

Date: _____

Approved: _____

POLICIES & PROCEDURES

SLEEP RESEARCH LAB

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I. Set up

A. Paperwork

1. A data folder containing the consent form, questionnaires, body habitus data sheet, and other forms is prepared for each volunteer and placed in the appropriate mail slot in the lab.
2. Check the lab scheduling calendar to match volunteer with correct folder.
3. Check the folder to make sure it contains the proper paperwork. The volunteer should receive two consent forms, a health questionnaire, a self- evaluation questionnaire, a circadian rhythms questionnaire, and if female, a women's health questionnaire. All questionnaires should contain the correct cohort id number at the upper right hand corner. Place the paperwork and a pen in the assigned research room on the rolling cart.
4. The folder should also contain a body habitus form, a PM sleep evaluation / AM review, an AM sleep evaluation, an envelope containing a letter of thanks from Terry Young and a comment sheet, and a sleep cohort pen. The body habitus form and PM sleep evaluation should be dated with the night of study date. The AM sleep evaluation should be dated with the following morning date. Place the body habitus form and PM sleep evaluation / AM review in the assigned research room on the bedside table. The AM sleep evaluation and envelope can stay in the sleep lab until ready to be given to the volunteer in the morning.
5. Prepare the data collection checklist with the volunteer's id number and study date. Keep this form in the sleep lab and complete after the volunteer finishes all paperwork.
6. Prepare a post-it note with information regarding the volunteer's bedtime, rise time, snack and breakfast. Include with the volunteer's paperwork a piece of paper with the volunteer's name and room number and space for him/ her to write down preferences for snack and breakfast. The technician will call down the selections at the appropriate time.

B. Logbook

1. Record the volunteer information in the logbook as follows:

Ex. Study Date *NL Bed _____ NL Rise _____ Ht _____ cm
Cohort ID In Bed _____
NameCode L out _____ L on _____ Wt _____ kg
Tech: _____
Bed ___ Room #__

*Fill in normal bedtime and rise time from the intake form.

C. ECG disk

1. Set out the ECG disk and prepare the WI Sleep Cohort ECG paperwork. Write down the cohort id number and name code on the 3 x 5 slip of paper for the ECG technician. Include the volunteer's room number on the slip of paper. Keep paperwork and disk in the sleep lab for the ECG technician to find.
2. Save one month of ECG data to each disk. When the ECG disk is full, download the ECG disk to the Reviewer computer at the lab in the ECG data folder.
3. The data is also saved to the Reviewer computer at Walnut St. in the ECG data folder located in the GrassPSGv4 folder. Create a subfolder with the date range of the ECG data and move files from the lab to Walnut St.
4. ECG data is also saved to CD for additional backup.

D. Grass PSG Recorders.

1. If Recorders are not already turned on, power up Recorder 1 and 2 computers from the main power switch. After computers finish booting up, enter user id and password.
2. Double click Gamma icon on desktop.
3. Single click "PSG recorder".
4. In the subject information screen, click 'New' and make the following entries:
 - ID: Cohort ID#
 - Last Name: Cohort name code
 - Test Type: NPSG
 - Sex: M or F
 - Tech: Initials of both techs
5. Verify that all entries are correct and select 'Next'. 'Next' again.
6. After information is written to the amplifiers, the recording screen will open.

E. Rooms

1. Make sure the rooms are clean. If they are not clean by 5:00 pm, call the prep center and ask the GCRC nurse to change the status of the room to "stat". If the housekeeping staff has not arrived in 30 minutes, call the prep center again or page the housekeeping supervisor. The rooms must be cleaned by 6:00 pm to have enough time to set them up.
2. Place soap, shampoo and conditioner next to the sink. These items are stocked in the lab supply closet.
3. Put three towels and two washcloths on the bathroom towel rack. Bed and bathroom materials are found in the clean materials room on the sixth floor.
4. Check the beds to make sure they are properly made. The bed should have a bottom fitted sheet, a top sheet, a white blanket, a bedspread, and two sleep cohort study pillows.
5. Set out paperwork on rolling cart and bedside table.
6. Set a nasal pressure cannula on top of the oximeter and put an oral/nasal flow cable and snore microphone in the top drawer of the bedside table. Include one large and one

medium oral/nasal flow sensor in the drawer.

