risk: 10 hours
Personnel Management	Management of study staff.	Effort will depend on the effort of other personnel required to complete the proposed scope of work.

Research Assistant/Data Manager

ACTIVITY	DESCRIPTION	ESTIMATED # HOURS
Protocol Training	Completion of study-specific protocol training. May include: data collection, clinical procedures, laboratory specimen processing, and logistics for all study visits. Training on completion of study protocol related forms (specimen requisitions, specimen labels, clinical flow sheets, etc.).	Average hours per protocol: □ Clinical Protocol w/ more than minimal risk (some or all procedures conducted in hospital): 10 hours □ Clinical Protocol w/ more than minimal risk (all procedures conducted at MWCCS clinic): 5 hours □ Clinical Protocol w/minimal risk: 5 hours □ Non-clinical protocol w/ minimal risk: 4 hours
Recruitment of Study Participants	Recruitment of study participants may include contacting participants outside of their study visit (by telephone), consenting for new study, coordinating study visits (if a separate visit is required), coordinating transportation and logistics and consenting of participants prior to study procedures.	Average time per participant: □ Studies that require a separate visit: o Recruitment: 0.5 hours per participant o Scheduling/Coordinating Travel: 0.5 hours per participant o Consenting: 0.4 hours per participant □ Studies conducted at CORE visit: o Recruitment: 0.1 hours per participant o Consenting: 0.6 hours per participant
Collection of Specimens	Includes specimen collection and initial processing.	Average time per participant: □ Blood Specimens: 0.05 hours for line placement + 0.02 hours per tube □ Oral Specimens: 0.02 hours per sample □ Other Specimens: depend on protocol
Collection of Interview Data	Collection of interview data on MWCCS approved data collection forms.	Average time per participant: □ 0.03 hours for form introduction + 0.01 hours per question (on average).
Implementation of Clinical Procedures	Collection of clinical measurement, data from clinical procedures (e.g., ankle brachial index, blood pressure, anthropometry).	Rate will depend on procedure.
Medical Record Abstraction	Request and review of medical records and abstraction of medical records onto MWCCS approved data collection forms or redaction/upload of records to MWCCS secure data management system.	Average time per participant: □ Clinical Labs/ Progress Notes from Single Event: 0.3 hours per event □ Hospitalizations (inpatient or outpatient): 1.5 hours per event
Data Management	Data entry, data management, data transmission and response to centralized queries from study PI.	Rate will depend on protocol.

ACTIVITY	DESCRIPTION	ESTIMATED # HOURS
Shipping	Shipment of study samples, forms or other collected material to study Investigator. Includes email of shipping manifest to study contact.	Average time per participant: □ Non- Hazardous Materials: 0.25 hours per shipment. □ Category A or B Hazardous Materials: 0.5 hours per shipment.

MWCCS Clinicians

ACTIVITY	DESCRIPTION	ESTIMATED # HOURS
Protocol Training	Completion of study-specific protocol training. May include: data collection, clinical procedures, laboratory specimen processing, and logistics for all study visits. Training on completion of study protocol related forms (specimen requisitions, specimen labels, clinical flow sheets, etc.).	Average hours per protocol: □ Clinical Protocol w/ more than minimal risk (some or all procedures conducted in hospital): 10 hours □ Clinical Protocol w/ more than minimal risk (all procedures conducted at MWCCS clinic): 5 hours □ Clinical Protocol w/minimal risk: 5 hours □ Non-clinical protocol w/ minimal risk: 4 hours
Collection of Specimens	Includes specimen collection and initial processing. **NOTE:** Protocols that require collection at an off-site facility will also be required to compensate staff travel time.	Average time per participant: □ Blood Specimens: 0.05 hours for line placement + 0.02 hours per tube □ Oral Specimens: 0.02 hours per sample □ Gynecologic Specimens: o Cervico-vaginal swabs: 0.16 hours for speculum-based exam +0.06 hours per specimen o Biopsies/ECC: 0.5 hours per sample □ Other Specimens: time will depend on the protocol
Collection of Interview Data	Collection of interview data on MWCCS approved data collection forms.	Average time per participant: □ 0.03 hours for form introduction +0.01 hours per question (on average).
Implementation of Clinical Procedures	Collection of clinical measurement, data from clinical procedures (e.g., arterial brachial index, blood pressure, anthropometric measures).	Rate will depend on procedure.
Medical Record Abstraction	Request and review of medical records and abstraction of medical records onto MWCCS approved data collection forms or redaction/upload of records to MWCCS secure data	Average time per participant: □ Clinical Labs/Progress Notes: 0.3 hours per event □ Hospitalizations (inpatient or outpatient): 2 hours per event

	management system.	
Data Management	Data entry, data transmission and response to centralized queries from study PI.	Rate will depend on length of form.
Shipping	Shipment of study samples, forms or other collected material to study Investigator. Includes email of shipping manifest to study contact.	Average time per participant: - Non- Hazardous Materials: 0.25 hours per shipment. - Category A or B Hazardous Materials: 0.5 hours per shipment.

2. Equipment

Study investigators will need to provide any new equipment that will be needed to conduct their protocol. Protocols that require the use of existing study equipment (e.g., Fibroscan, Spirometry, ECG) will be required to cover a portion of the service maintenance agreement, commensurate with their use (i.e., study related use as a percentage of total use by the MWCSS site).

