Sueño – Sleep Habits in HCHS

Field Center Procedures

Version 6.0
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1. FOREWORD

This manual, entitled **Field Center Procedures** is the manuals of operation for the Sueño – Sleep Habits in HCHS. This manual provides an overview of the interviews and clinical measurements conducted as part of the field center examination, references to the procedures not covered here, and appendices of forms and question by question instructions for their administration. The steps of participant interaction and data collection are presented in the order in which they occur (i.e., reception, interviews, procedures, medical data review). Table 2-A lists the main components of the field center examination.

Because high quality of data and a strict standardization of the examination and interview techniques across all field sites are essential it is important that Sueño field center personnel be familiar with this manual of procedures. To meet our scientific goals and to make this study a success, all Sueño field center technicians must be fully trained and certified in the procedures described in this manual, and must remain standardized throughout the data collection phase. A complete knowledge of the procedures detailed in this manual is required so that patterns in the Sueño data can reflect differences between study participants and between groups of Hispanic ancestry, as opposed to differences between study technicians or deviations from study protocol. Strict and sustained adherence to study protocol by all Sueño personnel is required for us to be able to meet our obligations to the study participants, to the scientific community and to our funding agencies.

To the degree that this is applicable, the description of each interview/exam component in this manual includes a brief rationale for its use, operational procedures, an overview of training requirements and certification criteria, routine quality assurance measures, and data collection procedures.

This manual as well as all forms used in this study can be found on the HCHS website at http://www.cscc.unc.edu/hchs/ under the Ancillary Studies Hub.

2. STUDY RATIONALE AND AIMS

2.1. Sleep and Health

Since the development of indoor electric lighting, humans have steadily increased the time they spend awake at the expense of sleep. The advent of cable television and the internet has further accelerated the prevalence of curtailed sleep. While Americans slept about 9 hours per night in 1960, mean sleep duration was only 7.5 hours by 2001 and had fallen to 6.8 hours by 2004. At the same time, the growth of a 24-hour society has led to marked increases in the prevalence of shift work, which not only reduces sleep duration but also often fragments sleep into multiple blocks. Shift work, as well as irregular sleep patterns, may also dampen circadian rhythms, the molecular clock mechanism that regulates and coordinates essential metabolic pathways within and between cells. Although the biologic determinants regulating sleep drive have been well worked out, the behavioral determinants of when and for how long an individual sleeps are still unclear. Twin studies implicate a genetic basis for sleep behaviors. However, the rapid change in sleep patterns over the past half century suggests the presence of strong environmental regulators as well. Those with the lowest socioeconomic status (SES), who have the least choice of work schedules, most financial strain, and sleep in the most crowded environments tend to have worse sleep habits. Cultural attitudes and beliefs about sleep are also important. For example, the process of acculturation in Latino immigrants to the U.S. has been implicated in adversely impacting sleep habits.

While it has long been known that reduced or irregular sleep can lead to neurocognitive deficits, increasingly, poor sleep has also been implicated as a novel risk factor for cardiovascular and metabolic disease (CVD). As such, understanding sleep patterns in modern society and the determinants of these patterns takes on substantial public health importance. In studies of predominantly Caucasians, chronically reduced sleep has been repeatedly identified as a risk factor for obesity, diabetes, hypertension, heart disease, and mortality. Experimental studies have provided insights into potential mechanisms as a few days of partial sleep restriction alters appetite, impairs insulin sensitivity, and increases sympathetic tone and inflammation. Other sleep habits are also associated with poor health. Long sleep durations are an independent predictor of diabetes, heart disease, and mortality. Disruption of the molecular clock in animal experiments produces obesity, insulin resistance, and heart disease. Shift work is associated with many features of the metabolic syndrome and elevates risk of cardiac events and cardiovascular disease mortality. Increased sleep fragmentation is associated with hypertension and obesity in cross-sectional analyses, while napping predicts myocardial infarction and mortality in prospective studies. Given the strong ties between psychosocial factors and poor sleep and between poor sleep and CVD, the possibility that effects on sleep may mediate the association between psychosocial stress and disease has been raised. One study found sleep could explain 21% of the relationship between SES and physical health, but this may well be an underestimate of the true magnitude of effect given sleep was measured solely by self-report.

2.2. Sleep in Hispanic Americans

The relevance of poor sleep habits on health is of particular importance to the Hispanic American (HA) community. HAs are at increased risk for obesity, diabetes, and stroke. At the same time, many of the most important predictors of chronic sleep restriction (lower income levels, greater number of children, lower levels of education, renting rather than owning one's home, and living in an urban area) are more commonly observed among HAs. HAs are more likely than non-Hispanic whites to report extremes of sleep duration. In one study, the prevalence of reporting a habitual sleep duration less than 7 hours was similar in HAs and whites in 1965 (12% vs. 15%), but by 1999, the prevalence of short sleep was substantially greater in HAs (37% vs. 25%), suggesting Hispanics may be

particularly susceptible to the societal changes promoting reduced sleep over the past 40 years. Because work schedule is an important determinant of sleep habits, it is relevant to note that compared to whites, HAs are more likely to work night shifts and less likely to have flexible work schedules. Furthermore, cultural background makes certain sleeping habits such as the siesta potentially more common among HAs. Finally, several studies have found that sleep duration declines with increased acculturation in HAs. However, prior studies of sleep in HAs have for the most part been limited by their narrow focus on sleep duration and reliance on self-report as well as the almost exclusive focus on Mexican-Americans. Considerable variability exists across Hispanic subgroups in relation to socio-demographic characteristics, historical immigration patterns, cultural beliefs and health behaviors. For example, survey data suggest Mexican-Americans are 18% less likely to report short sleep and 29% more likely to report long sleep compared to non-Mexican Hispanics. Thus far, studies examining heterogeneity in sleep habits across HA subgroups are lacking.

2.3. Study Aims

The goal of Sueño is to provide the first comprehensive assessment of sleep in a Hispanic-American population and will do so using objective assessments. It will identify the specific psychosocial factors associated with altered sleep and the patterns of abnormal sleep associated with rigorously assessed cardiovascular outcomes. In addition, it will provide the first evaluation of variability in sleep habits across ethnic subgroups within the Hispanic community.

The Specific Aims of this project are:

Aim 1: To objectively define the prevalence of abnormal sleep habits in five domains (sleep duration, sleep continuity, circadian phase, variability in sleep patterns, and daytime napping) and define differences across ethnic subgroups.

Aim 2: To assess the association between measures of SES, social networking, home and neighborhood environment, work schedule, acculturation and acculturative stress, sleep-related beliefs, mood, and anxiety with objectively measured sleep habits.

Aim 3: To assess the association between objectively measured sleep habits with prevalent cases of hypertension, obesity, diabetes, and heart disease as well as measures of inflammation, lipids, diet and activity.

Aim 4: To assess the association between psychosocial factors and CVD outcomes in this cohort and then determine the extent to which these associations can be explained through effects on sleep duration and other sleep measures.

In addition to these aims, given the likely long term follow-up to occur in HCHS, the phenotyping of sleep patterns close to the baseline exam will allow for future assessments of the role of poor sleep on incident cases of cardiovascular disease and related outcomes.

Table 1-A Overview of Participant Flow through Study

Procedure	**Form Code**
Pre-visit screening (eligibility, safety)	ANE
Reception	
Informed consent	
Anthropometry	APE
Medication & Supplement use	MDE/MDS
Interviews:	
Medical Hx	MQE/MQS
Sleep Attitudes	SSE/SSS
Work Schedule	WSE/WSS
Sleep Questionnaire	SPE/SPS
Neighborhood Stress	NSE/NSS
Sleep Questionnaire II	SQE/SQS
Acculturation Stress	ATE/ATS
Wellbeing	WLE/WLS
Sleep monitoring instructions and tracking	
Reimbursement and summary letters	

3. SAMPLING AND RECRUITMENT

3.1. Rationale

The sampling and recruitment plan for the study is designed to support three analysis objectives. First, the study sample supports estimates of prevalence of five key sleep habits – sleep duration, sleep efficiency, sleep timing, sleep regularity, and napping. Prevalence in these habits will be estimated both in the overall Hispanic/Latino population and by country of origin as well as other key demographic subgroups (male vs. female, old vs. young, etc.). Second, the sample supports evaluation of the relationships between various social, cultural, economic, and psychological factors in influencing sleep habits. Third, the sample supports evaluation of the relationship between poor sleep habits and relevant disease outcomes – obesity, hypertension, diabetes, and cardiovascular disease. While the current study is funded to only look at prevalent cases of disease, ongoing follow-up of participants by the parent HCHS/SOL study should allow for assessing the relationship between poor sleep and incident disease outcomes identified in the future. To accomplish all three objectives, a representative sample of participants from the parent HCHS/SOL study is selected, weighted to ensure sufficient numbers from each of five key Hispanic subgroups (Mexican, Cuban, Puerto Rican, Dominican, and Central/South American) so as to allow meaningful assessments of these subgroups as well as comparisons between subgroups.