7. Turn on room microphone, check thermostat for proper room temperature (70 degrees), and press “self test” on the nasal pressure machine to see if the batteries need changing. The test light will continue to flash if new batteries are indicated.

8. Turn on cameras and lights in the control room.

9. Set out body habitus and blood pressure equipment in the sleep research lab.

II. Admissions

A. The volunteer enters the University of WI Hospital main entrance and goes directly to admissions.

B. The volunteer is admitted as an inpatient. He/she must sign and date the contact and insurance information and the “Subject Rights and Responsibilities” form and HIPPA form.

C. Admissions staff will call the sleep research lab when the volunteer arrives to get the assigned room number (D6/656 or D6/654).

D. The technician meets the volunteer in admissions and escorts him/her to the assigned room. The technician must obtain the volunteer’s paperwork, blue chip and wristband from the admissions staff.

III. Room, paperwork, and food explanations

A. Room explanation

1. Bathroom – The bathroom has a toilet, shower, and towels set on the towel rack. The volunteer can take a shower in the morning if they are not staying for an MSLT. If the volunteer is staying the next day for an MSLT, he/she will be able to take a shower after the nap study, not in the morning. The head electrodes will stay on for the MSLT and cannot get wet. The light switch for the bathroom is on the wall as you enter the room, not inside the bathroom. There is an emergency call rope in the bathroom, which will alert a GCRC nurse if the volunteer is in need of immediate help. The shampoo, conditioner and soap are left by the sink in the main room.

2. Closet – Show the volunteer the closet he/she can use to hang up clothes.

3. Television – The hospital has cable television with a movie channel. Explain the remote control and bed control. Both can be used to control the television. The sound can be heard through the bed control speaker. There is a radio on the television, which can be accessed through the black remote control.

4. Camera – Explain that the camera in the room is for monitoring purposes only, not for recording. The technicians use the camera when the volunteer goes to bed to determine body position. The camera can be turned off during the evening procedure if the volunteer would be more comfortable.

5. Intercom system – There is 2-way speaker system in the room, which can be used for communication after lights out. If the volunteer has to use the bathroom in the middle of the night, he/she can speak up and let the overnight technician know. The technician

will respond and come into the research room to unhook the volunteer so that he/she can walk to the bathroom. The technician must unhook the jackbox cable, respiratory belt connection, nasal pressure cannula and body position monitor. This process takes two to three minutes. If the technician does not respond within a minute, the volunteer should speak up again, the technician may not have heard the first time. If the volunteer is male, offer him a urinal to use in bed instead of calling for the overnight technician. Some men prefer this option.

6. Bed – There is a full sized bed in each room with a headboard. More blankets and pillows should be offered to the volunteer.

7. Temperature control – The technician can change the temperature in each room separately. Ask the volunteer if the room temperature is satisfactory and change as needed.

8. Telephone – The volunteer can use the telephone in the research room by dialing “9” first and then the number. If the volunteer would like to receive a phone call, give him/her the sleep research lab phone number and bring the cordless phone to the volunteer when the call comes in. Incoming calls are not allowed on the phones in the research rooms.

9. Window – The window has heavy drapes and black shades that can be opened until bedtime if the volunteer prefers. If volunteer prefers some light in the room after Lights Out, a nightlight is available, or the bathroom door can be left slightly ajar.

B. Meal delivery service explanation

1. Snack – From the Room Service menu, the volunteer can choose from the menu a light snack before bedtime. The volunteer is on a general diet with no caffeine. Ask the volunteer to write down his/her selections for snack and the technician will call the food into the dietary office. The snack will arrive within 45 minutes of ordering. If the volunteer has not had dinner, he/she can order a full meal which must be delivered at least two hours before bedtime.

