# CHAPTER 9 VASCULAR FUNCTION STUDIES: TRAINING AND DATA TRANSMISSION

## 9.1 Form 114: Identification of Clinical Center Vascular Function Laboratories

Form 114 entitled "Vascular Function Laboratory Form" provides information about the laboratories at which Vascular Function studies will be performed. The Clinical Centers will complete a separate form for each laboratory at the Clinical Center performing Vascular Function studies. The DCC should be contacted if the ultrasound machine used at a center for the FMD/NMD studies is not one of the options on the form.

## 9.2 Training and Certification of Vascular Function Laboratory Personnel

Personnel at the Clinical Centers will be trained by the Vascular Function Core to perform the three types of Vascular Function Studies (venous occlusion plethysmography, arterial pulse wave velocity (PWV) and brachial artery flow-mediated dilation /nitroglycerin-mediated dilation (FMD/NMD). The FMD/NMD studies must be performed by individuals with experience in ultrasonography. The Clinical Center Vascular Function Studies personnel will not read the ultrasound images. The images will be transmitted to the Vascular Function Core at Boston University and read centrally. The PWV and venous occlusion plethysmography studies do not involve ultrasound and do not require an ultrasonographer. New personnel joining the Vascular Laboratory to perform HFM Study after the initial training session at the Clinical Center will need to travel to Boston University to be trained by the Vascular Function Core.

## 9.3 Form 210: Data Completed at the Beginning of Vascular Function Study Sessions

Form 210 entitled "Getting Ready for Vascular Function Studies" is completed at the beginning of each session at which Vascular Function Studies are performed. If all Vascular Function tests are performed at one visit, the form is completed only once. The form documents timing of last eating, exercise, smoking, and use of sildenafil (Viagra)/vardenafil (Levitra)/tadalafil (Cialis), and documents 3 blood pressure measurements and 3 pulse rate measurements performed at the beginning of the Vascular Function study session. These measurements are performed once if all 3 types of studies are performed during the same visit. If the studies are performed over the course of multiple visits, the measurements will be performed at each visit and a separate form should be completed for each visit. The form will be filled out by the individual performing the vascular function studies and the data should be transmitted to the DCC by the study coordinators or other designated members of the study team. Form 210 will also be maintained in the subject's study file at the Clinical Center.

## 9.4 Form 211: Transmission of Venous Occlusion Plethysmography Data to the DCC

Form 211 entitled "Venous Occlusion Plethysmography Study Form" will be completed at the time of the venous plethysmography study by the individual performing the study and the data will be transmitted from the paper form to the DCC by the study coordinators or other designated members of the study team. Measurements documented on the form include: forearm circumference, wrist circumference, elbow circumference, length of forearm, and distance between the base of the palm and the tip of the patient's

middle finger. Measurements generated by the Hokanson EC6 device that need to be transcribed onto the paper form include % Increase in Capacitance (CAP %), and Maximum Venous Outflow (MVO). There will be five total sets of measurements generated by the EC6 that correspond to five different venous pressures that will be tested. Form 211 and the print-out from the Hokanson machine with primary data will be maintained in the subject's study file at the Clinical Center.

## 9.5 Form212: Arterial Pulse Wave Velocity Form

Form 212 entitled "Arterial Pulse Wave Velocity Form" will be completed at the time of the arterial pulse wave velocity study by the individual performing the study. Data that is generated by the PWV study will be exported from the SphygmoCor program and transmitted to the DCC. (Method to be determined). Form 212 and a copy of the exported data file will be maintained in the subject's study file at the Clinical Center.

## 9.6 Form 213: Brachial Artery FMD/NMD Image Study Form

Form 213 will be completed at the time of the brachial artery FMD/NMD studies by the individual performing the study and the data will be transmitted from the paper form to the DCC by the study coordinators or other designated members of the study team. The form includes information about the ultrasound machine, time of study, and documentation that the images were sent to the Vascular Function Core Lab which will function as the Central Reading Facility. The form also documents the results of a pregnancy test if necessary, and the blood pressure obtained after the NMD portion of the study has been completed. The form does not include any FMD/NMD results as those will be obtained by the Central Reading Facility from the ultrasound images. See section **10.6.6** for instructions for sending the FMD/NMD ultrasound images to the Vascular Function Core.