Recruitment is planned for a three-year period. Participants in the HCHS/SOL parent study who have expressed a willingness to be contacted about future ancillary studies and are less than ~~two years~~30 months out from the baseline exam of the parent study are eligible to participate in Sueño, provided they have not participated in more than 1 other ancillary study in the prior year. In order to maximize recruitment, the Data Coordinating Center (DCC) will identify a roster of individuals, in a monthly fashion, who are more than 18 months but less than ~~24~~ 30 months out from their baseline exam for contact.

3.2. Recruitment and Examination Goals by Center

Study participants are recruited from four field centers located in Bronx, New York; Chicago, Illinois; Miami, Florida; and San Diego, California in parallel with the four sites of the parent HCHS/SOL study. Each field center was initially responsible for recruiting 550 persons in the age range of 18-64. The goals for national origin subgroups by site are shown in Table 3-A reflecting both the make-up of Hispanic populations at each site as well as the need to ensure a minimum goal of 330 participants per each national origin subgroup in order to adequately power analyses in each subgroup.

On May 15, 2013, recruitment at the San Diego field center ended prematurely with 371 subjects recruited. The remaining 179 participants were reassigned to the remaining three sites in order to meet overall study recruitment targets. Thus, the revised recruitment targets by site were Bronx 587, Chicago 605, Miami 639, and San Diego 371. In order to facilitate recruitment to these higher targets, the three remaining sites were allowed to over-recruit in any of the national origin subgroups assigned to that site and in addition Bronx was permitted to recruit participants of Mexican backgrounds. Thus, the available subgroups by site were Mexican, Puerto Rican and Dominican for Bronx; Mexican, Puerto Rican and Central/South American for Chicago; Cuban and Central/South American for Miami; and Mexican for San Diego.

Table 3-A Original Breakdown of Subgroup Recruitment by Site

	BRONX	CHICAGO	MIAMI	SAN DIEGO	TOTAL
CUBAN	0	0	330	0	330
MEXICAN	0	110	0	550	660
PUERTO RICAN	220	220	0	0	440
DOMINICAN	330	0	0	0	330
CENTRAL/SOUTH AMERICAN	0	220	220	0	440
TOTAL	**550**	**550**	**550**	**550**	**2200**

3.3. Inclusion and Exclusion Criteria

All participants in the parent HCHS/SOL study who expressed willingness to be contacted about ancillary studies, and who have been involved in no more than one other ancillary study in the prior year, are potentially eligible for recruitment into Sueño. In addition, subjects must be aged 18-64 at the time of recruitment, be able to converse in either English or Spanish, and have no sleep apnea baseline exam revealing severe sleep apnea (apnea hypopnea index or AHI <50 per hour). Exclusion criteria include a physician diagnosis of narcolepsy or a physician diagnosis of sleep apnea, or ~~and~~ having~~e~~ been treated with continuous positive airway pressure (CPAP) or bi-level positive airway pressure (BPAP). Women who are pregnant will be deferred until 3 months after completion of the pregnancy, assuming they are still within the ~~24~~ 30 month window from the baseline parent HCHS/SOL visit.

On June 18, 2013, the inclusion and exclusion criteria were revised regarding severe sleep apnea. Instead of requiring a sleep apnea study on baseline HCHS exam that demonstrates an AHI < 50 as an inclusion criterion, an AHI ≥ 50 on sleep apnea study is regarded as an exclusion criterion. Given that severe sleep apnea is rare, ~~In other words,~~ those with a failed or absent sleep study are assumed to not have severe sleep apnea, and are deemed eligible for participation.

4. CONTACTING PARTICIPANTS / MAKING THE CLINIC APPOINTMENT

HCHS/SOL participants who meet the Sueño eligibility criteria will be identified by the DCC. The DCC will send a list of eligible participants to each field center. Field centers will then send the eligible participants a letter to inform them of the new ancillary study. Study staff members who are responsible for recruitment will then call the participant at least one week after the mailing to assess their interest in participating in Sueño. The eligibility of the participant will be confirmed on this call using the Screening form (ANE). A visit, either in the subject's home or to the field center, will be scheduled on this call, for anyone who is eligible and willing to participate. Updated records of recruited individuals are made available to field center personnel through periodic reports by the coordinating center for tracking and scheduling purposes.

Before calling a participant, field center personnel must have appropriate scheduling forms and worksheets used locally, the available clinic appointment dates/times, and the Recruitment Call Script (see Appendix, Section I). Interviewers make the number of call attempts specified for each HCHS/SOL field center, tracking them on the Sueño Screening Contact Worksheet. The interviewee is first reminded of the recruitment letter the staff person reviews this information and answers questions about the study and its procedures, as required.

4.1. Participant Safety Screening

Verification of eligibility for all study procedures and pre-screening to ensure safety are part of the visit scheduling procedures. For this purpose Sueño personnel use the Screening form (ANE), supported by the HCHS/SOL Data Management System (DMS) on the staff person's laptop/desktop. Following an explanation of the Sueño study and the procedures involved, the interviewer requests an opportunity to verify the individual's eligibility for all procedures. The conditions reviewed during this interview (and listed on the form) include age, pregnancy, narcolepsy, and sleep apnea. In addition, the participant's language preference (English or Spanish) is assessed at this time. Study participants who are pregnant are asked to schedule an examination visit at three months after delivery, and to provide a date by which the Sueño staff can re-contact them for this purpose. Breast-feeding is neither an impediment for the field center examination nor a reason for rescheduling; field centers should work with the nursing mother to accommodate her needs. During this interview, staff also inquires about special needs, such as any medical conditions that would affect the examination or the appointment time or impediments in hearing or reading. Arrangements for a safe and comfortable examination visit are made, consulting with the Clinic Manager as appropriate. Participants should be reminded to bring all their medications to the field center.

4.2. Appointment Reminders and Instructions for the Clinic Examinations

The instructions for the visit to the field center are specified on an information sheet prepared by each field center, and mailed to the participant soon after the appointment is made. The instructions include:

1. Appointment date and time.
2. Preparations:
    a) Instructions on appropriate clothing to wear for the examinations.
3. Items to bring to the field center:
    a) Eyeglasses for reading;
    b) Medication Instruction Sheet: Instructions to bring all prescription and over-the-counter medications, including vitamins and mineral supplements, taken within one month prior to the examination. This includes pills, liquid medications, skin patches, inhalers, and injections.

4. Overview of Clinic Operations:
    a) A listing of the interviews and procedures for the examination (optional);
    b) Clinic hours and phone number for questions or rescheduling appointment.
5. Directions to the clinic (e.g., a map) and to parking facilities:
    a) A reminder of the arrangements for parking and/or reimbursement.
6. Transportation, if applicable (some centers provide transportation and arrange for participant pick-up).

For those sites that choose to conduct data collection in the participant's home, a mailing should still be performed containing items 1-4 above.

5. INFORMED CONSENT

Upon arrival to the Field Center, participants should be welcomed. For home visits, the participant should be thanked for their hospitality. Once participants are comfortable, they are given the opportunity to read and review the informed consent as described below. No data collection can take place before informed consent has been obtained.

Informed consent is the first data collection form administered during the course of the Exam. Its core content complies with guidelines from the National Heart, Lung, and Blood Institute and the Sueño Ancillary Study Committee. Its content and format are tailored to meet the specific requirements of each field center's Institutional Review Board.

