

POLICIES & PROCEDURES

SLEEP RESEARCH LAB

Date: _____

Revised: 3/3/06

OUTPATIENT CARDIOVASCULAR STUDY Report of Abnormal Findings

The following procedures undertaken during the outpatient cardiovascular day study may yield abnormal findings that have a clinical significance and are reported to the volunteers (and their physicians if requested). All other procedures undertaken in the study are research and have no clinical significance at this time. Therefore the volunteers will not be informed of their results except for the procedures listed below.

Blood Chemistry

1. Hospital lab faxes results directly to Linda.
2. Lab results outside the normal range are marked with an asterisk.
3. The lab results are included in the standard summary letter with an advisory to follow up with a physician on any results marked with an asterisk.

cIMT

1. The Cardio-doppler Research Lab personnel inform Dr. Stein of an emergent abnormal finding of either a clinically significant stenosis or a thyroid abnormality.
2. Dr. Stein reviews the study and sends a letter directly to the study participant. A copy of the letter is sent to Linda Evans for filing.
3. Data results for cIMT (and BAR) are given to the Sleep Lab in batches after analysis.
4. The data sheets are given to Linda Evans who provides copies for Dr. Hla. Dr. Hla reviews the data sheets for those having a composite cIMT => than the 80th percentile and writes a letter to the volunteer informing them of the abnormal finding and the need to follow up with his/her physician.
5. A copy of Dr. Hla's letter is given back to Linda for filing.

Retinal Photography Eye Pathology

1. The Ophthalmology Reading Center generates a pathology notification when the images have been reviewed and an abnormality detected.
2. The Reading Center faxes a form to the Coordinating Center (Jen Reinke) who then sends it to Linda.
3. Linda matches the pathology to the correct text defined in the Sleep Apnea-Eye Pathology Notification document (in the Manual of Operations) provided by the Ophthalmology coordinator to be used in the letter informing the volunteer and his/her physician.
4. Linda generates and sends the letter and places a copy in the files.

Mercury Pilot

1. The State Lab of Hygiene sends the results to Linda.
2. Results for volunteers that are over the EPA advisory for mercury will be identified from the cut points defined by Dr. Bautista.
3. Linda sends a form letter written by Dr. Bautista to the volunteer and a copy is placed in the files.