3. Travel

Study investigators will need to cover travel-related costs related to the protocol (e.g., training travel). The PD will provide specific quotes regarding the cost of travel as part of the protocol review process.

4. Materials & Supplies

Study investigators will need to provide any supplies that will be needed to conduct their protocol. The PD will provide specific quotes regarding the cost of supplies as part of the protocol review process. On average, data collection protocols require $1 per participant to cover the cost of office supplies (e.g., toner, office paper, etc.). On average, clinical protocols that require specimen collection require $2 per participant to cover the cost of clinical supplies (e.g., gloves, exam table paper, speculums, etc.).

5. Other Research Costs

Study investigators will need to cover all other research costs that are borne by the site as part of protocol implementation. Common categories of "other costs" are outlined below.

ACTIVITY	DESCRIPTION	ESTIMATED COSTS
Service as sIRB Lead Site (if required)	Submission of a new sIRB application for human subject's research, includes completion of sIRB application, development of protocol specific template consent forms, finalization of reliance agreements with all participating organizations,	Cost varies considerably by site, please contact site directly for details. Please note that protocols may be subject to additional fees if they require review by more than one IRB "board", for example: radiation

	coordination of local IRB submissions, response to IRB stipulations/requests.	studies, human imaging, investigational drugs or devices.
Laboratory Costs	Laboratory service costs may include: transport of specimens from the MWCCS clinic to the laboratory, specimen processing and aliquoting, processing, storage, and shipment.	Reimbursement rates vary by site; however, Investigators should consider the following categories of costs. • Specimen Transport • Specimen Processing • Specimens Shipping and Storage (e.g., dry ice)
Participant Transportation Reimbursement	Participant reimbursement for transportation costs for attending study visit appointments.	Reimbursement rates will vary considerably by site. No average rate is provided.
Participant Compensation	Participants are compensated for time and effort required to consent, complete any additional forms, questionnaires and for the provision of additional specimens.	Reimbursement rates vary according to protocol and must be approved by the IRB. Average reimbursement rates for common protocol components are estimated below: □ Completion of 1 extra form (no additional consent) o <10 mins: $5 o 10 mins-20 mins: $10 □ Completion of 1 extra form (additional consent) o <10 mins: $10 o 10 mins-20 mins: $15 □ Completion of clinical assessment (non-invasive, additional consent) o <20mins: $20 o 20mins- 30 mins: $30 □ Specimen Collection (no additional consent) o Low Volume Blood Collection (<20ml): $10-$15 o All Others: varies by specimen □ Specimen Collection (additional consent) o Low Volume Blood Collection (<20ml): $15-$20 All Others: varies by specimen

F&A Rates

Investigators need to take into account F&A rates at each institution which will be levied on all applicable costs. Please note that F&A rates may increase annually, and "Total Direct Costs" definitions vary by institution. Both the current rate and MTDC definition will need to be verified during the request for an official budget. Additionally, for some of the MWCCS sites, F&A may vary at their participating subsites.

F&A rate range from 26% to 65.9% and vary by institution. Investigators are responsible for contacting each site to determine their current F&A rate during the budget process; however, for the purposes of **feasibility assessments**, we recommend Investigators use an F&A rate of 55%.

For questions about feasibility planning for MWCCS nested sub studies and grants please contact the Project Directors Working Group Co-Chairs (ccs-pdchair@googlegroups.com).

APPENDIX B. BUDGET GUIDELINES FOR DACC SUPPORT

The Data Analysis and Coordination Center (DACC) for the MWCCS provides data sets and coordinates request of biospecimens from the study repository for all studies with approved concept sheets (see mwccs.org to submit a CS). They work with investigators who propose ancillary study components, and no additional support is required to access already collected MWCCS data.

If you would like additional DACC support beyond this scope for a grant you are planning in the MWCCS, here are suggested guidelines for planning a DACC subcontract. This would include projects that have any of the following:

1. Are collecting new data in the MWCCS (new forms, new samples, and/or new protocols) outside the scope of the core MWCCS grant and need DACC support for these activities.
2. Need support with study design and/or implementation as part of grant project nested in the MWCCS.
3. Need more analytic support (beyond analysis for single paper).

Subcontracts with the DACC would include % effort for a DACC faculty member overseeing the project as well as:

Activity	**DACC % effort recommended**
COLLECTING NEW GRANT DATA IN MWCCS	
Program sub-study forms.	5-10% coordinator for one year
Track sub-study enrollment or sample collection (eligibility lists based on inclusion criteria, progress reports, tracking refusals, etc.).	5-10% data manager for each year of the study
Perform data quality assurance and data management on sub-study data (codebook generation, development of data transfer protocols, data triangulation, and quality assurance).	5-15% data manager for each year of the study, depending on scope of data
STUDY DESIGN AND IMPLEMENTION	
Study design epidemiologic support.	5% faculty effort
Study implementation support (recruitment materials, protocol development, coordination with sites, training, monitoring).	5-15% coordinator each year of the study, depending on scope
ENHANCED ANALYSIS	
Study design analytic support.	5% faculty effort
Analytic support (run multiple analyses, data exploration and presentation, when need support beyond analysis for single paper).	15-50% biostatistician each year analysis needed, depending on scope

For questions about DACC support for nested sub studies and grants please contact Dr. Amber D'Souza, DACC Multi-PI, gdsouza2@jhu.edu.