2. Breakfast – If the volunteer is staying for an MSLT the next day, ask the volunteer to write down his/her selections for breakfast from the Room Service menu. The technician will call the order in to the dietary office in the evening and specify an arrival time for breakfast. Breakfast should arrive a half an hour after the volunteer wakes up. If the volunteer is not staying the next day for an MSLT, the volunteer has a choice of ordering from the menu for room service delivery or receiving a meal voucher to be redeemed in the cafeteria. The earliest meal service will deliver breakfast is 7:15 am. The cafeteria opens at 6:00 am on weekdays and 6:30 am on the weekends. If the volunteer is an early riser, he/she may choose to go to the cafeteria early instead of waiting for the food to be delivered to the room. If the volunteer chooses to receive a voucher, inform the GCRC nurses. The morning GCRC nurse will give the voucher to the volunteer. If the volunteer wakes up earlier than planned and had ordered a breakfast tray, the tray should be cancelled and a voucher issued.

C. Paperwork explanation

1. Bedtime / Rise time - Ask the volunteer what time he/she would like to go to bed and what time he/she would like to wake up. The process in the morning takes an hour from taking off the electrodes and having the blood drawn to eating and getting ready.

2. Consent form – Have the volunteer read over the consent form and sign the back if they agree. The consent form will explain the overall evening process. There is an optional blood draw in the morning. There is also an optional genetic analysis of the blood, which should be explained to the volunteer. To opt out of the blood draw or genetic analysis, an additional signature is needed on the back of the consent form. The volunteer should read the consent form over first and be given an opportunity to ask questions.

3. Questionnaires – Have the volunteer fill out all questionnaires after reading and signing the consent form. The technician will periodically check to see if the volunteer has any questions.

IV. GCRC nurse interview

A. After the volunteer has signed the consent form, the technician will paperclip the consent form to the admissions paperwork and blue chip and give it to the GCRC nurse.

B. Let the nurse know that the volunteer has consented and is now ready to be administered the health interview. Inform the volunteer that a nurse will be entering the room to give a health interview.

V. Seated blood pressures

After the GCRC nurse administers the health interview and the volunteer has been seated for 5 minutes, take two blood pressures on the left arm with two minutes in between each blood pressure.

VI. Review paperwork

As the volunteer completes the questionnaires, read over the questionnaires and review for completeness. Write down any missed questions on the data collection checklist. Ask the volunteer each missed question during supine blood pressures.

VII. Electrocardiogram

A. When the volunteer has finished filling out the questionnaires, page ECG and let the technician know the volunteers are ready to have their electrocardiograms administered. Time this so both volunteers have completed their questionnaires and ready at the same time.

B. When the ECG technician comes to the sleep research lab, give him/her the ECG disk and paperwork. Tell the ECG technician which room to enter first.

C. When the ECG technician is finished administering the other electrocardiograms, obtain a copy of each ECG printout and the ECG disk. Look over the printouts. If they are abnormal, check to see if it fits the ECG medical alert criteria and follow the directions specified. (*See Medical Alert Protocol and Procedures*)

VIII. Physiological Measurements

A. Supine blood pressures (*See Blood Pressure Measurement protocol*)

1. The volunteer must be supine for five minutes with his/her shoes and socks off before the technician can start the blood pressures.
2. Take two blood pressures on each arm and each ankle with two minutes in between each blood pressure after the volunteer has been resting on his/her back for at least five minutes. The supine blood pressures are obtained with an ultrasound Doppler. Use the appropriate cuff size for each arm and ankle.

B. Body Habitus (*see Body Habitus Measurements protocol*).

1. Measure the volunteer's head, neck, waist and hips to the nearest 0.5 centimeters.
2. Measure skinfold on the volunteer's triceps, biceps, suprailiac, and subscapular in millimeters.
3. Measure the volunteer's weight in kilograms and height in centimeters.

IX. Prepare for bed

A. After the electrocardiogram and body habitus measurements, ask the volunteer to prepare for bed. Inform the volunteer to not put moisturizer on his/her face or legs. It interferes with good adhesion of the electrodes.

B. Volunteer should eat his/her snack if not already eaten.

X. Electrode hook-up

A. When the volunteer is ready for bed, apply electrodes, respiratory bands, and snore microphone. Check electrodes with the impedance meter.

