

Center for Human Phenomic Science

Cardiovascular Core Protocol and IRB Language

Electrocardiography

Protocol Description

All electrocardiograms will be performed in the ECG laboratory by a trained technician. Fifteen lead studies will be performed on a 5500/MAC 1600 System Trolley.

Consent Description

An electrocardiogram study is a standard clinical test that is not experimental. It is used to diagnose rhythm and electrical problems of the heart as well as to screen for other congenital heart problems. Small patches will be placed on your skin in multiple locations to measure your heartbeat. These patches will be connected by wires to the electrocardiography machine.

Consent Risks

There are no risks related to the electrocardiogram study itself except for possible minor skin irritation from the patches put on the skin.

Echocardiography

Protocol Description

All transthoracic echocardiograms will be performed in the echocardiography laboratory by a trained sonographer. Studies will be performed on a Philips IE-33 echo machine with probes appropriate size for the patient. Digital images will be captured and will be based on the protocol of the study but will usually include two-dimensional imaging, color Doppler, and spectral Doppler. A full echocardiographic report and the images will be archived and stored in syngo Dynamics (Siemens, Ann Arbor, Michigan).

Consent Description

An echocardiographic study is a standard clinical test that is not experimental. It is used to diagnose congenital and acquired heart disease. Small patches will be placed on your skin in three locations to measure your heartbeat. These patches will be connected by wires to the echocardiography machine. An ultrasound probe with gel on it will be used over your abdomen, chest, and neck area to acquire images of your heart on the screen. This probe does not hurt but, in some regions, it can cause mild discomfort if pressed too hard. You should alert the sonographer if he/she is pressing too hard.



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Consent Risks

There are no risks related to the echocardiographic study itself except for possible minor skin irritation from the patches put on the skin and minor discomfort from the probe.

Vascular Testing for Cardiovascular Risk Assessment

All vascular testing will be performed in the CHOP echocardiography laboratory by a trained sonographer. Testing can be performed in our laboratory in subjects less than or equal to 21 years of age. Subjects must be able to lie still for this testing.

Carotid Intima Media Thickness

Protocol Description

Measurement of carotid intima media thickness (cIMT) will be performed on a Philips IE-33 echo machine with linear array transducers appropriate size for the patient. Digital images will be captured and will be based on the protocol of the individual study but will usually include two-dimensional imaging, color Doppler, and spectral Doppler. Imaging of the common, internal, and external carotid arteries, as well as the carotid bulb, can be acquired according to the study protocol. The angle of insonation will also be recorded. cIMT will be measured using edge detection software (Vascular Research Tools, Medical Imaging Applications LLC). Similar to echocardiography, a full report and the images for cIMT will be archived and stored in syngo Dynamics (Siemens, Ann Arbor, Michigan).

Consent Description

Carotid intima media thickness is a standard clinical test that is not experimental. It is a subclinical marker to assess risk for future heart attack and stroke. Small patches will be placed on your skin in three locations to measure your heartbeat. These patches will be connected by wires to the ultrasound machine. You will lay down on your back with your head extended about 45 degrees and turned to one side. An ultrasound probe with gel on it will be gently placed on the opposite side of your neck to acquire images of your carotid artery (the arteries that carry blood to your brain) on the screen. Images will be recorded and you will then be asked to turn your head to the opposite side to acquire similar images of the other carotid artery. This ultrasound probe does not hurt but in some regions, it can cause mild discomfort if pressed too hard. You should alert the sonographer if he/she is pressing too hard.



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Consent Risks

There are no risks related to the cIMT study itself except for possible minor skin irritation from the patches placed on the skin and minor discomfort from the probe.

Pulse Wave Velocity/Pulse Wave Analysis

Protocol Description

Pulse wave velocity (PWV) measures the speed at which your blood travels through your aorta. Pulse wave analysis (PWA) measures central aortic blood pressure. These are measures of arterial stiffness. Studies will be performed using the SphygmoCor CPVH system (AtCor Medical, Itasca, IL). A full report is generated at the time of the study from the system software. The report and the images will be archived and stored in a password-protected computer in the echocardiography laboratory.

Consent Description

PWV/PWA is a standard clinical test that is not experimental. It is a subclinical marker to assess risk for future heart attack and stroke. You will be asked to lie down. Small patches will be placed on your skin in three locations to measure your heartbeat. These patches will be connected by wires to the SphygmoCor machine.

To measure PWV, a pencil-like probe will be placed gently over your neck and record a blood pressure signal from your carotid artery pulse. It will then be placed at the crease between your leg and hip and record a blood pressure signal from your femoral artery pulse. The distance between your neck and hip crease will then be measured with a measuring tape. To measure PWA, the probe will be placed gently on your wrist to record a blood pressure signal from your radial artery pulse. The probe does not hurt but it can cause mild discomfort if pressed too hard. You should alert the sonographer if he/she is pressing too hard.

Consent Risks

There are no risks related to the PWV/PWA study itself except for possible minor skin irritation from the patches put on the skin and minor discomfort from the probe.

