Wisconsin Sleep Cohort Study

Manual of Operations

I. Wisconsin Sleep Cohort Study

A) Cohort Selection

This Wisconsin Sleep Cohort was based on a random sample of state employees in Wisconsin. A two-stage sampling scheme, designed to optimize the study's precision by oversampling subjects more likely to have sleep-disordered breathing, was used to construct a cohort representing a wide range of sleep-disordered breathing.

In the first stage, all 30 to 60 years of age who worked for four large state agencies were surveyed about their sleep patterns and other characteristics by a mailed questionnaire. These four agencies were the Department of Corrections, Department of Health and Human Services, and the University of Wisconsin Madison. There was a 74% response rate to this survey.

In the second stage, data from six survey questions were used to classify survey participants as high risk and low risk for sleep apnea.

To determine those at high-risk for sleep apnea, the following survey questions were used:

Q3: According to what others have told you, please estimate how often you snore. 1: Rarely – only once or a few times ever 2: Sometimes – a few nights per month; under special circumstances 3: At least once a week, but pattern may be irregular 4: Several nights (3 to 5) per week 5: Every night or almost every night
Q4: How loud have others said your snoring is? 1: Only slightly louder than heavy breathing 2: About as loud as mumbling or talking 3: Louder than talking 4: Extremely loud – can be heard through a closed door
Q8: According to what others have told you, how often – if ever—do you gasp, choke, or make snorting sounds during sleep? 1: Never 2: Rarely – only once or a few times ever 3: Sometimes – a few nights per month 4: Often –at least once a week but pattern may be irregular 5: Very Often-every night or almost every night
Q9: How often – If ever – have you awakened suddenly with the feeling of gasping or choking? 1: Never 2: Rarely – only once or a few times ever 3: Sometimes – a few nights per month 4: Often –at least once a week but pattern may be irregular 5: Very Often-every night or almost every night
Q10: According to shat others have told you, how often – if ever – do you seem to have momentary periods during sleep when you stop breathing or you breathe abnormally? 1: Never 2: Rarely – only once or a few times ever 3: Sometimes – a few nights per month 4: Often –at least once a week but pattern may be irregular 5: Very Often-every night or almost every night
Q16a: Please check whether or not you have been told by a physician that you had or have Sleep Apnea: Y/N

High Risk were identified as those individuals that reported YES to q16a or (4 or 5) to Q8, Q9, Q10 or 5 to Q3 or (3 to Q8,Q9,Q10 and 4 to Q3) or a 4 to Q4.

High risk were sampled at 100% and Low risk were sampled at a 1:1.5(High/Low Risk) ratio within sex stratified 2 year age groups. Overall response rate for the WSCS has been about 50%.

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B) **Recruitment**

Subjects were mailed a recruitment letter, brochure, and response card. They were given the option of calling our study coordinator directly or returning the response card with their interest in participating in an overnight sleep study. Subjects were mailed up to 4 invitation letters approximately one month apart when no response was received. After 4 letters, it was assumed they were not interested in participating.

All participants scheduled their visit over the phone and completed an intake form and were screened for eligibility.

Reminder letters are sent to all participants prior to their overnight PSG visit.

C) Exclusions

During the phone call, participants are asked if they are currently being treated for any serious medical conditions. They are excluded from participation if: currently pregnant; have had recent upper airway surgery; have a tracheostomy; have had recent cancer surgery; or have unstable or decompensated cardiopulmonary disease. The 2nd stage for exclusions involves a mailed History and Physical Form which must be completed within the 30 days prior to their admission for the study. If the form is not received from the volunteer, they are called and the form is completed over the phone. A copy of this is referred to our study physician for review. If all items on the questionnaire are marked “NO,” or “YES, but is NOT a current serious health problem,” the form is signed and submitted to the General Clinical Research Center. If any item is marked “YES”, the study physician phones the participant for further inquiry about their stability to undergo the protocol and this decision is based on physician discretion.

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II. Data Collection Protocols

A) Overall Overnight Protocol

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1) Set Up
   a) Paperwork
      i. 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.
      ii. Check the lab scheduling calendar to match volunteer with correct folder.
      iii. 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.
      iv. 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.
      v. 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.
      vi. 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

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

i. 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.
ii. 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.
iii. 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.
iv. ECG data is also saved to CD for additional backup.

d) Grass PSG Recorders

i. 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.
ii. Double click Gamma icon on desktop.
iii. Single click "PSG recorder".
iv. 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
v. Verify that all entries are correct and select 'Next'. 'Next' again.
vi. After information is written to the amplifiers, the recording screen will open.

e) Rooms

i. 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.

ii. Place soap, shampoo and conditioner next to the sink. These items are stocked in the lab supply closet.

iii. 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.

iv. 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.

v. Set out paperwork on rolling cart and bedside table.

vi. 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.

vii. 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.

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

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

2) 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.

3) Room, Paperwork, and Meal Explanations

Room explanation:

a) 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.

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

c) 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.

d) 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.
e) 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.
f) Bed – There is a full sized bed in each room with a headboard. More blankets and pillows should be offered to the volunteer.
g) 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.
h) 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.
i) 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.

Paperwork Explanation:

j) 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.
k) 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.
l) 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.

Meal Delivery Service Explanation:

m) 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.

n) 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.

4) General Clinical Research Center (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.

5) Seated blood pressures
   a) After the GCRC nurse administers the heath 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.

6) Review paperwork
   a) 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.

7) 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 Follow up protocol)*

8) Physiological Measurements
   a) Supine Blood Pressures *(See Blood Pressure Measurement protocol)*
      i. The volunteer must be supine for five minutes with his/her shoes and socks off before the technician can start the blood pressures.
      ii. 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)*
      i. Measure the volunteer's head, neck, waist and hips to the nearest 0.5 centimeters.
      ii. Measure skinfold on the volunteer's triceps, biceps, suprailiac, and subscapular in millimeters.
      iii. Measure the volunteer's weight in kilograms and height in centimeters.

9) 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.

10) 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.

11) 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)*

12) 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."

13) 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.

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B) Seated Blood Pressure

1) Seat the subject in a quiet, calm environment with legs uncrossed, both feet on the floor, back well-supported and a bared arm resting on a standard table or other support so the midpoint of the upper arm is at the level of the heart.
2) Estimate the circumference of the bare left upper arm at the midpoint between the shoulder and the elbow, by inspecting or tape measuring, and select an appropriate cuff. The bladder inside the cuff should encircle 80% of the arm.
    a) For an arm circumference of 22-26 cm, use a small adult cuff (12x22 cm)
    b) For arm circumference of 27-34 cm, use a regular adult cuff (16x30 cm)
    c) For arm circumference of 35-44 cm, use a large adult cuff (16x36 cm)
    d) For arm circumference of 45-52 cm, use an adult thigh cuff (16x42 cm)
3) Place the cuff so that the midline of the bladder is over the arterial pulsation, then wrap and secure the cuff snugly around the subject's bare upper arm.
4) The lower edge of the cuff should be 2.5 cm above the antecubital fossa where the head of the stethoscope is to be placed.
5) The subject should have rested for about 5 minutes before the first reading.
6) The subject should be instructed not to talk during the measurement procedure.
7) Palpate the radial pulse.
8) Inflate the cuff rapidly to 70 mm Hg and then by 10 mm increments while palpating the radial pulse. Note the reading at which the pulse disappears and subsequently reappears during deflation.
9) At pulse obliteration, the palpated systolic pressure is established.
10) Rapidly deflate the pressure system and elevate the arm to disengorge it of blood.
11) Palpate the brachial artery on the inner side of the arm, just about the elbow and below the base of the cuff.
12) Place the stethoscope bell lightly but firmly over the palpated brachial artery
13) Inflate the bladder rapidly and steadily to a pressure 20-30 mm above the level previously determined by palpation, then allow the bladder to deflate at 2-3 mm/sec while listening for the appearance of the Korotkoff sounds.
14) Note the systolic blood pressure at the onset of Phase 1 Korotkoff sounds.
15) Continue to deflate the cuff at 2-3 mm each second.
16) Note diastolic 4^{th} phase pressure at the onset of Phase 4 Korotkoff sounds (muffling).
17) Note diastolic 5^{th} phase pressure at the onset of silence after muffling.
18) After the last Korotkoff sound is heard, the cuff should be deflated slowly for at least another 10 mm to ensure that no further sounds are audible, and then rapidly and completely deflate; the subject should then be allowed to rest for 30 seconds.
19) Record systolic and diastolic phase 5 BP.
20) Two readings of the above should be taken at intervals of at least 2 minute and recorded.
21) If there is a greater than or equal to 10 mm Hg difference (systolic) or greater than or equal to 5 mmHg difference (diastolic) between the first and second readings, additional (1-2) readings should be obtained.

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C) Ankle and Arm Blood Pressures

1) Have the patient lie in a supine position with shoes, socks and stockings removed for at least 10 minutes prior to obtaining blood pressure measurements.
2) Apply the blood pressure cuff snugly on the upper arm with the lower edge of the cuff 1 inch above that antecubital fossa. Usually the cuff that is the appropriate size for the patient's arm will also be suitable for the ankle pressure measurement. In the rare instance that upper arm and ankle pressures are markedly different, choose cuff sizes that are appropriate for each site.
3) Apply a 1-2 centimeter ribbon of Doppler gel to the antecubital area. Be sure to use enough gel.
4) Turn the Doppler probe on and place it at the antecubital area at approximately a 60-degree angle to the surface of the skin. Move the probe around until the clearest arterial pulse sounds are heard and keep the probe at that position.
5) Inflate the blood pressure cuff to approximately 20 mm Hg above that numerical reading where the pulse sounds cease.
6) Deflate the cuff at a rate of 2 mm Hg per second until the first arterial pulse sound is heard. When this number is determined, deflate the cuff completely and record this systolic reading. Repeat the procedure to obtain a second arm reading. Remove the gel from the patient's skin with a tissue.
7) Apply the same blood pressure cuff snugly to the ankle on the same side of the body.
8) Palpate the area around the medical malleolus to find the posterior tibial (PT) arterial pulse.
9) If this pulse is palpable, apply a 1-2 centimeter ribbon of Doppler gel to the area. If there is no palpable pulse, apply gel to the general area, turn on the Doppler probe, and move the probe around until the clearest arterial sound is heard. Keep the probe in that position. Continue inflating the blood pressure cuff as before, followed by deflation and reading (Steps 5-6). Repeat the procedure for a second ankle reading.
10) Apply the blood pressure cuff to the opposite ankle and record a set of the PT pressures as before (Steps 8-9).
11) Then repeat steps 2-6 on the other arm twice to obtain 2 brachial readings.
12) Measurements should be noted in the measurement forms.
13) If there is a greater than or equal to 10 mm Hg difference between the first and second readings, additional (1-2) readings should be obtained.
14) Some subjects, particularly some elderly and diabetic individuals, have calcification in their arteries that prevents occlusion of flow by the pressure cuff. This will cause an abnormally high reading. Typically any reading greater than 1.50 is considered abnormal. Such people should be referred for additional testing in a vascular laboratory.