B. Thirty minutes before the volunteer wants to go to bed, have the volunteer lie down in bed and connect the jackbox to the input cable. Attach the oximeter probe, oral/nasal flow monitor, nasal pressure monitor, body position monitor and respiratory oscillator. If the volunteer is wearing a CPAP machine, use a flat two-channel oral/nasal flow thermistor. A nasal pressure cannula cannot be used for CPAP wearers.

C. Turn off the alarm on the oximeter by pushing the alarm silence button three times within 3 seconds. Decrease the pulse rate tone volume by pushing the down arrow three times.

D. Have the volunteer read and mark the pm sleep evaluation. Record the times and room temperature on the pm sleep evaluation.

XI. Calibrations

A. Explain the bio-calibrations to the volunteer. Demonstrate the iso- maneuver.

B. Do machine calibrations by pressing the CAL button. Make sure that the electrode selector panel is set to a 50uV calibration signal. Check that the cal signal is equal in all channels. Increase the gain on any AC channel tracings that are too low, and decrease the gain on any tracings that are blocking.

C. Select the **bio-cal** button on the computer screen until it is highlighted and blinking. By communicating through the intercom system, talk through the bio-calibrations with the volunteer. When finished, click the **bio-cal** button off. See *Calibrations Procedures*.

XII. LIGHTS OUT

- A. After calibrations, explain to the volunteer that he/she can sleep on any side and if he/she needs anything, please speak up and the overnight technician will respond. Turn the room lights out from the control room and mark LOUT on the computer. Make an entry in the comment field if the volunteer is a CPAP user – (used in study or not used in study), and if a two-channel thermistor was used on any volunteer. Indicate in the comment field if snoring was heard and if events were seen. Make sure to put up a sign in the hallway to indicate a sleep study is in progress and change the sign on the volunteer’s door to say, “do not enter, sleeping or changing.”

XIII. OVERNIGHT MONITORING

- A. Manually enter all body position changes to ensure body position data in the event that the body position monitor fails.
- B. When volunteer needs to use the bathroom, enter annotation “To Bathroom” on the recording. Do not stop the recording.
- C. Enter the room without putting on overhead lights. Use the bathroom light and night light over the bed.
- D. Disconnect oximeter, RespiTrace oscillator, nasal pressure cannula, body position monitor and jackbox. Hang the jackbox over the volunteer’s shoulders and lead to the bathroom. Reconnect all monitors and plug in jackbox after returning to bed. Turn off all the lights.
- E. Check in the control room on the monitor that all signals are working. Enter annotation “Back from Bathroom” on the recording.

XIV. Overnight Timeline

PM Procedures for one volunteer. (For two volunteers, increase time accordingly. 2nd tech arrives at 8:00pm and some procedures overlap between techs and volunteers.)

Arrive at information desk	6:30 pm	
Admissions, transfer to unit	6:40 pm	10 min.
Overview, settle-in, consent form	6:50 pm	10 min.
CTRC unit administration	7:00 pm	10 min.
History and physical-CTRC nurse	7:10 pm	45 min. 1 st volunteer
Neuropsych testing	7:10 pm	45 min. 2 nd volunteer
Questionnaires	7:55 pm	45 min. minimum. (Some volunteers can take up to 90 min. to complete.)
BP and Body Habitus	8:40 pm	15 min.
Snack, prepare for bed	8:55 pm	10-15 min.
Electrode and monitor hookup	9:10 pm	45 min.
In-bed monitor hookup and final check	9:55 pm	10 min.
Calibrations	10:05 pm	10min.
Lights Out	10:15 pm	

Questionnaires are checked and double-checked for errors during gaps in

procedures as time permits.

AM Procedures

Lights On, calibrations, logbook	Time varies	5 min.
Partial unhook of volunteer for bathroom		5 min.
Remove electrodes and monitors		5-10 min.
AM questionnaire		3 min.
Pay volunteer. Give directions to cafeteria and parking ramp, serve breakfast tray etc.		5 min.
GCRC blood draw		10 min. (can be up to 30 if complications with veins)
Discharge from unit		5 min.
While volunteer showers, dresses and prepares to leave, tech cleans electrodes, completes checklists		30 min.
Room cleaning by Environmental Service		20 min.