The primary objective of administering Informed Consent is to inform the participant of the procedures of the Sueño, protect the rights of the Sueño Study participants and meet local Institutional Review Board requirements. The informed consent makes the study participant aware of the right to withdraw from the study, to not participate in a procedure, or to decline to answer question(s) without penalty.

5.1. Administration

The purpose of the Sueño study and the measurements to be made are reviewed with the participant. The consent form is available in Spanish and English and bilingual HCHS/SOL staff is available for its review and administration. Early on in this process, confirm the participant's language preference as noted on the Screening Interview.

After introducing the consent form to the participant in a private area, ask whether s/he prefers to read the consent form or to have it read by the staff person.

At field centers that mail the informed consent prior to the field center visit, staff should be attentive to the possibility that participants may have had the form read to them prior to their arrival. Questions of clarification should be solicited. Note that the consent portion of the form must be filled out and signed in the presence of the staff person who serves as witness.

If he/she is visually handicapped or otherwise incapable of reading the study description and informed consent page, the narrative portion is read to him/her and then the participant is asked to sign the document. The original Informed Consent document is filed in the participant's study folder. A copy of the informed consent is given to the participant if requested by the participant or required by the local Institutional Review Board.

5.2. Training and Certification

Study coordinators and the local Field Center Principal Investigator are responsible for providing local staff training. Certification by the Study Coordinator is required. Quality assurance is provided at each field center by means of observation by the local study coordinator and/or Field Center Principal Investigator.

5.3. Data Collection

The Informed Consent is a paper form. When the participant receives a COPY of the informed consent, the field center has the option of providing a copy of the entire form, or signed consent

pages. In all cases, the original signature page must be kept at the field center and stored in the participant's study folder.

5.4. Ability to Comprehend the Informed Consent

Although the capacity to provide informed consent is required for the Sueño study to be conducted in an ethical manner, it can be challenging to identify individuals who may not have the ability to comprehend the informed consent. There are no nationally recognized standards for this purpose and somewhat different findings have emerged when some states (and courts) have taken up this issue. As a result, each field center follows the guidance of its local IRB on whether specific procedures are required for identification of such individuals.

Unless impairment is obvious, recognizing cognitive impairment in a potential participant is difficult (even for professionals), particularly since social skills can remain intact for participants who otherwise do not perform well on testing. As an added consideration, decision-making capacity is frequently task specific. As a result, depending on the type and extent of impairment cognitively impaired individuals can remain fully capable of making a variety of decisions, including whether or not to participate in a study. Field center personnel need to be attentive to indicators of potential cognitive impairment, such as repetition (i.e., repeating questions/stories over the course of just a few minutes) and empty or poor responses (i.e., the participant who frequently responds with "I don't know"). Individuals who seem to always be looking to their spouse or a companion for answers to historical questions or medical history questions also warrant consideration for a reduced capacity to answer all Sueño questionnaires.

Unless an IRB specifies specific procedures for vulnerable individuals there is need for guidelines common to the HCHS/SOL field centers to provide an environment that assists participants in comprehending the informed consent. To ensure that participants understand the informed consent, staff can ask the participant to explain back (in their own words) certain portions of the study. This can be introduced by stating that it is very important that the participant understand his/her rights and the process by which the Sueño project protects the confidentiality of the participant’s information. If the responses from the participant suggest that he/she has difficulty comprehending the consent process or the form contents, the staff person brings this to the attention of the local PI.

6. PARTICPANT FLOW AND ITINERARY

The sequence of examination procedures (participant flow) includes a series of fixed and flexible components which are organized to accommodate the collection of informed consent prior to any data collection, followed by four data collection blocks: Medication Usage, Anthropometry, Interview, and Actigraphy Instruction. In order to standardize data collection, the order of certain examination procedures should follow a standardized format. In particular, the order of the Interviews should follow the prescribed order so that the discussion generated from one set of questions does not influence responses to subsequent questionnaires. In addition, the Actigraphy Instruction should be the final data collection block. Flexibility is allowed in the timing of Anthropometry and Medication Usage blocks as long as they occur after Informed Consent and before Actigraphy Instruction. These blocks may be performed in the middle of the Interview block as long as each is performed between the completion of one form and the start of the other. The Anthropometry block in particular may be used to provide a break between questionnaires.

Examples of acceptable exam sequences are shown below.

Informed Consent	Informed Consent	Informed Consent
Medication Usage	Anthropometry	Medication Usage
Anthropometry	Medication Usage	Interview – First Half
Interview	Interview	Anthropometry
Actigraphy Instruction	Actigraphy Instruction	Interview – Second Half
		Actigraphy Instruction

7. RECORDING MEDICATIONS AND SUPPLEMENTS

The Medication Use Questionnaire (MDE/MDS) records all prescription and over-the-counter medications, including cold and allergy medications, vitamins, herbals or supplements used by participants in the four weeks preceding their interviews. The MDE and the Question-by-Question instructions for its use are found in the study appendix, section II. The survey ascertains usage of up to 25 medications. Ascertainment includes scanning of twelve-digit Universal Product Code (UPC) bar code symbols when available. Medical Therapeutic Classification (coding) is automated where possible. Otherwise, manual coding is centralized (performed only in the Coordinating Center).

The goal of the MDE is to ascertain usage of all prescription and over-the-counter medications, vitamins, herbals, and supplements. This information assists in measuring patterns of medication use in the study communities and diagnostic classification of sleep disorders as well as relevant medical outcomes (hypertension, diabetes, and cardiovascular diseases). The MDE process and form is identical to that used by the parent HCHS/SOL study to ensure comparability of data collection.

7.1. Administration of the MDE

The MDE is divided into three major sections: (A) Reception, (B) Medication Record, and (C) Medication Use Interview, administered as described below. If multiple staff is available, section B, Medication Record can be completed by one staff person while the participant is occupied with getting weighed or interviewed by a second person in order to reduce the length of the visit.

7.1.1 Reception

The interviewer checks with the participant to determine they brought any medications that require refrigeration. Medications that require refrigeration are labeled with the participant's ID and placed in the refrigerator. The interviewer then determines and records whether the participant has brought in all medications taken within the last four weeks. If the participant has not brought in any (all) medications, the interviewer inquires to differentiate between non-compliance with pre-visit instructions or non-use of medications in the prior four weeks. In case of inadvertent omissions, the interviewer makes arrangements for obtaining the information, preferably by either having the participant return at a later date to the Field Center with the medications for scanning or transcription or if that Field Center sends staff to the participant to retrieve the actigraph, missing medication information should be obtained at that time point. Obtaining missing medication data over the telephone is a backup in case participants decline another face to face visit. The interviewer records deliberate omissions of medications on the MDE

7.2. Medication Record

The interviewer places all medication containers on the work area. When there are more than 25 medications for scanning / transcription, staff uses the following algorithm to guide prioritization: [1] prescription medications; then [2] aspirin, aspirin containing medications and anti-inflammatory drugs (see appendix, section II, Question-by-Question instructions, List #1 and List #2); followed by [3] over-the-counter medications; and finally [4] vitamins, herbals, and supplements.

The interviewer scans/transcribes the UPC (part a of Items 5-29) into the Data Entry System. The Data Entry System will try to match a Medical Therapeutic Classification (MTC) to the UPC. If MTC-UPC matching is successful; the Data Entry System will skip the rest of the fields (parts b-d) for this medication item and move to the next medication. If an UPC is not available or the Data

Entry System does not successfully match the UPC, the interviewer transcribes the medication National Drug Code (NDC) (part a). If an NDC is not available or the Data Entry System does not successfully match the NDC, the interviewer transcribes the medication name (part b), strength (part c) and units (part d).

If this is done in the presence of the study participant, the interviewer shows each medication to the participant as it is scanned / transcribed, while keeping the other medications in view. The interviewer verifies scanned / transcribed information against container labels, making corrections when necessary to ensure accuracy. If a bar code label is not on the medication container or a bar code cannot be successfully scanned and a medication name exceeds the number of positions for the medication name (b) in the Data Entry System, the interviewer right-truncates the name without abbreviating the name in any other fashion. After successfully scanning / transcribing each medication, the interviewer returns corresponding containers to the participant.