HELPFUL HINTS

- Follow the instructions specific to the Doppler probe you are using.
- Be sure to use enough gel.
- Use a cuff size that is right for both arm and ankle of the patient.
- Be sure you're centered on the pulse when you take the reading; if you're off to the side, the reading will be low.
- Be aware of known diabetics with calcified vessels and abnormally high ABI.
- In a small percentage of patients, one of the ankle pressures will be nondetectable; use the detectable pressure for calculation the ABI.

Subjects with and ABI of 0.90 or less are diagnosed as having PAD and considered at increase risk for cardiovascular ischemic events. Prompt investigation and risk-reducing treatments are then warranted.

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D) Body Habitus and Weight Measurements Protocol

1) Height and Weight
    a. Record height (without shoes) to the nearest cm. on mechanical beam scale with participant facing outward and measuring bar perpendicular to floor.
    b. Record weight to the nearest 0.5 kg. on mechanical beam scale. Indicate on measurement sheet if weight was obtained on the digital platform scale on those participants over 300 lbs.
2) Body Habitus Measurements

    Take two (2) measurements of each site and record to the nearest 0.5 cm. When taking body measurements make sure the tape is not twisted and is kept in the horizontal plane.

    a. Head Circumference
        i. Position the tape slightly above the eyebrows in a horizontal plane to the back of the head, measuring the maximum circumference. Make sure not to include large amounts of hair and hair accessories under the tape. Pull tape slightly to compress hair and record measurement to the nearest 0.5 cm. Make sure the tape is not twisted and it completely parallel around the head.
    b. Neck
        i. With participant sitting or standing erect, measure below “Adam’s Apple” at the smallest circumference of neck with tape perpendicular to the long axis of the neck.
    c. Waist
        i. With participant standing erect with arms at side and abdomen relaxed, measure at the smallest circumference near the navel and above the pelvis at the natural waistline. If no obvious waist, measure at the navel.
    d. Hips
        i. Measure at largest circumference over the buttocks with participant standing erect with arms at side.

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E) Blood Draw Protocol

NPSG Tubes drawn and analysis

- Blood is drawn by a trained nurse in the Clinical and Translational Research Core of the UW Hospital. (if consented). All blood is fasting and is obtained the morning after the overnight PSG. The table below summarizes the blood samples:
- One or two tubes consumed and (3) tubes stored – if full consent (consent option 1)
- One or two tubes consumed and (0) tubes stored – if not consenting to the genetic analysis

Sample	Amount	Analyzed for:	Consumed for analysis or stored
Blood serum	5 ml SST	Magnesium, lipid panel ELDL, creatinine, uric acid, potassium, glucose, C-reactive protein	consumed
Blood serum	5 ml SST	Women <60 only - FSH and LH	consumed
Blood serum	5 ml SST	future analysis	stored
Plasma WBC	10 ml ACD 10 ml ACD?	leptin, ghrelin, TNF-a DNA	stored stored

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F) Polysomnography

1) Resources

a) Description and Location:

The Sleep Research Laboratory is part of the Clinical and Translational Research Core of the University of Wisconsin. The Research Laboratory is in a dedicated wing of the CTRC unit in University of Wisconsin Hospital and Clinics. The Sleep Research Lab consists of two sleep rooms and a control room. The sleep rooms are used almost exclusively by the Wisconsin Sleep Cohort Study, but are also available for other researchers.

b) Equipment:

[6/2000-10/2009]: Heritage System, Grass - Telefactor

Each sleep room is served by a single-bed Grass-Telefactor Heritage digital sleep system. The systems have 16 channels, 8 selectable and 8 fixed, with 4 DC coupled auxiliary inputs. Both systems are equipped with 15A54 research amplifiers having a bandwidth of 0.5Hz-6kHz.

[10/2009 – current]: Comet Lab Based system, Grass Technologies

Each sleep room is served by a single-bed Grass Technologies Comet Lab - based digital sleep system. The systems have 40 AC channels, 31 referential and 9 bipolar, with 8 DC coupled auxiliary inputs. Both systems are equipped with AS40 research amplifiers having a bandwidth of 1.0Hz-100Hz.

- In addition to the two recording systems, the control room also has a reviewer station for data analysis. All systems are networked, allowing for off-site review and analysis.
- The two sleep rooms and control room are equipped with state-of-the-art video and audio monitoring. Input/output connections between sleep room and control room are made through in-the-wall connector panels for increased assurance of optimum signal-to-noise ratios.
- Polysomnography is obtained from EEG scalp electrodes, electrooculogram, EMG of chin and legs, ECG, snore microphone, airflow from Dymedix nasal-oral thermistor, Pro-Tech nasal pressure transducer, breathing effort from Pro-Tech zRIP inductance plethysmography summation systems, and oxygen hemoglobin from the Ohmeda 3900 oximeter using a 3-second averaging rate.

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2) Electrode Placement

Measurement and location of EEG electrodes are based on the International 10-20 System of Electrode Placement.

a) Electrode application procedures.

i. All electrode sites are first prepped with Nuprep on a cotton swab. Nuprep should be wiped away with alcohol when used on bare skin to ensure proper adhesion.

ii. Electrodes on the scalp are applied by placing Elefix under the disc of the electrode and placing on the site, pushing down to spread the paste. Apply EC2 cream over the top of the disc and cover with a gauze square. Again push down lightly to spread the paste. The EC2 cream will harden in about 15-30 minutes. Applying air to the electrode will shorten the drying time. Place Cover-Roll tape over reference electrodes on the mastoid bone to ensure adhesion.

iii. Bio-potential electrodes are used on the face and applied with an electrode collar. Remove the white tab from the electrode collar and apply electrode gel with a syringe and stub adapter to the metal part of the electrode. Very little gel is needed. Position the electrode in place. Cover electrode with Cover-Roll tape.

iv. ECG and Leg electrodes are snap leads and used with self-adhesive, pre-gelled Huggables snap electrodes. Prep the skin vigorously with Nuprep, wipe with alcohol, and position electrode in place. Cover each electrode with Transpore or Microporetape. On men use Co-Flex tape instead of Transpore over leg electrodes to prevent hair pulling when removing.

v. Check electrode impedance by plugging in the electrodes into the jackbox and the jackbox into the impedance meter. Check that the k ohm setting is at 5. Depress each electrode site. A red light indicates that the impedance is over 5 k ohms, and the electrode site should be re-prepped and the electrode reapplied or replaced. Electrodes for recording EMG signals can be over 10 k ohms and still produce an artifact-free signal.

b) NPSG Electrode Placement

i. EOG (electrooculogram)

a) Left eye (L EOG) – Place electrode 2 cm to the left and 2 cm down from the outer canthus of the left eye.
b) Right eye (R EOG) – Place electrode 2 cm to the right and 2 cm up from the outer canthus of the right eye.

ii. EEG (electroencephalogram)

a) Ground electrode is placed at CZ.
b) Central electrodes are placed at C3 and C4
c) Occipital electrodes are placed at O1 and O2
d) Reference electrodes, A1 and A2, are applied to the mastoid bone behind each ear.

iii. EMG (electromyelogram)
   a. Place an EMG electrode on the submental muscle under the chin and one EMG electrode on each side of the face over the mandibular muscle. Ask the volunteer to clench his/her teeth and feel where the muscle is flexed.
   b. A pair of leg electrodes are placed over the anterior tibialis of each leg. To find the correct position, have the volunteer flex his/her big toe and feel for the flexion.

iv. ECG (electrocardiogram)
   a. Place a pair of electrodes, one on each side of the body on a flat surface right below the notch of the collarbone.

v. Monitors and sensors
   a. Respitrace: Place band around chest and one around the abdomen with velcro closure in front. Tape down bands to sleepwear using Micropore tape. Chest band is plugged into white wires of transducer cable, abdomen is plugged into black wires. Oscillator is taped to the chest band.
   b. Snore mic: Snore mic is taped at a point below the microphone to the volunteer's forehead. It also can be placed near the trachea with the amplifier gain turned down.
   c. Body position sensor: The body position sensor is taped to the oscillator or on the chest band on a flat surface of the center of the body. The arrow on the sensor should point up to the head.
   d. Airflow and nasal pressure:
      i. Use the Dymedix disposable airflow sensors on all volunteers except those men with mustaches or those using CPAP. Wire ends of sensor are plugged into the adapter cable which plugs into the jackbox.
      ii. For CPAP users, use the SleepMate flat sensor with adapter cable.
      iii. For men with mustaches, use the Pro-Tech reusable 2-channel airflow sensor.

iv. Use a nasal cannula for the Pro-Tech nasal pressure transducer (except for CPAP wearers), placing it over the top of the airflow sensor. Tape cable wires to face left and right of nose.

c) Oximeter: Attach oximeter probe to middle or ring finger, placing the red light over the mail bed. Secure with Co-flex tape using several layers to obscure the light. Pinch the top to seal the tape. Tape the cable wire using a slack loop to the back of the wrist.

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3) Airflow Sensor Usage/Jackbox Placement Protocol

a) Use Dymedix disposable sensors (oral/nasal) for all volunteers, except those with mustaches or CPAP units. Plug sensor into connect cable and cable into jackbox in Channel 10 (Blue – G1, White – G2).
b) Volunteers with mustaches: Use Protech 2 channel thermistor
    i. Nasal- Blue in G1, Black (ground) in G2 in channel 9
    ii. Oral – While in G1, Black in G2 in Channel 10
c) Volunteers with CPAP: Use SleepMate sensor with connect cable
    i. Cut End of sensor is Nasal. Plug Red end of connect cable and other end of cable in G1 in hannel 9. Black (ground) into G2 in channel 9
    ii. Plug Oral (uncut end) into blue end of connect cable and other end into G1 in Channel 10. Lack (ground) into G2 in Channel 10.

