CHAPTER 1 CLINIC CENTER MANAGEMENT

1.1 Recommendations for Supplies/Equipment

The Study Coordinator or designated person will be responsible for ordering and maintaining an inventory of supplies sent from the central facilities and those purchased or obtained locally. Supplies will include office and laboratory supplies as well as patient binders.

1.1.1 Office Supplies/Equipment

Office supplies such as xerox paper, pens, pencils, water proof markers, staples labels, notebooks, dividers, file folders, computer maintenance supplies, etc. should be readily available.

1.1.2 Laboratory Supplies/Equipment

Supplies for laboratory functions, processing, and handling should include items from the following list that is comprehensive but not inclusive:

- SphygmoCor CVP System with Accessories
- EC6 Strain Gauge and Photo Plethysmography
- Mercury Strain Gauge Forearm Set
- NIVP3 Venous Tests Only
- E20 Rapid Cuff Inflator
- AG101 Air Source
- (2) SC300 Aneroid Sphgmomanometer
- SC10D Cuff
- (2) SC5 Tourniquet Cuffs
- PAK 5 Positioning Aid
- SphygmoCor® System with hardware version EM3
- Repeating Pipette http://www.usascientific.com/index.asp?PageAction=VIEWPROD&ProdID=426 (Make sure to order the correct positive displacement tips for the amount you want to aliquot)

1.2 Scheduling of Activities

A system and an organization that will facilitate the orderly and efficient management of multiple activities including administrative, recruitment, specimen collection, data management, and quality control must be developed. The Study Coordinator will be in charge of these activities but has the authority to delegate when appropriate to team members.

1.2.1 Recruitment Activities

The Study Coordinator or designated person will coordinate and implement strategies to ensure that recruitment goals are met and enrollment proceeds in an organized manner. Maintaining a log of all participant contacts is encouraged.

1.2.2 Quality Data Collection

The Study Coordinator will review all data forms for completeness and accuracy and to ensure timely submission to the Data Coordinating Center. The procedure for mailing blood and vein samples will be coordinated with the Study Coordinator and technical personnel to ensure prompt shipment to the Central Labs. Data forms will be filed in an area convenient for study personnel's access. Prior to each visit, appropriate forms will be assembled, headed, and

distributed to designated personnel. To ensure that the study has quality data, team members must know the purpose of the study, the protocol design, and the sections of the Manual of Operations that are pertinent to their roles in the study. If protocol expectations and study goals are clear and common to all team members, then protocol adherence by staff will help ensure quality data collection and a pleasant working environment.

1.3 HFM Study Reference Materials

Each center should maintain copies of the Protocol, Manual of Operations, Forms Manual, and Address Directory.

1.3.1 Patient forms binders

All patients enrolled in the study should have binders which include patient consents, completed forms, and source documents (including op reports, run sheets, hospitalization discharge summaries, etc.).

1.4 Documenting your Center's Personnel

Study form 101 (Study Personnel Form) should be completed for each person other than the principal investigator who will provide research data in HFM Study. Active Status is “yes” as each person begins working on the study. If someone leaves your institution, file a data change with the DCC so their status can be set to "no" and the status date changed.

1.5 Training of HFM Study Staff Members

The US Core, directed by Michelle Robbin, M.D. at the University of Alabama Birmingham (UAB), will be responsible for the central UAB training of sonographers from each HFM Study clinical center. The Vascular Function Core, directed by Dr. Joseph Vita at Boston University School of Medicine, will train technologists at each clinical center to perform the Vascular Function Studies, and oversee quality control for the Vascular Function studies. The Data Coordinating Center will provide centralized training for the study coordinators on an annual basis. Training will include but not be limited to study background, patient eligibility, forms completion, recruitment and patient consent, data collection, ultrasound data, serum/blood/DNA biorepository sample collection, processing and shipment; vascular function testing documentation, vein tissue sample collection, processing and shipment; surgery documentation, study follow-up, events and data entry.