Loose pills and medications in containers that are unmarked are examined only in the presence of the participant. With his/her permission and help, the interviewer examines loose pills and unclearly labeled containers, or those which hold more than one medication (e.g. medisets). The interviewer uses pill imprints, the Facts and Comparisons Drug Identifier on the desktop computer, and the Ident-A-Drug Reference on the web to identify these medications.

7.3. Medication Use Interview

The interviewer ascertains via a series of questions whether any of the participant-reported medications were used to treat pulmonary or cardiovascular diseases and/or their symptoms, whether any aspirin or aspirin-containing medications were used in the last four weeks, and whether any other non-steroidal anti-inflammatory drugs are being used on a regular basis.

7.4. Training

Since this process is identical to the parent HCHS/SOL study, Sueño staff should contact the HCHS/SOL Study Coordinator at their local Field Center to obtain staff training on medication scanning/transcription.

7.5. Certification

Interviewers for Sueño will need to be trained by HCHS/SOL study staff. Procedures for certification include:

- The candidate is trained by the lead certified interviewer at the corresponding Field Center.

7.6. Data Collection

The MDE is designed to be interviewer-administered and collected by direct data entry unless a computer with internet access is not available. Where a computer but not internet access is available, direct data entry can still be performed with later upload to the DMS server when internet access is available. However, in this case, verification checks by the DMS program as well as on-line references to identify pills and drugs will not be available at the time of data entry. Finally, a paper version of the form is available for back-up and delayed data entry. Medication UPC/NDCs (part a of Items 5-29), medication names (part b), strengths (part c), and units (part d) are listed alphabetically in hard copy and Data Entry System versions. Details of data collection are provided in the Question-by-Question instructions for the MDE (see Appendix, section II).

8. ANTHROPOMETRY

Anthropometry consists of assessing the participant's height, weight and body composition measurements. These measurements are used to assess the relationship between obesity and sleep problems.

8.1. Equipment and Supplies

The equipment and supplies necessary for body measurements are as follows:

- Wall mounted or portable stadiometer
- Tanita Body Composition Analyzer, TBF-300A or other digital scale
- Battery powered digital scale (available at all times as back up)
- Calibration weights (10 kg)

8.2. Staff

A technician will perform the measurements and enter the data into the ANT record in the data management system (DMS). The examiner is responsible for positioning the participant, taking the measurement, and entering the information into the data entry system. The examiner will confirm or re-measure any out-of-range messages identified by the data entry system. The participant should remain on the scale until the examiner enters the measurement on the data entry screen.

8.2.1 Anthropometry Form (APE)

The APE form records presence of an electronic implantable device (EID), ability to stand, height, weight and bio-impedance output values from the Tanita scale. As the technician progresses through the examination procedures, they will record (or directly enter) the measurements into the ANT form. They will then record any reason why any measurements were not obtained or any notes that may be applicable (if the subject has a prosthetic, etc).

8.3. Examination Procedures

Participants should wear scrub suits or light, non-constricting clothing (no jeans). Participants should remove any coats, jackets, sweatshirts, or other outerwear prior to weighing. Shoes should also be removed. Participants can wear slippers or socks during the height measurement, but must be barefoot for the bio-impedance measurements.

8.3.1 Measurement Feasibility

Before obtaining any measurements the technician must ask the participant if they have an EID and record this information on the anthropometry form. Common EID's are pacemakers and defibrillators, but participants could also have deep brain stimulators and spinal cord stimulators. If a participant has an EID it is very important to weigh them in the WEIGHT ONLY mode (see section 8.3.3d). Performing BIA measurements in these participants can be dangerous and caution should be taken to avoid doing so.

Secondly, before beginning anthropometric measurements, the participant's ability to stand should also be assessed. The technician should be able to assess this as the participant is traveling to the scale area. If a person can stand, but is not fully erect it should be noted on the anthropometry form. If the participant cannot stand at all, then no further measurements can be made. This should be

noted on the anthropometry form and the technician should move on to the next phase of data collection.

8.3.2 Standing Height

Standing height is an assessment of maximum vertical size. Standing height is measured with a fixed (wall mounted) stadiometer with a vertical backboard and a moveable headboard. Have the participant move or remove hair ornaments, jewelry, buns, braids, and corn rolls from the top of the head in order to measure stature properly.

Have the participant stand on the floor (see Figure 1) with the heels of both feet together and the toes pointed slightly outward at approximately a 60° angle. Make sure the body weight is evenly distributed and both feet are flat on the floor. Check the position of the heels, the buttocks, shoulder blades, and the back of the head for contact with the vertical backboard. Depending on the overall body conformation of the individual, all points may not touch. In such case, make sure the participant's trunk is vertical above the waist, and the arms and shoulders are relaxed.

Align the head in the Frankfort horizontal plane. The head is in the Frankfort plane when the horizontal line from the ear canal to the lower border of the orbit of the eye is parallel to the floor and perpendicular to the vertical backboard. Many people assume this position naturally, but for some it may be necessary to make a minor adjustment. If required, gently tilt the head up or down until proper alignment is achieved with eyes looking straight ahead. Once correctly positioned, lower the headboard and instruct the participant to take a deep breath and stand as tall as possible. A deep breath allows the spine to straighten, yielding a more consistent and reproducible stature measurement. Position the headboard firmly on top of the head with sufficient pressure to compress the hair. Then have the participant relax and step away from the stadiometer and record the participant's height to the nearest centimeter on the computer system. The examiner should read the height at eye level to avoid parallax; a small stool may be required.

Some participants may have conditions that interfere with the specific procedure for measuring stature. One of the more common conditions is kyphosis. Kyphosis is a forward curvature of the spine that appears as a hump or crooked back condition. In these cases it is important to get the best measure possible according to the protocol, record that the participant could not stand erect on Q2, and note the circumstances on Q10 of the anthropometry form.

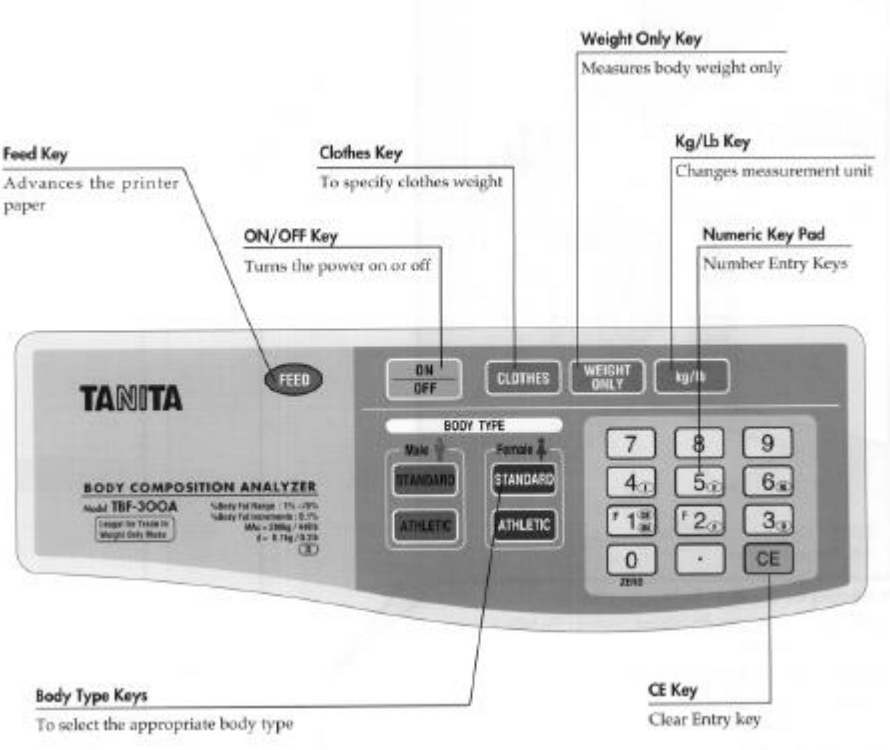
Figure 8-A Position for Standing Height

8.3.3. Weight and Body Composition

The participant's weight and body composition analysis are measured using the Tanita scale. This scale calculates the weight of the participant and using a bioelectrical impedance method provides percentage body fat, fat mass, lean body mass and total body water. All these measures are recorded on the Sueño Anthropometry Form.