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4) Grass Recording Montage Information / Electrode Visual

Grass Comet Lab Based System (2009-present)

edf channel #	channelName	type	input1	input2	samplingRate	lowFilter	HighFilter	Comment	Make / Model
E1	Left EOG	EOG	LEOG	M2	200	0.3	35		
E2	Right EOG	EOG	REOG	M1	200	0.3	35		
F3_M2	Left Frontal EEG	EEG	F3	M2	200	0.3	35		
Fz_M2	Frontal EEG	EEG	FZ	M2	200	0.3	35	FZ added 6/2013	
Cz_M2	Central EEG	EEG	CZ	M2	200	0.3	35	CZ added 6/2013	
C3_M2	Left Central EEG	EEG	C3	M2	200	0.3	35	C4 also collected, re-referenced when needed	
Pz_M2	Parietal EEG	EEG	PZ	M2	200	0.3	35	PZ added 6/2013	
O1_M2	Left Occipital EEG	EEG	O1	M2	200	0.3	35	O2 also collected, re-referenced when needed	
cchin_l	Linked Center and Left Chin EMG	EMG	Chin1	Chin2	200	10	70	Chin3 also collected and re-referenced when needed	
lleg_r	Linked Left & Right Leg EMG	Leg EMG	LLEG1	RLEG1	200	10	70	Leg movements, we also recorded LLEG2 and RLEG2 and re-referenced when needed	
ECG	ECG	EKG	EKG1	EKG2	200	0.3	35		
Snore	SNORE	microphone			200	10	70	Snore Microphone	Pro-Tech snore sensor
flow	Airflow	thermister			200	0.1	15	Nasal and oral airflow thermister	Dymedix disposible oral nasal airflow sensor
nas_pres	Nasal Pressure	transducer			200	0.1	15	Nasal Pressure transducer	Pro-tech nasal pressure transducer
thorax	Thoracic IP	ZRIP - Effort			200	0.1	15	Respiratory inductance plethysmography	Pro-Tech Z-Rip inductance plethysmography summation system
abdomen	Abdominal IP	ZRIP - Effort			200	0.1	15	Respiratory inductance plethysmography	Pro-Tech Z-Rip inductance plethysmography summation system
sum	IP Sum	ZRIP- Effort			200	0.1	15	Respiratory inductance plethysmography	Pro-Tech Z-Rip inductance plethysmography summation system
position	Position	Position			200			Body Position	Natus Neurology DC body position sensor
SpO2	SpO2	oximeter			200			Sp02 (calibrated)	Ohmeda 3900 Oximeter with a 3 second averaging rate

Grass Heritage System (2000-2009)

edf channel #	channelName	type	input1	input2	samplingRate	lowFilter	HighFilter	Comment	Make/Model
E1	Left EOG	EOG	LEOG	A2	100	0.3	30		
E2	Right EOG	EOG	REOG	A1	100	0.3	30		
C3_M2	Left Central EEG	EEG	C3	A2	100	0.3	30	C4 also collected, re-referenced when needed	
O1_M2	Left Occipital EEG	EEG	O1	A2	100	0.3	30	O2 also collected, re-referenced when needed	
chin	Chin EMG	EMG	EMG 1	EMG 2	100	10	30	EMG 3 also collected and re-referenced when needed	
lleg_r	Linked Left & Right Leg EMG	Leg EMG	LLEG1	RLEG1	100	10	30	Leg movements, we also recorded LLEG2 and RLEG2 and re-referenced when needed	
Snore	SNORE	microphone			100	3	30	Snore Microphone	Pro-Tech snore sensor
ECG	ECG	EKG	ECG1	ECG2	100	3	30		
nasalflow	Nasal Airflow	thermister			100	0.1	30	Nasal Airflow Thermister. Sometimes this channel was Nasal and Oral Airflow combined	Dymedix, Protech or SleepMate sensor
oralflow	Oral Airflow	thermister			100	0.1	30	Oral Airflow Thermister. Sometimes this channel was Nasal and Oral Airflow combined	Dymedix, Protech or SleepMate sensor
nas_pres	Nasal Pressure	transducer			100	0.1	30	Nasal Pressure	Pro-tech nasal pressure transducer
thorax	Thoracic IP	Effort			100			Respiratory inductance plethysmography (calibrated)	Pro-Tech Z-Rip inductance plethysmography summation system
abdomen	Abdominal IP	Effort			100			Respiratory inductance plethysmography (calibrated)	Pro-Tech Z-Rip inductance plethysmography summation system
sum	IP Sum	Effort			100			Respiratory inductance plethysmography (calibrated)	Pro-Tech Z-Rip inductance plethysmography summation system
position	Position	Position			100			Body Position (calibrated)	Natus Neurology DC body position sensor
SpO2	SpO2	oximeter			100			Sp02 (calibrated)	Ohmeda 3900 Oximeter with a 3 second averaging rate

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5) **Calibrations:** The purpose of doing calibrations, both machine and biophysical, is to validate the integrity of the input data. The following procedure should be followed after hookup and plug-in to the Grass system.

a) Check that there is data coming in on all channels and the data is artifact-free

i. EOG and EEG channels*

1. 60 Hz artifact or electrode popping
2. Do impedance check on Grass system. Reapply electrode if necessary.

ii. Airflow Channels

1. If signal amplitude is low, first try repositioning the sensor. Then increase gain on the Grass.
2. If airflow is not in phase with Respitrace inspiration and expiration, reverse plug-in in jackbox or invert polarity on Grass.

iii. Nasal Pressure*

1. Hit <gain set> on Nasal Pressure remote box. Hold for 3 seconds. Gain will automatically adjust to individual's pressure.
2. If amplitude decreases during the night's study, hit <gain set> again, or reposition cannula if volunteer wakes up.
3. If no signal, check the battery in unit and replace if necessary.

iv. Respitrace*

1. Tighten the Velcro straps on the oscillator and transducer cable before every study.
2. Calibrate the Respitrace box according to operating instructions. When finished, set button to <Operate>.
3. Check that there is no noise or artifact in the channels.
4. Noisy signal may indicate a bad belt or loose connection. First check that the belt pins are plugged in all the way into the transducer cable.
5. If noise persists, change the belt.
6. If the noise still persists, change the following the this order.
7. Transducer cable
8. Cable from oscillator to wall connector.
9. Any persistent problem beyond this point, contact Laboratory Manager.

v. Oximeter*

1. Turn down pulse volume after turning on unit. Turn off alarm.
2. Check that signal is coming into Grass and that indicators on Grass SaO2 channel match what is seen on the oximeter.
3. If digital value seems too low (below 90), reposition finger probe.
4. If there is no signal coming in, check that cable between oximeter and wall connection is plugged in.
5. If still no signal, replace BNC cable from Grass system to wall in control room.

b) Do not start the recording on the Grass system until all of the above procedures have been completed.

c) After starting the recording, begin Bio-Calibrations. After each bio-calibration, check the appropriate channel to see the response. If no response, repeat the bio-cal. Reposition any sensors if no response is seen.

i. Iso-maneuver

1. After instructing the volunteer on the iso-maneuver procedure, have the volunteer begin by twice taking in a deep breath and exhaling. After the second exhalation, have the volunteer hold his/her breath, apply the nose clips, and with mouth tightly closed make paradoxical movements of the chest and abdomen, simulating an apneic event. Check the computer monitor and whichever channel (Rib Cage or Abdomen) is lowest in amplitude, adjust the gain on the Respitrace calibration box until it is equal to the other and the SUM is as flat as possible. If both Rib Cage and Abdomen are low, adjust both until they are equal and the SUM is flat.
2. Once gain has been adjusted, lock down the gain button for each channel. Once the gain has been set, it should not be adjusted unless absolutely necessary to see the amplitude of the signal.

ii. Perform the remaining bio-calibrations:

1. Eyes closed for 15 seconds
2. Eyes open for 15 seconds
3. Move eyes up and back to center
4. Move eyes down and back to center
5. Move eyes left and back to center
6. Move eyes right and back to center
7. Blink several times
8. Clench teeth and relax
9. Move tongue back and forth in mouth
10. Flex left big toe
11. Flex right big toe
12. Count from 1 to 10
13. Simulate snore sounds
14. Put on nose clip and breathe through mouth
15. Remove nose clips, close mouth and breathe through nose
16. Take a deep breathe, exhale, and hold breath as long as possible
17. Record peak SAO2 and lowest value as a user-defined annotation.
18. Close eyes and start steady state for 2 minutes
19. Open eyes and start steady state for 2 minutes
20. End steady state

***Data channels critical to the analysis process**. Loss of data in these channels may cause data to be un-scorable.

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6) Scoring Guidelines

a) SLEEP STAGING

i. Follow rules in Rechtschaffen and Kales:

Sleep Stage	EEG	EOG	EMG
Stage W	Alpha activity and/or low voltage mixed frequencies	REM's and eye blinks	High tonic EMG
Stage 1	Relatively low voltage, mixed frequency EEG predominantly in the 2-7 Hz range, at about 50-75 uV. Vertex sharp waves up to 200 uV	Slow eye movements of several secs duration. No REM's.	Tonic EMG levels below those of Stage W.
Stage 2	Sleep spindles and/or K-complexes (0.5 sec duration), and absence of sufficient high amplitude to define presence of Stage 3 or 4.		
Stage 3	20% but not more that 50% of epoch consists of 2 Hz or slower waves with amplitude greater than 75 uV peak to peak. Sleep spindles may or may not be present.		
Stage 4	More than 50% of epoch consists of 2 Hz waves or slower with amplitudes > 75 uVpeak to peak. Sleep spindles may or may not be present.		
Stage REM	Relatively low voltage, mixed frequency EEG. Presence of "saw tooth" waves in vertex and frontal areas. Alpha activity that is 1-2 Hz slower than wakefulness may be prominent. Absence of K-complexes and sleep spindles.	Tonic mental-submental EMG at lower level than preceding sleep stage.	REM's

i. SCORING DECISIONS FOR STAGE TRANSITIONS:

1. **Stage W vs Stage 1 -** When amount of record characterized by alpha activity combined with low voltage activity drops to less than 50% of the epoch and is replaced by relatively low voltage, mixed frequency activity, the epoch is scored as Stage 1.
2. **Stage 1 vs Stage 2 -** If less than 3 min of record which would ordinarily meet the requirements for Stage 1 intervene between sleep spindles and/or K-complexes, these intervening epochs are to be scored Stage 2, if there is no indication of arousals or increased EMG activity. If the

interval without sleep spindles or K complexes lasts 3 min or longer, the interval is scored as Stage 1, even if it contains no movement arousal.

