

PROTOCOL FOR CARDIOVASCULAR DAY STUDY

Preparation, Introduction and Sample Collection

1. Sleep tech enters into the lab logbook the participant information (Cohort ID#, study date, time of arrival, time of dismissal, time of blood draw, consent option, information on caffeine consumption and smoking). The cassette tape for Heart Rate Variability, the Photo Completion form and the Data Collection Checklist is labeled with Cohort ID# and study date and kept with the study folder.
2. When study participants arrive at the sleep lab, the overnight urine collection is given to the GCRC nurse who takes it to the specimen lab where the frozen samples are processed. The remaining collection is kept refrigerated until the daytime collection is complete and samples processed and frozen. The remaining collection is sent to the hospital laboratory for analysis.
3. The sleep tech orients the participant to the room, explaining the daytime urine collection, the consent and HIPPA form, and the outpatient menu.
4. After obtaining consent, the HIPPA and consent form are given to the GCRC and a copy of the consent is retained in the data folder.
5. The blood draw is done by the GCRC nurse and the samples processed according to the option selected by the participant concerning use of DNA.

Measurements, Questionnaire Data Collection, and Doppler Studies

6. Heart and respiration rate are taken by the GCRC nurse and recorded on the Physical Exam Form.
7. The sleep tech reviews and confirms the menu selection and orders the selection to arrive after the participant returns from the carotid doppler/brachial reactivity study.
8. The participant completes the Recent Medical History Form.
9. When the participant has been seated for over 5 minutes, the sleep tech takes two blood pressure measurements in the left arm with a 2 minute interval between the measurements.
10. Height (in cm) and weight (in kg.) is taken and recorded on the Measurement/Review form and height is also recorded on the Physical Exam Form.
11. The Physical Exam form and the Recent Medical History form are faxed to the VA physician as part of the cerebral blood flow study. The physician notifies the sleep lab if the participant does not qualify for the CBF.
12. The participant is given the Health Status Survey, the Health Questionnaire, the Current and Past Physical Activity questionnaires and the Women's Health questionnaire (if applicable) to complete.
13. After the participant is asked to use the bathroom, he/she is escorted to the research doppler procedure room for the carotid doppler and brachial reactivity studies.
14. The participant is escorted back to the Sleep Lab.
15. The participant has breakfast in the sleep lab room and when finished is given the Self-Evaluation questionnaire.
16. The sleep tech administers the ARIC interview.
17. The participant is asked to remove shoes and socks and lie down on the bed for at least 5 minutes in preparation for the arm/ankle blood pressure measurements which are done according to WSCS standard protocol and recorded on the Measurement/Review form.
18. After the blood pressure measurements have been completed, while the participant is still lying down, the holter monitor is attached for the heart rate variability data collection. The recording is done for a minimum of 15 minutes.
19. The cassette tapes and data sheets are taken to Dr. Russell's office at the VA Hospital approximately every two weeks for analysis. Completed data sheets are retrieved from his office and given to Linda Evans for data entry.
20. Body habitus and skinfold measurements (according to the standard WSCS procedures) are taken and recorded on the Measurement/Review form.
21. The participant is asked to make a menu selection for lunch if desired. The menu is called in before the retinal eye photos are begun and after the Cerebral Blood Flow study has been completed.
22. If eligible, the study participant is escorted to the pulmonary research lab at the VA for the Cerebral Blood Flow protocol.
23. During the CBF on the first participant, retinal photographs on the second participant are taken and vice versa.

Retinal Photography

24. The sleep tech sets up the retinal camera equipment in the sleep room and administers the Eye Vision History questionnaire. The sleep tech explains the procedure for taking retinal photographs, sets up computer with Cohort ID#, properly adjusts the position of the camera, and has the participant apply the pulse monitor to the left earlobe. The sleep tech checks the indicator light that the monitor is working properly.
25. Three photos of the study eye and two of the non-study eye are obtained. The study eye is determined by the Cohort ID# (if last number in ID is odd, left eye is the study eye; if even, then the right eye is the study eye.) The sleep tech enters on the Eye Photo Completion form for each photograph the flash setting, the pupil dilation, the visual field and the eye photographed.
26. After completion of approximately 6-8 eye photo studies, the data is sent to the Department of Ophthalmology Fundus Reading Center for analysis.
 - a. The data on the computer is first backed up to another folder. A CD is formatted and labeled and the data archived to it.
 - b. The archived data is uploaded to the Ophthalmology server. The CD is stored in the Sleep Lab.
 - c. The Photo Completion Forms are faxed to the Eye Study Coordinator along with a Data Transmittal Form on which the information from the Photo Completion Form is entered.

Study Completion and Ambulatory Blood Pressure

27. The participant eats lunch, provides final daytime urine collection, and is issued a check and given the comment form/doctor's information in a SASE. The GCRC discharges the study participant.
28. If study participant is doing the 24-hour ambulatory blood pressure study, the final urine collection is given at the end of the blood pressure monitor hookup.
29. If participating, the cohort volunteer is consented and hooked up with the ambulatory blood pressure monitor at the end of the outpatient cardio day according to the procedures for ABP. The participant is then discharged.