The control panel of the Tanita scale is depicted in Figure 2. A number of settings must be specified before using the scale for the first time. Once the settings are selected, these are recorded automatically and there is no need to make changes. Just press ON/OFF key to start.

Figure 8-B Control Panel of Tanita Body Composition Analyzer, TBF-300A



a. Initial set up

1. Place the scale platform on a flat and level surface as possible, preferably not on carpet. Don't worry if balance bubble indicates it is not exactly level.
2. Connect the keyboard to the scale with the gray cord attached to the scale and plug it into the back of the keyboard in the socket marked "input."
3. Connect the keyboard to an electrical outlet using the black power cord and AC adapter. Plug the black cord into the socket on the back of the keyboard marked "DC5V."

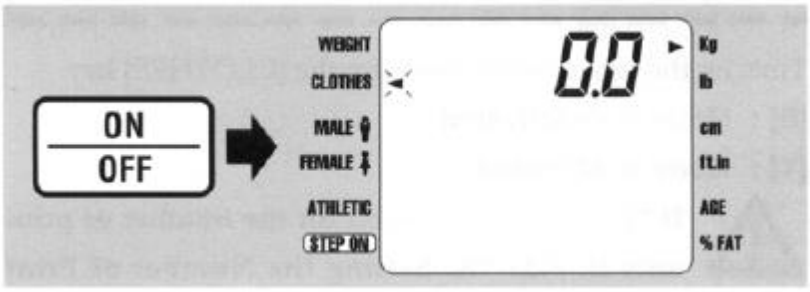
b. Setting the number of print outs and printing language

Press and hold the 0 key, and press the ON/OFF key once. Release the 0 key after "Prt-1" is displayed on the screen. Select 0 (no print out). When no print out is selected there is no need to select the printing language. The panel will switch to the measurement screen.

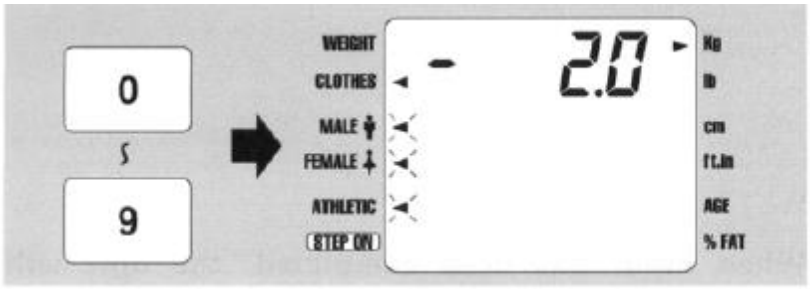
c. Operating Instructions

➔ <u>IMPORTANT SAFETY ALERT</u>**:** PARTICIPANTS WITH A PACEMAKER, DEFIBBRILLATOR OR OTHER ELECTRONIC IMPLANTABLE DEVICE SHOULD BE MEASURED IN 'WEIGHT ONLY' MODE (see below, section 8.3.1 d).

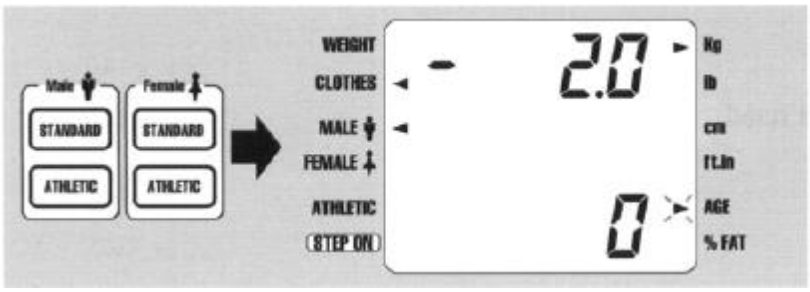
If participant does not have internal electronic device, proceed with the following instructions:



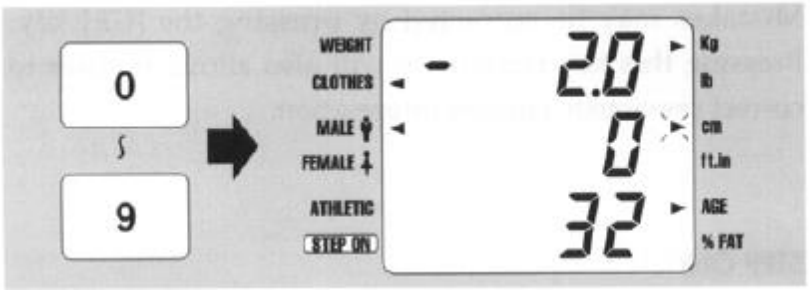
Press ON/OFF key to turn the machine on. Wait until 0.0 and an arrow appear on the screen. Check that the arrow points to "Kg". If arrow point to "lb", press the Kg/Lb key on the control panel and the arrow will shift to "Kg"



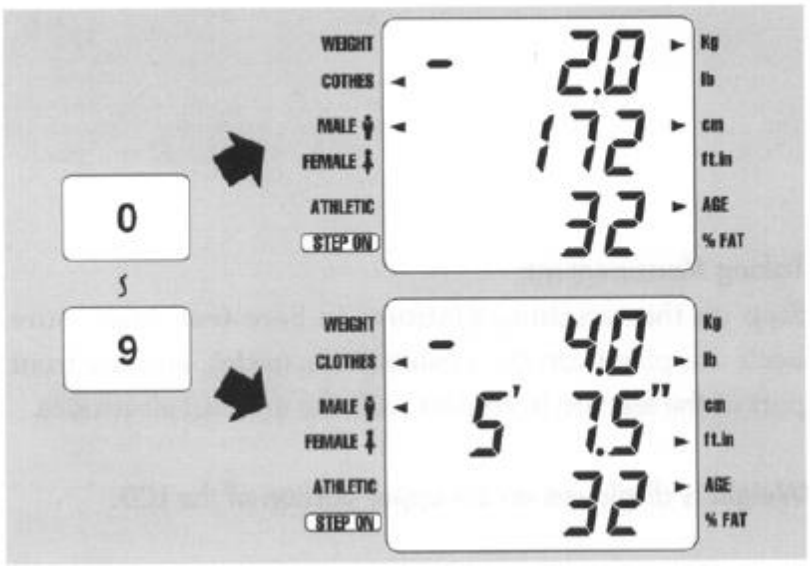
Enter Clothes weight:
1.0 kg using the numeric pad on the control panel



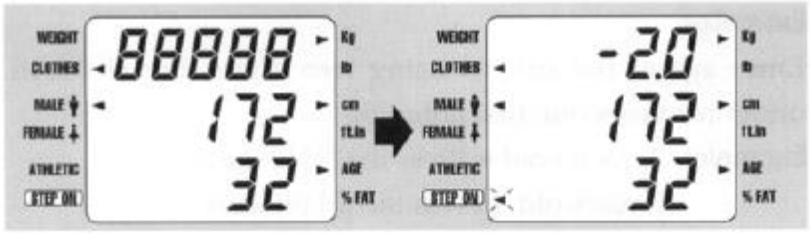
Select Gender and Body type:
Standard Female or Standard Male



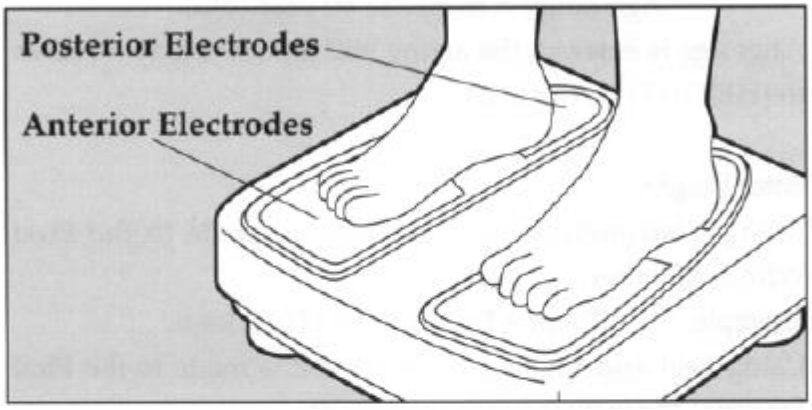
Enter age of participant using the numeric pad of the control panel. After age is entered, the arrow will direct you automatically to enter the height.