3. **Stage 2 vs Stage 3 –** Epoch must have at least 20% (but not more than 50%) high amplitude waves of 2 Hz or slower to be staged as 3. Measurement may be necessary. An attempt should be made to distinguish between spontaneous K complexes and delta waves.
4. **Stage 3 vs Stage 4 –** More than 50% of the epoch must consist of waves 2 Hz or slower and of amplitudes > 75 uV p-p. However, most Stage 4 epochs have the appearance of being completely dominated by this activity. Interval of lower amplitude, faster activity rarely persist for more than a few seconds in Stage 4, but are usually prominent in Stage 3 epochs.
5. **REM start vs REM end – Refer to R& K, Pages 9-11**

b) SCORING OF BREATHING EVENTS

i. APNEAS : No indication of airflow in Nasal Pressure, no detectable breathing pattern in the thermistor, a clear amplitude reduction in effort, followed by an associated desaturation

1. Definition of Apneas:
    1. Obstructive - No indication of airflow by thermocouple and an indication of effort in Respitrace channels.
    2. Central - No indication of airflow by thermocouple and no indication of effort in Respitrace channels.
    3. Mixed – No indication of airflow by thermocouple and areas of no effort followed by effort in Respitrace channels.
2. Scoring Procedure:
    1. Determine if there is flow or no flow

        Criteria for No flow:

        - Does not follow previous pattern of flow **and/or**
        - is <20% of amplitude of the largest previous breath (determined by uV/mm of unclipped air flow sensitivity, if necessary) **and**
        - has an interruption of airflow that is ≥ 10 sec. in duration.
    2. Determine if there is effort or no effort

        Criteria for No effort (from Respitrace):

        - Does not follow previous pattern of breathing **and**
        - has no discernable amplitude of the signal in the Respitrace.
    3. Measure duration of event
        a) Measure from the beginning of the last expiration on the air flow channels to the beginning of the next

inspiration on the air flow channels to determine the 10 second criterion.

b) If 10 seconds, measure the duration of the event from the beginning of the last expiration to the beginning of the next inspiration on the sum channel of the Respitrace that best corresponds to the points of measurement of duration in the airflow channels.
c) If not 10 seconds, determine if the event meets the criterion for a hypopnea : 4% desaturation. If it does not, then the event is ignored and not scored.
d) NOTE: When the event is obviously an apnea and is between 9.5 and 10 seconds, round the duration up to 10 seconds and score.

ii. <u>HYPOPNEA</u>

1. Definition – A discernable decrease in flow in nasal pressure channel and/or thermistor with an associated oxygen desaturation of 4% or greater indicated in the SaO2 channel beginning in sleep.
2. Scoring procedure –
    1. Use the <Event Scoring> display view and at least a 120 second window
    2. Determine a discernable decrease in the SUM channel defined as a >50% decrease in the mean amplitude of the three largest breaths preceding the onset of the event, or a clear reduction in amplitude that is <50% with an associated oxygen desaturation of <u>≥</u> 4%.
    3. Measure the duration of the event

        a) Measure from the beginning of the last expiration on the SUM to the beginning of the next inspiration on the SUM to determine the 10-second criterion by clicking the beginning and end of the event.
        b) If not 10 seconds, delete the event mark.
        c) Mark the desaturation event on the SaO_2 channel following the respiratory event, beginning within 30 sec. of the end of the respiratory event.
        d) Delete the desaturation event for a hypopnea if the desat is <4%
        e) Determine that the desaturation occurs in sleep. Events that begin in sleep and end in wake are always scored. Events that begin and end in wake are never scored.
        f) Mark the beginning and end of the event in the SaO_2 channel corresponding to the desaturation. Duration of desaturation events should not be greater than 120 sec.

4. Mark the corresponding event in the SUM channel as Hypopnea if associated with a desaturation of ≥ 4%
5. Without the presence of an adequate signal in the nasal pressure channel, use the nasal/oral thermistor channel for determination of flow.

iii. Leg Movements

1. Use the <Event Scoring> display view
2. Definition:
    1. A leg movement shall have a minimum to maximum duration of 0.5 to 5.0 seconds and have an amplitude of at least 50% of the subject's voluntary leg flexion are recorded during pre-sleep calibrations.
        a) Example: Pre-sleep calibration of leg flexion = 2 cm. Amplitude of leg movement EMG must be at least 1 cm to be considered.
    2. Movements occurring within 4 seconds of each other are counted as one movement. Movements which are separated by at least 4 seconds are counted as separate movements.
    3. Movements that occur during wake epochs are not counted.
3. Arousals associated with Leg movements
    1. Arousals occurring within 1 second before or after a Leg Movements are marked as LMA

Note: other AHI definitions available upon request (e.g 3 % desaturation)

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7) Data Management Procedures and Policy

a) Unscored, raw data is initially saved to the recorder hard drive. The unscored raw data is transferred from the data recorder to C (UWCTRC server administered by biostat). Unscored, raw data is saved to CD at the completion of the recording in multi-session format.
b) Raw data CDs are labeled and kept in the Sleep Lab.
c) The study is copied to the hard drive of the Reviewer computer and scored. After the report is generated, the technician runs a program to check for errors. All errors are corrected and the report is generated again with the corrections.
d) At the completion of scoring and report generation, the event scoring file, staging file and database variables file generated in the Excel report are saved as tab delimited text files and copied to a preliminary folder. The program to calculate 4% AHI data is performed on the files in the preliminary folder (Grassprelim) and the result is manually entered into the

printed report. These files are deleted from the preliminary folder after the AHI program is run and recorded in the report.

e) The corrected scored study is transferred to C – Unreviewed NPSG Data folder.
f) Scorer enters his/her initials into Scoring Logsheet upon completion of Step D.
g) A review of scoring is completed on a randomly selected group of 20% of the studies. In addition, studies are reviewed that are rated as problematic to score by the scorer (i.e. that contained excessive artifact), those whose AHI was near one of the three cutoffs (5, 15, 30), those studies in which the sleep architecture appears to be outside the expected percentages for each sleep stage, and those studies in which there was less than 4 hours of total sleep time. (see "Criteria for Editing Grass Data")
h) If the study requires editing, the edited database files are regenerated and replace those in the Unreviewed NPSG Data. The reviewer moves the edited study on C (CTRC biostat server) from the "Unreviewed NPSG Data" to the "NPSG Data" folder when complete. The reviewer also moves the studies determined not to need editing to the "NPSG Data" folder.
i) After the reviewer moves the finalized studies into the "NPSG Data" folder, the reviewer enters the study ID and date into the database logsheet entitled, "database_toload." When the studies are loaded into the database, the DBA enters his/her initials into the "database_toload" document. If it is later found that a study that had been loaded has to be reloaded, the study will again be added to the database_toload.txt list (with a note that it had to be changed.)
j) Reviewer enters his/her initials into the Scoring Logsheet upon completion of step nine. The database administrator is notified by email when the transfer has been made. The email will include the date through which the studies are complete. (Ex. All studies are reviewed through 2/10/2009)
k) A CD of scored studies is made when there are enough studies to fill a CD. Entry is made in the Scoring Logsheet of the CD number for each study.
l) The unscored, raw data is deleted from the recorder computer after the scored study is reviewed and saved to CD.
m) Scored data CDs are labeled and kept at Medical Sciences Center in a locked office closet.
n) The "NPSG Data" and "reclassified_studies" folders will solely contain this data: a subdirectory for each subject visit that has the most up to date and best quality data for that study. This will be the only place required to look to find the best data for a study. No combined subdirectories of any type will be created in the NPSG Data and reclassified_studies directories for any purpose.

CRITERIA FOR EDITING GRASS DATA

- Staging – Changes in >2 consecutive epochs between wake and sleep, REM and non-REM, SWS and Stage 1 or 2
- Events – Changes are made based on percentage of mis-scored events to the total number of events, and whether the AHI borders on one of the statistical groups. The following types of scoring errors are edited:
    - Misclassifications (apnea vs. hypopnea)
    - Incorrectly marked durations
    - Incorrect associations (desat does not match respiratory event)
    - Missing events
    - Incomplete events (respiratory or desat event missing)
    - Non-events (no clear indication of change in SUM and artifact in SaO2)
    - Two events scored as one and visa-versa.

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8) Protocol for CPAP Users

a) Ask if they are able to sleep without their CPAP unit for the study.
b) If they cannot, indicate on the record, the log sheet, **and** the front of the folder that CPAP was used. On the record and log sheet, record the level.
c) If they can sleep without CPAP, they should do so. Indicate on the front of the folder that they are a CPAP user and that they did **not** use it for the study.

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9) Medical Follow up protocol

a) Sleep Disordered Breathing

i. All studies with an apnea-hypopnea index >30 will receive a follow up contact from the Medical Director. Copies of previous sleep studies and the intake form with contact information will be provided to the Medical Director. A copy of the contact letter to the volunteer from the Medical Director will be returned and filed with the volunteer's folder.

ii. In some cases where the AHI is close to 30 and the desaturation index is in the 80 percentile for a significant time during the study, a medical follow up may be indicated and requested by the Lab Manager or Principal Investigator.

iii. Volunteers who have received previous medical follow ups will not receive additional follow ups unless there has been a known change in their medical status.

b) ECG Medical Alert Criteria

i. After a 12-lead ECG has been completed, please note the preliminary diagnosis at the top part of the printout for the following abnormalities:

2nd or 3rd degree AV (atrioventricular) block
Ventricular tachycardia
Any tachycardia above 120 bpm
Any bradycardia below 40 bpm
Acute infarct (or any infarct marked as acute)

i. If any of these diagnoses are noted on the ECG printout, please notify the GCRC nurse to call the appropriate resident or PG-3 on call.

ii. If there are any questionable findings on the printout, do not hesitate to ask the GCRC nursing staff.

iii. NON-EMERGENCY ABNORMALITIES

- If any of the following non-emergent abnormalities appear on the ECG printout at the top of the page, please make a copy of the printout along with the volunteer's intake form and send to Medical Director for medical followup:

Old infarct
ST T-wave changed indicative of possible ischemia
Atrial fibrillation

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III. Data Collection Forms

A) Health Interview Questions

How many cups of coffee or tea, **with caffeine**, do you usually drink in a typical day? __(cups_coffee)

How many cans of cola or other soft drinks, **with caffeine**, do you usually drink in a typical day? _____(cans_cola)

The next section asks about specific medical problems. Please indicate if you have been told *by a doctor within the last 5 years* that you have or have had any of these conditions.