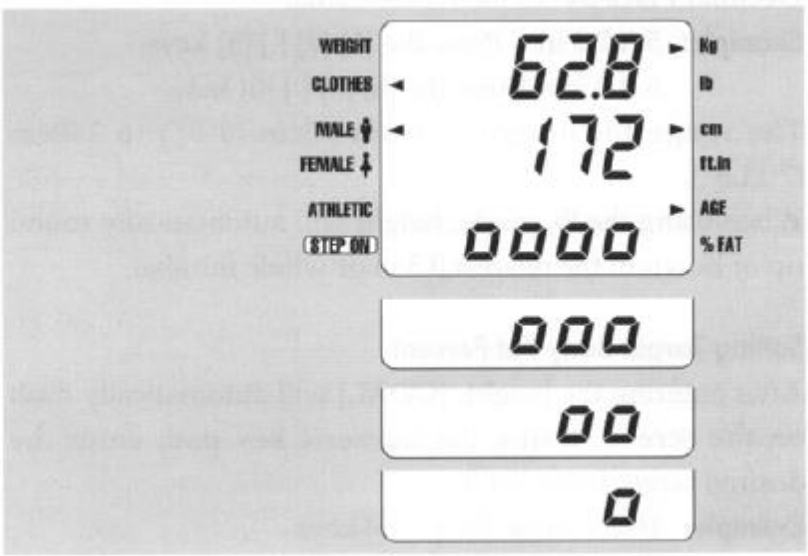
Enter height in cm. For example, for 172 cm, press the [1] [7] [2] keys.



Mistakes may be corrected by pressing the [CE] key. Pressing this key repeatedly will allow correcting the previous information.



Wait until the screen displays "88888' and then ask the participant to step on the scale. Participants should be barefoot. Each foot should be touching both the heel and toe plates, with weight evenly distributed on both feet.



Weight will be displayed on the upper section of the screen. After weight stabilizes, impedance measurement is taken. Bubbles "oooo" will appear on the bottom half of the screen as these measurements are being analyzed. Once body composition measurements are ready, the bubbles will disappear one by one. Record weight and each body composition measurement including impedance on the Anthropometry form. Ask the participant to step off the scale.

If the screen returns to ---- for weight, the participant weighs more than 440 lb. Record 999.9 for weight and 99.9 for % body fat on the data form.

If screen returns error messages **E-01** or **E-16** it means that the unit could not get a good reading, either because: 1) the participant stepped off the scales before the beep; or 2) the participant was wearing socks or has thick calluses on his/her feet. If the problem appears to be #1, just repeat the measurement procedure.

If the problem appears to be #2, place a drop or two of saline on each scale plate to help signal conduction. If the error messages appear again after adding saline, measure weight in "Weight Only Mode" (section 8.3.1 d) and only record weight on APE form. Once measurements are completed, the machine will automatically return to the Gender and Body Type screen in about 10 seconds. Leave keyboard on. Wipe off plates on scale with antiseptic wipes.
You can then measure the next participant.

Do not weigh participants who have a cast that cannot easily be removed, or that the participant is comfortable removing, if larger than a finger splint. If a participant has a prosthetic limb, measure weight with limb in the "Weight Only" mode (described below, section 8.3.1 d), make a note in the notes section of the form (Q10).

In the event of a power outage or if the scale is not functioning properly, use the battery-powered digital scale as back-up and notify the project coordinator.

d. Weight Only

To switch from all measurements to "Weight Only" mode turn the unit off, turn the unit on, press WEIGHT ONLY button on the Tanita scale control panel. Other digital scale could also be used. Record weight and reason for weigh only in the notes section (Q10) of the APE form.

8.4. Quality Assurance/Quality Control

8.4.1. Calibration Procedures and Equipment Check

The Tanita scale or other digital scale is calibrated weekly or when moved. For home visits, the scale should be calibrated with each use. Calibrate the scale by pressing WEIGHT ONLY key. Make sure the arrow pointing to weight is in Kg units.

Place the calibration weight (10 Kg) in the middle of the scale, and record the weight indicated on the LED in the daily log. If the calibration weight is less than 8.5 kg or more than 11.5 kg, use the back-up scale, and notify the clinic coordinator to have the scale recalibrated by the manufacturer or by the appropriate institution personnel.

Wipe off plates on scale with antiseptic wipes. Turn off scale by pressing the ON/OFF key.

8.4.2. Training, Certification and Quality Control

Technicians will be trained and certified locally by any HCHS staff person who has been previously certified. Each technician needs to perform a minimum of 5 observed procedures to receive certification.

9. INTERVIEW

Interviewing is a collaboration between the Sueño staff and the study participant to collect study data, using standardized techniques common to each examination site, that are unchanged for the duration of the examination. This section presents a general description of interviewing in the intake examination of the Sueño.

Interviews in Sueño are administered in English or Spanish – at the preference of the study participant – by trained and certified personnel who are bilingual. Participants need not be consistent in their use of Spanish or English between forms; for each form, the language of administration will be recorded in the database for quality assurance purposes. Interviews conducted at the field center are administered using the HCHS/SOL Data Entry and Management System (DMS) which supports the interviewer with automatic skip pattern implementation auto-fill features, and provides quality assurance features such as on-entry editing. Note that the daily sleep log is for the participant to complete at home and is NOT administered using the HCHS/SOL DMS. The most important factor influencing the study participant's satisfaction and the quality of the interview data is the interviewer, his/her skills and adherence to the study protocol.

9.1. Characteristics of a Good Interview

Interviews are friendly but businesslike. At the beginning of each encounter the interviewer makes introductions and verifies the participant's name. Participants are always thanked at the conclusion of interview sessions. Interview areas should be as quiet and private as possible. Although this is often out of the control of the interviewer, participants should be accommodated to have their interviews take place at a time when these conditions are possible.

Interviews are the structured, one-sided transfer of information, not a conversation. The pacing of questions is based on the comfort and comprehension of the participant with each interview; it may vary as the content, complexity or period of recall of the person or subject matter changes. During an interview, questions from the participant are answered with neutral, nonjudgmental responses and questions to the participant are limited to probes to clarify or resolve incomplete, ambiguous or inconsistent responses. Repeating a question is most appropriate when the participant does not appear to understand the intent or meaning of the question. Gently stressing the portion of the question which was not understood when the question is repeated (e.g., "has a doctor ever") is often more efficacious that rereading it in exactly the same manner.

9.2. Characteristics of a Good Interviewer

Interviewers are responsible for being fully familiar with the questions, response categories and skip patterns of each interview. At the beginning of an interview, the study participants may wish to be reassured of the confidentiality of each response/measurement. Interviewers use a conversational tone and establish a pace consistent with the interest and ability of the participant. A good interviewer projects the importance of the interview to the participant and attempts to gain his/her confidence, while remaining impartial and nonjudgmental. For example, a verbal response (or body language when the interview is being conducted in person) which indicates positive feedback is inappropriate, even in the light of participant reports of behavioral modifications (for example, "I quit smoking.") which in a clinical setting would result in praise and encouragement.

9.3. Communication Traps and Obstacles to Standardization

Communication traps include: (1) anticipating or answering questions directed to the participant with the interviewer's own thoughts; (2) hearing what one expects to hear; or (3) being drawn into a conversation. The likely sensitivity of a question is often as much a perceptual problem of the interviewer as it is the participant. Questions thought to be "sensitive" should be asked in a neutral manner which does not differ from the normal professional flow of the interview.

The most frequent obstacles to the administration of a standardized interview are: (1) a perceived conflict by the interviewer between the need to standardize the question with the desire to obtain the truth; (2) a conflict between the interviewer's desire to achieve rapport with the participant and adherence to standardization; (3) inadequate training of the interviewer; and (4) inadequate training of the respondent.