Coronary artery disease? ___Yes ___No (coronary_ynd)
If yes, indicate how many years ago ____ or the year ____ you were diagnosed. (coronary_year)

Atherosclerosis (hardening of the arteries)? ___Yes ___No (atheroscl_ynd)
If yes, indicate how many years ago ____ or the year ____ you were diagnosed. (atheroscl_year)

Irregular heartbeat or arrhythmia? ___Yes ___No (arrhythmia_ynd)
If yes, indicate how many years ago ____ or the year ____ you were diagnosed. (arrhythmia_year)

Heart attack or infarct? ___Yes ___No (heartattack_ynd)
If yes, indicate how many years ago ____ or the year ____ you were diagnosed. (heartattack_year)

Congestive heart failure? ___Yes ___No (congestivehf_ynd)
If yes, indicate how many years ago ____ or the year ____ you were diagnosed. (congestivehf_year)

Angina? ___Yes ___No (angina_ynd)
If yes, indicate how many years ago ____ or the year ____ you were diagnosed. (angina_year)

High blood pressure or hypertension? ___Yes ___No (hypertension_ynd)
If yes, indicate how many years ago ____ or the year ____ you were diagnosed. (hypertension_year)

Stroke? ___Yes ___No (stroke_ynd)
If yes, indicate how many years ago ____ or the year ____ you were diagnosed. (stroke_year)

Diabetes? ___Yes ___No (diabetes_ynd)
If yes, indicate how many years ago ____ or the year ____ you were diagnosed. (diabetes_year)

Emphysema or Obstructive Lung Disease? ___Yes ___No (emphysema_ynd)
If yes, indicate how many years ago ____ or the year ____ you were diagnosed. (emphysema_year)

Thyroid problem? ___Yes ___No (thyroid_ynd)
If yes, indicate how many years ago ____ or the year ____ you were diagnosed.
(thyroid_year)
Asthma? ___Yes ___No (asthma_ynd)
If yes, indicate how many years ago ____ or the year ____ you were diagnosed.
(asthma_year)
Arthritis? ___Yes ___No (arthritis_ynd)
If yes, indicate how many years ago ____ or the year ____ you were diagnosed.
(arthritis_year)
Have you had any of the following procedures?

a. Pacemaker __Yes __ No (pacemaker_ynd)
b. Coronary Artery Stent __Yes __ No (coronary_artery_stent_ynd)
c. Angioplasty __Yes __ No (angioplasty_ynd)
d. Coronary Bypass __Yes __ No (coronarybypass_ynd)
e. Other, Please Explain_____
(other_heart_surgery, other_heart_surgery2)

Please estimate your **usual** consumption of alcoholic beverages:

a. How many cans or bottles of beer might you have per week? _____ (beer_week)
b. How many glasses of wine might you have per week? _____ (wine_week)
c. How many mixed drinks or shots might you have per week? _____ (hard_week)
d. If you do not drink alcoholic beverages at all check here ____ (nondrinker)

Have you ever smoked tobacco regularly? ___Yes ___No (smoke)

Do you currently smoke? ___Yes ___No (smoke_curr) **If no**, when did you quit? _____Year (smoke_quit)

How much do you smoke now, **OR** if you quit smoking, how much did you smoke in the past (*answer <u>all</u> that apply*)?

_____Cigarettes per day **OR** _____packs per week; (packs_week)
_____Bowls of pipe tobacco per day; and (bowls_day)
_____Cigars per day. (cigars_day)

Overall, how many years total, have you been **OR** were you a regular smoker? _____Year
(smoke_years)

Many people have periods of low energy or fatigue, but, **<u>during a typical day</u>** do you experience excessive sleepiness when it is difficult to fight an **<u>uncontrollable urge to fall asleep</u>**? ___Yes ___No
(sleepiness)

<u>The following questions concern your sleep habits.</u>

According to what other have told you or to your own awareness, how often do you snore? (snore_freq)

_1__Never or rarely - only once or a few times ever.
_2__Sometimes - a few nights per month; under special circumstances.
_3__At least once a week, but pattern may be irregular.
_4__Several (3 to 5) nights per week.
_5__Every night or almost every night.
_9__Do not know.

How loud do you think, or have others said, your snoring is? (snore_vol)

_1__Only slightly louder than heavy breathing.
_2__About as loud as mumbling or talking.
_3__Louder than talking.
_4__Extremely loud, can be heard through a closed door.
_9__Do not know.
_8__Does not apply.

According to what others have told you, how often, if ever, do you gasp, choke, or make snorting sounds during sleep? (choke_freq)

__1_Never or rarely - only once or a few times ever.
__2_Sometimes - a few nights per month; under special circumstances.
__3_At least once a week, but pattern may be irregular.
__4_Several (3 to 7) nights per week.
__9_Do not know.

How often, if ever, have you awakened suddenly with the feeling of gasping or choking? (awake_freq)

__1_Never or rarely - only once or a few times ever.
__2_Sometimes - a few nights per month; under special circumstances.
__3_At least once a week, but pattern may be irregular.
__4_Several (3 to 7) nights per week.
__9_Do not know.

According to what others have told you, or to your own awareness, how often, if ever, do you have momentary periods during sleep when you stop breathing or you breathe abnormally? (apnea_freq)

__1_Never or rarely - only once or a few times ever.
__2_Sometimes - a few nights per month; under special circumstances.
__3_At least once a week, but pattern may be irregular.
__4_Several (3 to 7) nights per week.
__9__Do not know.

How many hours of sleep do you usually get during:

a. a workday night? _____#hours (workday)
b. a weekend or nonwork night? _____#hours (weekend)
c. a typical week from daytime or evening **naps**? _____#hours (*Enter 0 if none*) (naps)

About how many minutes does it **usually** take you to fall asleep at night? _____#minutes (tso)

How often, if ever, do you have any of the following problems sleeping? (*Circle one response for each item.*)

0=Never
1=Rarely (once a month)
2=Sometimes (2-4 times a month)
3=Often (5-15 times a month)
4=Almost always (16-30 times a month)

a. Do you have difficulty getting to sleep? (ps_diff)	0	1	2	3	4
b. Do you wake up during the night and have a hard time getting back to sleep? (ps_backsleep)	0	1	2	3	4
c. Do you wake up repeatedly during the night?	0	1	2	3	4

(ps_wakerepeat)

d. Do you wake up too early in the morning and can't get back to sleep? (ps_tooearly)	0	1	2	3	4
e. Do you not feel rested during the day no matter how many hours of sleep you had? (ps_notrested)	0	1	2	3	4
f. Do you find it very difficult to wake up in the morning? (ps_wakeup)	0	1	2	3	4
g. Do you have nightmares or disturbing dreams? (ps_nightmare)	0	1	2	3	4
h. Do you have feeling of excessive daytime sleepiness? (ps_eds)	0	1	2	3	4

Are you satisfied with your **usual** night's sleep (*check one*)? (eval_general)

__1__Most of the time _3__Not usually
__2__Some of the time _4__Never

How satisfied are you with the way you are spending your life (*check one*)? (eval_life)

__1__Completely satisfied
__2__Mostly satisfied
__3__Moderately satisfied
__4___Not very satisfied

In general, would you say your health is (*check one*): (eval_health)

__1__Excellent
__2__Very good
__3__Good
__4__Fair
__5__Poor

For your job, do you work (check one): (type_shift)

__1__Daytime hours _2___ Night shift ___3__Rotating shift __8__Does not apply

Have you had any nasal congestion or stuffiness **<u>today or tonight</u>** (check all that apply)?

__Y,N__Today (nasal_cong_today)
__ Y,N __Tonight (nasal_cong_tonight)
__ Y,N __None (nasal_cong_none)

Have you had surgery that caused your menstrual periods to stop permanently? _____ Yes _____ No (reproductive_surg)

If yes, please provide the following information:

a. Indicate the date of surgery: _____ Month/Year (reproductive_surg_date)

b. Identify the kind of surgery (check one): (reproductive_surg_type)

___1__ Hysterectomy, uterus and both ovaries removed.

___2__ Hysterectomy, uterus and only one ovary removed.

___3__ Hysterectomy, uterus removed, no ovaries removed.

___4__ One ovary removed, uterus and one ovary remain.

___5__ Both ovaries removed, uterus remains.

___6__ Unsure: _____

Please indicate which category listed below best describes your menstrual cycle (check one).

a. _____ I have fairly regular menstrual periods. Enter the onset and ending date of your most recent cycle: _____ Month/Day/Year Onset _____ Month/Day/Year End.

b. _____ My menstrual periods are irregular. Enter the onset and ending date of your most recent cycle: _____ Month/Day/Year Onset _____ Month/Day/Year End.

c. _____ I have no periods at all/menopause. Enter the date of your very last period or indicate how old you were when you had your last period: _____ Month/Year OR _____ Age.

(menopausal_status) 0: Regular periods (a), 1: Irregular periods (b), 2: Periods stopped due to menopause ((c) & reproductive_surg=N), 4: Surgery ((c) and reproductive_surg=Y)
(time_since_last_period) = difference between reported last menstrual period and sleep study date in years

Have you ever taken supplemental hormones for menopause? _____ Yes _____ No
Are you currently taking them? _____ Yes _____ No
(hormone_suppl) C: Current Use, P: Past use, N=Never use

At first visit: How many children do you have? ____
At follow up visits: Have you had any pregnancies since your last sleep study? _____ Yes _____ No
If yes, please indicate how many____
(numpreg)

Have you ever been **told by a doctor** that you have **sleep apnea**? ___Yes ___No
(apnea)
If yes, when was this? _____ Month/Year
(apnea_date)
Were you told you needed treatment? ___Yes ___No
(apnea_need)
If yes, what treatment was recommended? __ (apnea_treatment1, apnea_treatment2, apnea_treatment3)

Did you have the treatment? ___Yes ___No (apnea_treated)

Did the treatment help (*check one*)? __1__Not at all
__2__Helped a little
(treatment_help) __3__Helped moderately
__4___Helped a lot

If you are using the recommended CPAP/BiPAP, please indicate:
a. How many nights per week do you use it? _____ (comp_nights_wk)
1. How many hours per night do you use it? _____ (comp_hrnights)

Commonly Used Summary Variables

(TO BE ADDED)

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B) Zung Depression Scale

Please read each of the following statements and place an X in the box which best describes *how you feel in general from day to day.* (variable name in red, score for each variable in red)

	None or a little of the time	Some of the time	A good part of the time	Most or all of the time
I feel down-hearted, blue, and sad Zung_scored1	1	2	3	4
Morning is when I feel the best Zung_scored2	4	3	2	1
I have crying spells or feel like it. Zung_scored3	1	2	3	4
I have trouble sleeping through the night. Zung_scored4	1	2	3	4
I eat as much as I used to. Zung_scored5	4	3	2	1
I enjoy looking at, talking to and being with attractive women/men. Zung_scored6	4	3	2	1
I notice that I am losing weight. Zung_scored7	1	2	3	4
I have trouble with constipation. Zung_scored8	1	2	3	4
My heart beats faster than usual Zung_scored9	1	2	3	4
I get tired for not reason. Zung_scored10	1	2	3	4
My mind is as clear as it used to be. Zung_scored11	4	3	2	1
I find it easy to do the things I used to do. Zung_scored12	4	3	2	1
I am restless and can't keep still. Zung_scored13	1	2	3	4
I feel hopeful about the future. Zung_scored14	4	3	2	1
I am more irritable than usual. Zung_scored15	1	2	3	4
I find it easy to make decisions. Zung_scored16	4	3	2	1
I feel that I am useful and needed. Zung_scored17	4	3	2	1
My life is pretty full. Zung_scored18	4	3	2	1
I feel that others would be better off if I were dead. Zung_scored19	1	2	3	4
I still enjoy the things I used to do. Zung_scored20	4	3	2	1

Zung_score= sum (zung_scored1-zung_scored20)

If 2 or less missing, the missing score is replaced with the average of all other scores to use in the sum.

Zung_index = 100*(zung_score / 80)

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C) STATE ANXIETY

DIRECTIONS: A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel *right now, that is, at this moment*. There are no right or wrong answers. Do not spend too much time on any one statement, but give the answer which seems to describe your feelings best. (Variable names in red)

	Not at All	Somewhat	Moderately So	Very Much So
1. I feel calm.....	1	2	3	4
2. I feel secure.....	1	2	3	4
3. I am tense.....	1	2	3	4
4. I feel strained.....	1	2	3	4
5. I feel at ease.....	1	2	3	4
6. I feel upset.....	1	2	3	4
7. I am presently worrying over possible misfortunes....	1	2	3	4
8. I feel satisfied.....	1	2	3	4
9. I feel frightened.....	1	2	3	4
10. I feel comfortable.....	1	2	3	4
11. I feel self-confident.....	1	2	3	4
12. I feel nervous.....	1	2	3	4
13. I am jittery.....	1	2	3	4
14. I feel indecisive.....	1	2	3	4
15. I am relaxed.....	1	2	3	4
16. I feel content.....	1	2	3	4
17. I am worried.....	1	2	3	4
18. I feel confused.....	1	2	3	4
19. I feel steady.....	1	2	3	4
20. I feel pleasant.....	1	2	3	4

State _____ % _____ SS _____

state := (sum of scores for individual questions)

scored value is as stated except #1, 2, 5, 8, 10, 11, 15, 16, 19, and 20 are scored 4, 3, 2, 1

If 2 or less missing values, the missing are replaced with the average of all other scores to create summary score.

Individual item scores are available on request.

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D) TRAIT ANXIETY

DIRECTIONS: A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you *generally feel*. There are no right or wrong answers. Do not spend too much time on any one statement, but give the answer which seems to describe how you generally feel. (Variable names in red)

	Not at All	Somewhat	Moderately So	Very Much So
21. I feel pleasant.....	1	2	3	4
22. I feel nervous and restless.....	1	2	3	4
23. I feel satisfied with myself.....	1	2	3	4
24. I wish I could be as happy as others seem to be.....	1	2	3	4
25. I feel like a failure.....	1	2	3	4
26. I feel rested.....	1	2	3	4
27. I am "calm, cool, and collected".....	1	2	3	4
28. I feel that difficulties are piling up so that I cannot overcome them.....	1	2	3	4
29. I worry too much over something that really doesn't matter..	1	2	3	4
30. I am happy.....	1	2	3	4
31. I have disturbing thoughts.....	1	2	3	4
32. I lack self-confidence.....	1	2	3	4
33. I feel secure.....	1	2	3	4
34. I make decisions easily.....	1	2	3	4
35. I feel inadequate.....	1	2	3	4
36. I am content.....	1	2	3	4
37. Some unimportant thought runs through my mind and bothers me.....	1	2	3	4
38. I take disappointments so keenly that I can't put them out of my mind.....	1	2	3	4
39. I am a steady person.....	1	2	3	4
40. I get in a state of tension or turmoil as I thing over my recent concerns and interests.....	1	2	3	4

Trait _____ % _____ SS

trait := (sum of scores for individual questions)

scored value is as stated except #21, 23, 26, 27, 30, 33, 34, 36, and 39 are scored 4, 3, 2, 1

If 2 or less missing values, the missing are replaced with the average of all other scores to create summary score.

Individual item scores are available on request.

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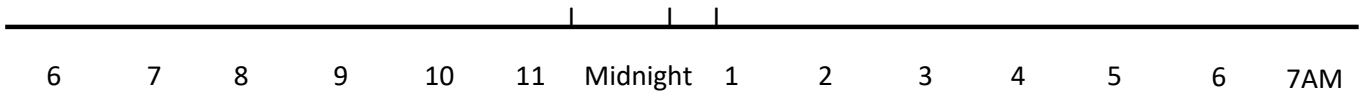
E) Horne Ostberg Questionnaire

(variables and coding in red)

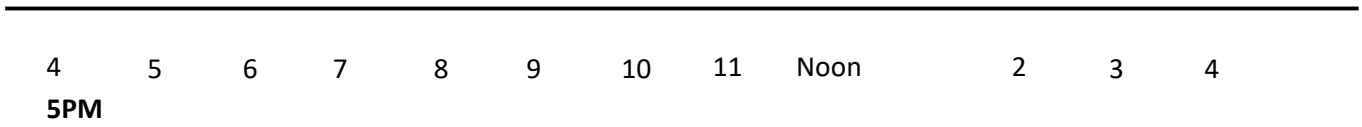
To answer the first two questions, please consider **ONLY** your own "feeling best" rhythm:

I. If you were free of any schedule and could **go to bed** at any time you wanted, what time would that be?

(Mark the time on the scale below)



2. If you were free of any schedule and could **wake and get up** at any time you wanted, what time would that be? *(Mark the time on the scale below. Please note that this scale begins at 3AM.)*



3. If there is a specific time at which you have to get up in the morning, to what extent are you dependent on being awakened by an alarm clock? *(Check one)*

_1_ Not at all dependent

_2_ Slightly dependent

_3_ Fairly dependent

_4_ Very dependent

4. One hears about **"morning"** and **"evening"** types of people. Which one of these types are you? *(Check one)*

_1_ Definitely a "morning " type

_2_ Rather more a "morning" than a "evening" type

_3_ Rather more an "evening" than a "morning" type

_4_ Definitely an "evening" type

5. How easy is it for you to get up in the morning? *(Check one*

1_ Not at all easy

2_ Not very easy

3_ Fairly easy

4_Very easy

6. How alert do you feel during the first half-hour after waking? *(Check one)*

1_Not at all alert 2_ Slightly alert 3_ Fairly alert 4_Very alert

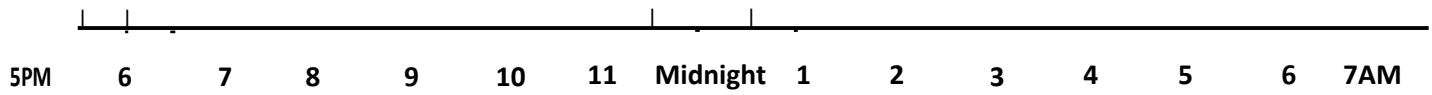
7. How is your appetite during the first half-hour after waking? *(Check one)*

1_Very poor 2_ Fairly poor 3_ Fairly good 4_Very good

8. During the first half-hour after waking, how tired do you feel? *(Check one)*

1_Very tired 2_ Fairly tired 3_ Fairly refreshed 4_ Very refreshed

9. At what time of evening do you feel tired and in need of sleep? *(Mark the time on the scale below)*



10. When you have no work or other responsibilities the next day, what time do you go to bed compared to your usual bedtime? *(Check one)*

*1*_Seldom or never later
2_Less than one hour later
3_1 to 2 hours later
4_More than 2 hours later

Please imagine yourself in the situations described in questions 11. thru 17. Check the answer that you think best describes your reaction.

11. Suppose you decided to join a friend for physical exercise twice each week. Considering your own "feeling best" rhythm. how do you think you would petform if the exercise was scheduled at 7 to 8 AM? *(Check one)*

1_ Would be in good form

2_ Would be in reasonable form

_3__ Would find it difficult

4_ Would find it very difficult

12. Suppose you had to ta1ce a very difficult written test lasting for 2 hours and wanted to be at your very best. Considering your own "feeling best" rhythm, which test time would you choose? *(Check one)*

_1_ 8:00 - 10:00 AM _2_ 11:00 AM - 1:00 PM _3_ 3:00 - *5:00* PM _4_ 7:00 · 9:00 PM

13. If you went to bed several hours later than usual, but there was no need to get up at any particular time the next morning, which of the following experiences do you think you would have? *(Check one)* *doze*

_1_ Will wake up at usual time and **will NOT** fall asleep

_2_ Will wake up at usual time and will doze thereafter

_3_ Will wake up at usual time, but will fall asleep again

_4_ Will not wake up until later than usual

14. Suppose that you have to stay awake between 4:00 and 6:00 AM to carry out a special task. You have no responsibilities the next day. Which one of the following plans for sleeping would suit you best? *(Check one)*

_1_ Would NOT go to bed until after task was over

_2_ Would take a nap before the task and sleep for several hours after

_3_ Would sleep for several hours before the task and take a nap after

_4_ Would get all your sleep before the task began and not have any sleep after the task

15. Imagine that you have to do two hours of hard physical work and you are entirely free to plan your day. Considering your own "feeling best" rhythm, which of the following times would you choose? (Check one)

_1_ 8:00 - 10:00 AM _2_ 11:00 AM - 1:00 PM _3_ 3:00 - *5:00* PM _4_ 7:00 · 9:00 PM

16. You plan to start doing an hour of hard physical exercise twice a week from 10:00 to 11:00 PM. Thinking of only your own "feeling best" rhythm, how well would you perform? *(Check one)*

_1_ Would be in good form

_2_ Would be in reasonable form

_3_ Would find it difficult

_4_ Would find it very difficult

17. Suppose you can choose your own work hours. Assume you work a 5-hour day (including breaks) & that your job is interesting and paid by results. *Mark the 5-hour period you would choose on this scale:*

12 I 2 3 4 5 6 7 8 9 10 11 12 1 2 3 4 5 6 7 8 9 10 11 12
MIDNIGHT NOON MIDNIGHT

18. At what level of tiredness would you be if you went to bed at 11:00 PM? *(Check one)*

_1_ Not at all tired _2_ A little tired _3_ Fairly tired _4_ Very tired

19. At what time of day do you think that you reach your "feeling best" peak? *(Mark the time on the scale below)*

12 I 2 3 4 5 6 7 8 9 10 11 12 1 2 3 4 5 6 7 8 9 10 11 12
MIDNIGHT NOON MIDNIGHT

Overall Horne-Ostberg Score (ho_score) is the sum of all of the responses with these scores as seen in coding, except:

alarm, no_work, exercise, best, doze	4, 3, 2, 1
ctype	6, 4, 2, 0
Sleep11	0, 2, 3, 5
Waketime	< 6:30 = 5, 6:30-7:45 = 4, 7:45-9:45 = 3, 9:45-11:00=2, > 11:00=1

Bedtime	17:00-21:00 = 5, 21:00-22:15 = 4, 22:15-0:30 = 3, 0:30-1:45=2, >1:45 = 1
Tired_time	3:00-21:00 = 5, 21:00-22:15=4, 22:15-0:45=3, 0:45-2:00 =2, >2:00 = 1
Opt_start	4:00-8:00 =5, 8:00-10:00=4, 10:00-14:00=3, 14:00-17:00=2, > 17:00 = 1
Peak	4:00-8:00=5, 8:00-10:00=4, 10:00-17:00=3, 17:00-22:00 = 2, > 22:00=1

Individual item scores are available on request.