9.4. Interviewer Bias

The use of standardized interviewing techniques is employed to reduce one of the many potential sources of misclassification; i.e., interviewer bias, a *systematic* difference between responses obtained by different interviewers. Although introductory scripts may be modified to respond to different situations an interviewer may encounter, administration of each question exactly as written and use of standardized definitions or explanations are critically important to avoid bias.

9.5. Conducting the Interview

Interviewers must keep in mind that the interviewee is not familiar with the questions, their sequence and response categories. Many interviews require the interviewer to “train” the respondent, mostly by using verbal instructions. For example, responses may follow a series of patterned questions, e.g., a doctor diagnosed condition, age at onset, and age at treatment during the participant's lifetime or may require the selection of the most appropriate category from a series of descriptors, e.g., almost never, sometimes, often and almost always. These instructions should be repeated until it is clear that the respondent understands them, and then subsequently offered only as needed. When the pattern of questions in a form changes to another repeated sequence of responses the interviewer should assist the study participant in making this transition.

The most important technique for conducting a rigorously standardized interview is to read the question in the exact words and in the exact sequence as printed in the questionnaire. With experience the interviewer can memorize specific questions. This helps in maintaining eye contact with the study participant, but care must be taken to avoid changing the wording of the question(s) that are being recalled and not being directly read. The review of taped interviews assists in maintaining standardization in that it can alert interviewers who inadvertently change the wording of a question. Every question must be asked, even if the participant appears to have provided the information in the answer to another question. If based on a previous answer, a question is asked out of the printed sequence; a skip pattern instruction is printed on the form (and presented on the monitor screen).

Reading the transition statements exactly as they are worded is equally important in maintaining standardization. The transition statements are designed to inform the participant about the nature of a question or a series of questions, to define a term, establish a time frame or describe what is being asked in the question.

The order in which the questionnaires are administered is also important. The Sleep Attitudes questionnaire asks about the subject’s opinion on statements about sleep. Administering another

sleep questionnaire before the Sleep Attitudes questionnaire could influence how the subject may respond. Also, the order is set up to develop a rapport with the subject before asking the sensitive questions on the Acculturation and Well Being questionnaires. The order in which the questionnaires should be administered are listed in section 9.6.

Response styles of an interviewer influence the willingness of the participant to respond to questions and the quality of the response. Inappropriate styles include those that are evaluative or judgmental, interpretive or pedantic. Interrupting responses for reasons other than to focus or channel the participant's answer should be avoided.

Appropriate styles of interviewing include providing neutral noises to reassure, pacify or reduce the intensity of the respondent's feelings. These include general clucking or an understanding murmur, as well as nondirective or understanding statements such as a repetition of what the respondent has just said (in contrast to paraphrasing). These are intended to reassure that participant or show interest without intruding on the flow of the response.

Probing is appropriate to seek further information, provoke further discussion along a certain line of thought or explanation, or to present a question to the respondent. In general, and unless specifically countermanded in the QxQ instructions of the interview, probing is appropriate when an answer is unclear, incomplete, inconsistent or no response is given. The best and most frequently employed probe is silence. In a silent probe, the interviewer pauses or hesitates and looks to the participant for an answer. What appears to be dead time to the interviewer may allow the participant to review a lifetime of events. Other types of probing include repetition of the original question, channeling ("tell me more about ..."), clarification ("when did your doctor tell you that?"), elaboration/ continuation ("what happened next?"), encouragement ("I see, um, uhuh") and completion ("anything else?"; "can you tell me anything more about that?").

The most effective, spoken probes are neutral, such as:

"How do you mean that?" instead of "Why?"
"Can you tell me more about this?"
"Can you give me an example?" or "Can you explain that in a little more detail?"
"How are you using that term?"
"If you had to choose, which would you say?"
"What else can you tell me about that?" instead of "Anything else?"

The cautions in using probes are similar to those for the other interviewing techniques: do not interrupt; do not give the impression you are not listening; do not paraphrase the respondent's words and do not suggest an answer.

9.6. Administration of the Interviews

Sueño questionnaires are interviewer-administered, using a specialized data entry and management system. The data entry and management system used by HCHS/SOL is designed to enhance data accuracy and security, while minimizing the burden for the participant and staff. The system displays screens that resemble the paper forms. The interviewer reads the items from the screen and keys the response into the computer. As data are entered, they are edited by the system. Values failing the edit checks cause an error message to be displayed prompting the interviewer to confirm the value, correct it, or flag it as in need of further investigation.

Order in which questionnaires should be administered and entered:

1) Medical Hx	MQE/MQS
2) Sleep Attitudes	SSE/SSS
3) Work Schedule	WSE/WSS
4) Sleep Questionnaire	SPE/SPS
5) Neighborhood Stress	NSE/NSS
6) Sleep Questionnaire II	SQE/SQS
7) Acculturation Stress	ATE/ATS
8) Wellbeing	WLE/WLS

9.7. Quality Assurance of Interviews

The quality of data collected during interviews is maintained through a series of quality assurance procedures. All interviewer-administered interviews are based on the reading of written questionnaires, supported by a Manual of Operations and question by question (QxQ) instructions for each form. Interviewers are trained and certified in interviewing techniques, in the subject matter, terminology, and flow of each data collection form. Certification requires reading through and review of all questions at the central training workshop at the beginning of the study and local practice with successful completion of one taped interview on a "practice" subject as reviewed by the overall Sueño principal investigator (PI).

Successful completion consists of demonstrated ability in the following five areas:

(1) Knowledge of the substantive matter in the interview;
(2) Use of an even pace and conversational tone;
(3) Demonstration of a professional and nonjudgmental demeanor;
(4) Use of appropriate probing techniques;
(5) Ability to accurately record the participant's response.

Interviewers unable to attend central training are trained at each field center by an individual who did attend central training, using the Sueño training materials, standards and certification procedures.

10. ACTIGRAPHY PROCEDURES

Wrist actigraphy is a technique for measuring movements of a limb over an extended recording period (days to weeks). The signals generated by wrist movement are sensed by a tiny micro-computer contained within the "watch" and translated into "activity" counts. Algorithms have been developed to translate these activity counts within "epochs" (or "periods") into a determination of whether the subject was asleep or awake at that time.

Actigraphy provides the ability to estimate sleep duration, sleep patterns (including timing of sleep and napping) and disturbed sleep (awakenings during the sleep period) more accurately than questionnaire. It is easier to use than other approaches, such as polysomnography. Newer devices such as the ones that will be used in Sueño also collect data on environmental light, which can help researchers understand the conditions surrounding the monitoring.

Actigraphy is being performed in Sueño to provide reliable estimates of the duration, timing and patterns of sleep in study participants. This information is important given recent research that has shown that insufficient sleep is associated with cardiovascular disease risk factors and cardiovascular disease as well as poor daytime functioning.

During the Sueño visit, the participant will be shown how to use the sleep watch. The participant will be instructed to wear the watch on the non-dominant wrist for 7 24-hour periods (minimum of 5 nights required to consider the study adequate). The participant also will be instructed on completing a diary concurrently, recording bed and wake times as well as any nap times. This will provide a "backup" in case there are questions about the recording.

10.1. Equipment and supplies

The equipment that will be used for this study, the Actiwatch Spectrum® (from Philips Respironics, Inc) is a small device that will be worn on the non-dominant wrist. The Actiwatch Spectrum® contains a solid-state piezoelectric accelerometer (sensitive to 0.025G and above), lithium battery, microprocessor, non-volatile 1Mbits of memory, and associated circuitry. The orientation and sensitivity of the accelerometer are optimized for highly effective sleep-wake inference from wrist activity, which has been previously validated. The device is designed to be compact, lightweight, waterproof, and to detect movement, time "off the wrist" and environmental light. After the watch data are scored by the Reading Center, a number of summary measurements will be generated for each participant, including: average sleep duration, average sleep efficiency (percentage of time in bed spent asleep), average time of sleep onset, average number and duration of naps, and measures of the night-to-night variability in sleep patterns. This information will be used to understand what factors predict poor sleep patterns and which aspects of sleep are most closely related to cardiovascular disease and its risk factors.