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F: Medications

7. Do you regularly take any medicines? _Y_Yes _N_N (drug_use)

If yes, please list the name of each drug : _____ (multiple lines given on health questionnaire)

The medications listed in this question are then coded into the following categories:

Listing of WSC Drug Groupings and Labels - 08FEB16

Large Group	Small Group	Drug Code	Drug Name
ALLERGY	ANTIHISTAMINES	203	Azatadine maleate and psuedoephedrine sulfate (Trinalin)
		207	Diphenhydramine HCl and pseudoephedrine (Benadryl)
		209	Terfenadine (Seldane)
		210	Triproline hydrochloride and pseudoephedrine (Actifed)
		218	Brompheniramine maleate and pseudoephedrine hydrochloride (Bromfed)
		219	Chlortrimetron (Chlorpheniramine)
		220	Codimal
		221	Rynatan (phenylephrine tannate and chlorpheniramine tannate)
		223	Contact
		228	Comhist (chlorpheniramine / phenylephrine / phenyltoloxamine)
		229	Clemastine fumarate / phenylpropanolamine HCl (Tavist-D)
		234	Dimetapp (brompheniramine-PPA)
		235	Chlorpheniramine Maleate
		236	Astemizole (Hismanal)
		238	Afrin Nasal Spray (Oxymetazoline hydrochloride)
		239	Chlorpheniramine maleate & Pseudoephedrine HCl (Deconamine)
		244	Triaminic, Phenergan, Tessalon, Benzonatate, or other syrups incl. those w/ codeine
		246	Tripelennamine HCl (PBZ)
		247	Resaid
		248	Loratadine (Claritin)
		254	Zyrtec (Cetirizine)
		256	Hydroxyzine (Atazine, Vistaril)
		262	Azelazstine (Astelin, Astepro)
	DECONGESTANTS	203	Azatadine maleate and psuedoephedrine sulfate (Trinalin)
		207	Diphenhydramine HCl and pseudoephedrine (Benadryl)
		208	Pseudoephedrine (Chlortab, Sudafed, or other unnamed antihistimines)
		210	Triproline hydrochloride and pseudoephedrine (Actifed)
		215	Decongestant or generic allergy meds (Wal-Fed et. al.)
		216	Pseudoephedrine hydrochloride and guaifenesin (Duratuss, Guaifed, Humbid, Qbid)
		218	Brompheniramine maleate and pseudoephedrine hydrochloride (Bromfed)
		220	Codimal
		221	Rynatan (phenylephrine tannate and chlorpheniramine tannate)
		222	Neosynephrine Nose Drops or Nasal Spray, other OTC nasal preparations
		226	Sinaid, Sinoff, Sinutab, Sinex, etc. / OTC sinus meds
		228	Comhist (chlorpheniramine / phenylephrine / phenyltoloxamine)
		229	Clemastine fumarate / phenylpropanolamine HCl (Tavist-D)
		234	Dimetapp (brompheniramine-PPA)
		238	Afrin Nasal Spray (Oxymetazoline hydrochloride)
		239	Chlorpheniramine maleate & Pseudoephedrine HCl

			(Deconamine)
		244	Triaminic, Phenergan, Tessalon, Benzonatate, or other syrups incl. those w/ codeine
		245	Entex (Duravent, Ornade)
		247	Resaid
ANXIETY	ANXIETY	410	Buspar (Buspirone)
		412	Xanax, Versed (Alprazolam)
		413	Limbitrol
		420	Clonazepam (Klonopin)
		421	Diazepam (Valium)
		427	Paroxetine(Paxil)
		428	Clorazepate (Tranxene)
		431	Lorazepan (Ativan)
		436	Hydroxytryptophan
		438	Effexor (Venlafaxine HCl)
		445	Desvenlafaxine (Pristiq)
ASTHMA	ASTHMA	211	Primatene mist
		212	Theophylline (Slobid, Theochron, Theodur, Uniphyl)
		242	Trimcinolone acetonide oral (Azmacort)
		251	Tilade
		255	Accolate (zafirlukast)
		257	Montelukast (Singulair)
		258	Ipratropium & Albuterol combined (Combivent, Duoneb)
		259	Formoterol oral (Foradil aerolizer)
		260	Pirbuferol oral (Maxair)
		265	Terbutaline Inhalation (Brethaire)
		266	Salemeterol oral only (Serevent)
		267	Tiotropium Bromide inhaler (Spiriva, Spiriva handhaler)
		269	Advair (fluticasone & salmeterol combined) (Advair diskus)
		270	Fluticasone oral inhalation (Flovent)
		273	Budesonide oral (Pulmicort, Symbicort)
		274	Albuterol Sulfate (Proventil, Ventolin, Volmax, Asmavent, Salbutamol, Ventodisk, AccuNeb, Proair, Vospire)
		275	Beclomethasone dipropionate oral aerasol (Beclovent, Vanceril, Qvar Inhaler)
		276	Flunisolide oral (Aerobid)
		277	Cromolyn Sodium oral (Intal)
		278	Ipratropium bromide oly (Atrovent, Arovent, Aerovent)
		281	Asmanex Twisthaler (monetasone oral)
	ASTHMA_CONTROL	212	Theophylline (Slobid, Theochron, Theodur, Uniphyl)
		242	Trimcinolone acetonide oral (Azmacort)
		251	Tilade
		255	Accolate (zafirlukast)
		257	Montelukast (Singulair)
		259	Formoterol oral (Foradil aerolizer)
		266	Salemeterol oral only (Serevent)
		267	Tiotropium Bromide inhaler (Spiriva, Spiriva handhaler)
		269	Advair (fluticasone & salmeterol combined) (Advair diskus)
		270	Fluticasone oral inhalation (Flovent)
		273	Budesonide oral (Pulmicort, Symbicort)
		275	Beclomethasone dipropionate oral aerasol (Beclovent, Vanceril, Qvar Inhaler)
		276	Flunisolide oral (Aerobid)
		277	Cromolyn Sodium oral (Intal)
		281	Asmanex Twisthaler (monetasone oral)
	ASTHMA_RESCUE	211	Primatene mist
		258	Ipratropium & Albuterol combined (Combivent, Duoneb)
		260	Pirbuferol oral (Maxair)
		265	Terbutaline Inhalation (Brethaire)
		274	Albuterol Sulfate (Proventil, Ventolin, Volmax, Asmavent, Salbutamol, Ventodisk, AccuNeb, Proair, Vospire)
		278	Ipratropium bromide oly (Atrovent, Arovent, Aerovent)

CHOLESTEROL	CHOLESTEROL	601	Lovastatin, Mevacor, Simvastatin, Zocor
		606	Cholestyramine Resin (Questran)
		607	Gemfibrozil capsules (Lopid, Lofibra)
		608	Probucol (Lorelco)
		613	Pravachol (pravastatin)
		617	Colestid (cholestipol)
		752	Antilipemic agents: Advicor, Crestor, Lescol, Lipitor, Niaspan, Niacin, Tricor, Vytorin, Zetia
		815	Lipitor
		875	Crestor, Rosuvastatin
		877	Niacin, Niaspan
		878	Tricor
		879	Vytorin (Simvastatin/Zetia combo)
		880	Zetia, Azetimibe
	STATIN	601	Lovastatin, Mevacor, Simvastatin, Zocor
		613	Pravachol (pravastatin)
		815	Lipitor
		875	Crestor, Rosuvastatin
		879	Vytorin (Simvastatin/Zetia combo)
DEPRESSION	DEPRESSION	401	Fluoxetine hydrochloride (Prozac, Savella)
		403	Nortriptyline (Pamelar)
		406	Fluvoxamine
		407	Imipramine
		408	Trazodone HCl (Desyrel)
		409	Amitriptyline (Elavil)
		411	Doxepin (Sinequan)
		413	Limbitrol
		414	Desipramine HCL (Norpramin)
		415	Clomipramine HCl (Anafranil)
		416	Bupropion NCl (Wellbutrin)
		424	Nardil (Phenelzine), Parnate (Tranylcypromine)
		426	Zoloft (Sertraline hydrochloride)
		427	Paroxetine(Paxil)
		432	Serzone (Nefazodone)
		435	Remeron (mirtazepine)
		436	Hydroxytryptophan
		438	Effexor (Venlafaxine HCl)
		439	Citalopram hydrobromide (Celexa,Lexapro)
		444	Cymbalta (duloxetine)
		445	Desvenlafaxine (Pristiq)
	DEP_MAOI	424	Nardil (Phenelzine), Parnate (Tranylcypromine)
	DEP_SSRI	401	Fluoxetine hydrochloride (Prozac, Savella)
		406	Fluvoxamine
		408	Trazodone HCl (Desyrel)
		426	Zoloft (Sertraline hydrochloride)
		427	Paroxetine(Paxil)
		439	Citalopram hydrobromide (Celexa,Lexapro)
	DEP_TCA	403	Nortriptyline (Pamelar)
		407	Imipramine
		409	Amitriptyline (Elavil)
		411	Doxepin (Sinequan)
		413	Limbitrol
		414	Desipramine HCL (Norpramin)
		415	Clomipramine HCl (Anafranil)
DIABETES	DIABETES	304	Insulins
		316	Precose (Acarbose, Diabetes mellitus med rs)
		715	Glyburide (Actos, Avandis, Diabeta, Glucovance, Glynase, Micronase, Rezulin, Troglitazone, amaryl)
		719	Glipizide (Amyryl, Glucotrol)
		795	Glucophage (Metformin)
		798	Tolazamide
		847	Byetta (exenatide), Prandin
		848	Sitagliptin (Januvia)

Listing of WSC Drug Groupings and Labels - 08FEB16

Large Group	Small Group	Drug Code	Drug Name
DIABETES	DIABETES	856	Liraglutide (Victoza injection)
		868	Dibeta, Glynase, Micronase, Glyburide
		869	Actos, Pioglitazone
		872	Glucovance (Glyburide / Metformin combo)
HORMONES	ANDROGEN	42	Estrogen & Methyltestosterone (Estratest, Menogen)
		852	Testosterone
	ESTROGEN	1	Contraceptives (Ethinyl estradiol, Levonorgestrel)
		10	Estrogen, conjugated (Cenestin, Premarin)
		11	Estrogen, esterified (Estratab, Menest)
		12	Estradiol (Alora, Climara, Esclim, Estrace, Estraderm, Estring, FemPatch, Gynodiol, Innofem, Vagifem, Vivelle, Vivelle-dot)
		20	Estradiol & Norethindrone (Activelle, Combipatch, Femhrt)
		21	Estrogen & Medroxyprogesterone (Premphase, Prempro)
		42	Estrogen & Methyltestosterone (Estratest, Menogen)
		319	Premarin cream
	PROGESTERONE	1	Contraceptives (Ethinyl estradiol, Levonorgestrel)
		20	Estradiol & Norethindrone (Activelle, Combipatch, Femhrt)
		21	Estrogen & Medroxyprogesterone (Premphase, Prempro)
		30	Medroxyprogesterone acetate (Amen, Androderm, Curretab, Cycrin, Depo-Provera, Provera)
HYPERTENSION	HTN	101	Metoprolol tartrate (Lopressor, nebivolol)
		102	Hydrochlorothiazide (Hydrodiuril, Zaroxolyn)
		103	Propranolol hydrochloride (Inderal)
		104	Enalapril maleate (Vasotec)
		105	Prazosin hydrochloride (Minipress)
		106	Nadolol (Corgard)
		107	Hydralazine
		108	Indapamide (Lozol)
		109	Atenolol (Tenormin, Zebeta)
		110	Amiloride HCl-hydrocholorothiazide (Moduretic, Midamor)
		112	Furosemide (Lasix, Bumex)
		113	Triamterene & Hydrochlorothiazide (Dyazide, Maxzide, Dyrenium)
		115	Guanfacine Hydrochloride (Tenex)
		116	Lisinopril (Accupril, Mavik, Prinivil, Zestril, Zestoretic)
		117	Captopril (Capoten)
		119	Spironolactone (Aldactone, Spironizide)
		120	Naqua (Trichlormethiazide)
		121	Betaxolol hydrochloride (Kerlone)
		122	Regroton (chlorthalidone and reserpine)
		123	Acebutolol hydrochloride (Sectral)
		124	Guanabenz Acetate (Wytensin)
		125	Clonidine (Catapres, other alphaadrenergic agonist agents)
		126	Atenolol & Chlorthalidone (Tenoretic)
		127	Terazosin Hydrochloride (Hytrin)
		128	Lotensin (benazepril)
		129	Enalapril Maleate - hydrochlorothiazide combo (Benazepril, HCT, Lotensin, Vaseretic)
		130	Felodipine (Plendil)
		131	Methyldopa (Aldoclor, Aldomet)
		132	Norvasc (amlodipine)
		133	Losartan (Avalide, Cozaar, Diovan, Hyzaar, irbesartan, other angiotensin II antagonist combinations)
		134	Unknown HTN Rx
		135	Altace (ramipril)
		136	Dynacirc (Isradipine)

Listing of WSC Drug Groupings and Labels - 08FEB16

Large Group	Small Group	Drug Code	Drug Name
HYPERTENSION	HTN	138	Doxazosin (Cardura)
		139	Metoprolol succinate (Toprol XL)
		140	Lotrel (Amlodipine/ benazepril)
		141	Diazac (dup see 604)
		142	Labetalol Hydrochloride (Normodyne, Tradate)
		143	Betachron (Propranolol)
		145	Ziac (Hydrocholorothiazide / Bisoprolol combo)
		146	Fosinopril Sodium (Monopril)
		147	Carvediol (Coreg, Cartrol)
		148	Olmesartan medoxomil (Benicar)
		149	Pindolol (Visken)
		150	Alfuzosin (Uroxatral)
		151	Candesartan (Atacand)
		604	Diltiazem HCL (Cardizem, Dilacor, Taztia XT, Tiazac)
		609	Verapamil (Calan)
		610	Nifedipine (Adalat, Procardia)
		744	Unknown diuretic
	HTN_ACEI	104	Enalapril maleate (Vasotec)
		116	Lisinopril (Accupril, Mavik, Prinivil, Zestril, Zestoretic)
		117	Captopril (Capoten)
		128	Lotensin (benazepril)
		129	Enalapril Maleate - hydrochlorothiazide combo (Benazepril, HCT, Lotensin, Vaseretic)
		135	Altace (ramipril)
		140	Lotrel (Amlodipine/ benazepril)
		146	Fosinopril Sodium (Monopril)
	HTN_ALPHA	105	Prazosin hydrochloride (Minipress)
		115	Guanfacine Hydrochloride (Tenex)
		124	Guanabenz Acetate (Wytensin)
		125	Clonidine (Catapres, other alphaadrenergic agonist agents)
		127	Terazosin Hydrochloride (Hytrin)
		138	Doxazosin (Cardura)
		150	Alfuzosin (Uroxatral)
	HTN_ARB	133	Losartan (Avalide, Cozaar, Diovan, Hyzaar, irbesartan, other angiotensin II antagonist combinations)
		148	Olmesartan medoxomil (Benicar)
		151	Candesartan (Atacand)
	HTN_BETA	101	Metoprolol tartrate (Lopressor, nebivolol)
		103	Propranolol hydrochloride (Inderal)
		106	Nadolol (Corgard)
		109	Atenolol (Tenormin, Zebeta)
		121	Betaxolol hydrochloride (Kerlone)
		123	Acebutolol hydrochloride (Sectral)
		126	Atenolol & Chlorthalidone (Tenoretic)
		139	Metoprolol succinate (Toprol XL)
		142	Labetalol Hydrochloride (Normodyne, Tradate)
		143	Betachron (Propranolol)
		145	Ziac (Hydrocholorothiazide / Bisoprolol combo)
		147	Carvediol (Coreg, Cartrol)
		149	Pindolol (Visken)
	HTN_DIURETIC	102	Hydrochlorothiazide (Hydrodiuril, Zaroxolyn)
		108	Indapamide (Lozol)
		110	Amiloride HCl-hydrocholorothiazide (Moduretic, Midamor)
		112	Furosemide (Lasix, Bumex)
		113	Triamterene & Hydrochlorothiazide (Dyazide, Maxzide, Dyrenium)
		119	Spironolactone (Aldactone, Spironizide)
		120	Naqua (Trichlormethiazide)

Listing of WSC Drug Groupings and Labels - 08FEB16

Large Group	Small Group	Drug Code	Drug Name
HYPERTENSION	HTN_DIURETIC	122	Regroton (chlorthalidone and reserpine)
		126	Atenolol & Chlorthalidone (Tenoretic)
		129	Enalapril Maleate - hydrochlorothiazide combo (Benazepril, HCT, Lotensin, Vaseretic)
		145	Ziac (Hydrocholorothiazide / Bisoprolol combo)
		744	Unknown diuretic
NARCOTICS	NARCOTICS	725	Darvocet (Propoxyphene)
		751	Propoxyphene HCl (Darvon, Wygesic)
		760	Morphine (MS Contin)
		781	Hydrocodone, Vicodin
		785	Oxycodone / APAP (Endocet, Opium tincture, Percocet, Roxicet, Suboxone, Tylenol w/ codeine & other unknown narcotics)
		812	Meperidine (Demerol)
		821	Fantanyl (Duragesic patch)
		835	Methadone
		883	Tramadol
SEDATIVES	SEDATIVES	402	Phenobarbitol (Mebaral)
		408	Trazodone HCl (Desyrel)
		412	Xanax, Versed (Alprazolam)
		420	Clonazepam (Klonopin)
		421	Diazepam (Valium)
		431	Lorazepan (Ativan)
		440	Restoril (Temazepam)
		705	Fiorinal w/ or w/out codeine (aspirin, butalbital, and caffeine)
		784	OTC Sleep Aids, Tylenol PM, Unisom
		793	Melatonin
		796	Flurazepam (Dalmane)
		808	Butabarbital or Butalbital (Axocet, Esgic, Esgic Plus)
		858	Hypnotics (Zolpidem, Ambien, Lunesta, Sonata)
		863	Benzodiazepines (Triazolam, Halcion)
STIMULANTS	STIMULANTS	706	Methylphenidate HCL (Concerta, Ritalin)
		769	Cylert (pemoline)
		777	Phentermine (Adipex-P, Fastin, Ionamin, Diethlopropion, Fastin, Ionamin & other rx appetite suppressants)
		779	OTC stimulants
		782	Fenfluramine (Pondimin)
		810	Phen-Fen, Orlistat, Xenical, other obesity rxs
		816	Meridea
		859	Modafinil (Provigil)
		861	Dexedrine (adderall, amphetamines)
THYROID	THYROID	303	Levothyroxin hydrochloride (Cytomel, Levothroid, Levoxyl, Synthroid))
		834	Methimazole (Tapazole)

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F: AM Sleep Evaluation

1. How well did you sleep last night? (Please check one) (A_EVAL_SLEPT)

_1___ much worse than usual

_2___ somewhat worse than usual

_3__ as well as usual

_4___ a little better than usual

_5___ much better than usual

2. About how many hours of restful sleep do you feel you got last night? _____ hours (A_EVAL_HOUR)

3. Finally, we would like you to rate how sleepy you feel right now, just as you did last night before sleep.
The scale ranges from 1 to 7, with 7 being the most sleepy.
Please read the entire scale below and then check the level that *best describes your current state of sleepiness*. (A_EVAL_SLEEP)

1____ feeling active and vital; alert; wide awake

2____ could function at a high level; but not quite at peak, able to concentrate

3____ relaxed; awake; responsive; but not at full alertness

4____ a little foggy; not a peak; let down

5____ fogginess; beginning to lose interest in staying awake; slowed down

6____ sleepiness; prefer to be lying down; fighting sleep; woozy

7____ almost in reverie; sleep onset soon; losing struggle to remain awake

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