Each Sueño field center will receive:

- 1 copy of Actiwatch® software
- 1 Actiwatch Spectrum® communications docking station
- 1 USB plug attachment with 6ft USB cord
- 10 Actiwatch Spectrum® actigraphs
- 1 Watchband Replacement Kit

System requirements:

You will need a PC computer with a Microsoft Windows operating environment that has an internet connection, a CD/DVD drive, a USB port, at least 512 MB RAM and 50 MB of disk space.

The number of actigraphs may be adjusted across the field centers as needed. Please contact the staff at the reading center in Boston if there is an increase in need at the field center.

10.2. Setting up the Spectrum software

a. Installing Actiware Software

The first step is to ensure the time on your computer is accurate as the Actiware software utilizes this time to set the clocks in the actigraphs. Right click on the time displayed in the lower right hand corner and then select **Adjust Date/Time**.

1) Select the **Internet Time** window. Make sure the box "Automatically synchronizes with an Internet time server" is checked. Go to http://tf.nist.gov/tf-cgi/servers.cgi to see a list of NIST Internet Time servers and choose the one whose status is listed as OK or Recommended for New Users closest to you. Click Apply.
2) Select the **Time Zone** window. Ensure the time zone displayed is correct for your location:
   (GMT-05:00) Eastern Time (US & Canada): New York and Miami
   (GMT-06:00) Central Time (US & Canada): Chicago
   (GMT-08:00) Pacific Time (US & Canada): San Diego
3) Select the **Date & Time** window. Adjust the clock to match with the official US time listed at the website www.time.gov

Actiware® is a Microsoft Windows compatible program that is used to initialize Actiwatch Spectrum® actigraphs and to download data from the devices.

The CD and software installation guide are provided with the Actiwatch Spectrum®.

1) Insert the Actiware® software CD into your computer's CD or DVD drive.

2) Click the **Install Respironics Actiware** in the window that automatically displays when the CD is inserted.

   - If the window does not automatically appear…
     a. Select **Start > My Computer**.
     b. Select the CD/DVD drive on the list and double-click.
     c. Select **CDMENU.EXE** and double-click to open.
     d. Click on **Install Respironics Actiware** to install the software.

   a. Within 30 days of installation, activate your software.
   b. E-mail mm.service@respironics.com with the last 8 digits of the Proof of Purchase Number on the back of the CD case.
   c. Respironics Customer Service will send you an e-mail with the activation code within a couple of hours.

d. Once the activation code is received, open the Actiware® software, then select **Enter Activation Key**. *If it's not activated, Actiware will stop working after 30 days.*
e. Enter the Activation Key and Registration Name exactly as written in the e-mail.

b. Connecting the Actigraph Docking Station

An Actiwatch Spectrum® communication docking station is necessary to communicate with an Actiwatch Spectrum® device.

1) Connect the USB communication cable to any available USB port on your computer.
2) Connect the other end of the cable to the USB port on the Actiware Spectrum® Communications Dock. The cable may be threaded through the cable-keeper on the back of the dock.
3) Wait for a few moments while the Actiwatch Spectrum® Communications Dock drivers are automatically installed.

c. Creating an Actigraph Folder for all Sueño participants

- On the Start Menu of your computer, find and open **My Documents**.
- Select **File > New > Folder**.
- Name the new folder **"Sueño Actigraph Data**". This folder will contain all Sueño actigraph data.

If more than one researcher is responsible for working with actigraphy data, make sure the Sueño Actigraph Data folder is created in a folder that all research staff can access.

10.3. Study visit

Before an Actigraph is given to a subject, it must be configured with basic subject information and data collection parameters. This should be done prior to the Study Visit.

10.3.1. Configuring an Actiwatch Spectrum

1) Open the Actiware® software.
2) From the main menu bar select **Communications > Actiwatch Console**.

Figure 10-A Actiwatch Console Wizard

3) On the Actiwatch Communications Console, click on **Actiwatch Spectrum**.

- The status of the connection appears as either 'Connected' or 'Disconnected'. If 'Connected' does not appear, try another USB port on your computer. Click on **Refresh Status**.
- 'Too many docks' may appear if more than one Actiwatch Spectrum® communication is connected.

4) Check the battery life of the watch and ensure 15 days of recording time are still available. If the estimated battery life is less than 15 days, then use a different Actigraph and contact both the Reading Center and Respironics to replace the actigraphy battery.

5) Place an Actiwatch Spectrum® in the communications docking station by placing it face up with the sensor windows matching the illustration on the communications docking station.

DO NOT leave actigraphs on the docking station for prolonged periods of time as this will lead to accelerated loss of battery life.

6) Wait a few seconds for the Actiwatch Communications Console to refresh or click **Refresh Status** to read the Actiwatch Spectrum status.

7) Click on the expansion arrow to view the Actiwatch Spectrum® configuration details.

8) Creating a Database

- Select **File > Database > New**.
- Select the drop down menu next to "Save in" and find the directory that contains your **Sueño Actigraph Data** folder.
- Save the database using an 8 digit number followed by a letter as the file name in the format: **"HCHS Study ID A/B."** The 8 digit number corresponds to the HCHS Study ID and the letter A or B corresponds to whether it is the first study of the

participant or a repeat study due to inadequate data. A new database should be created for each study – each time that each participant wore an Actigraph.

- This will appear as the active database in the database viewer on the left.

9) From the Actiwatch Console (**Communications > Actiwatch Console**), select the device you want to configure.

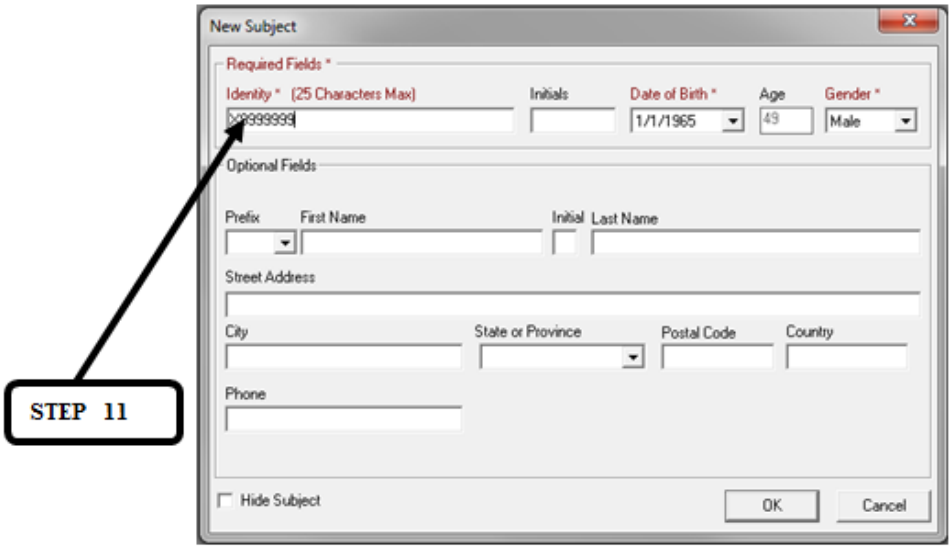
10) Click **Configure**.

*If the Actiware device selected has data in its memory, the **Retrieve** button is outlined. Click **Retrieve** if the data have yet to be retrieved. Configuring an Actiwatch Spectrum will delete all previous physiological data on device. Always retrieve data before configuring the Actiware devices.*

11) Select an existing subject from your database, and then click **Next**.

- If you need to create a new subject
  a. Click **New Subject** to create one.
  b. Type the subject name as Sueño participant ID; this is the HCHS Study ID. The participant ID should match the database ID, excluding A or B. The "Initials" box should contain the technician ID number of the person configuring the watch. Leave the "date of birth," "age," and "gender" fields as they are. Leave all "Optional fields" blank.
  c. Click **OK**.
  d. You are returned to the Select Subject window, with the new ID as the selected subject. Make sure that the participant ID and the database file name are both the same. Click **Next**.

Figure 10-B Actiwatch Console Wizard

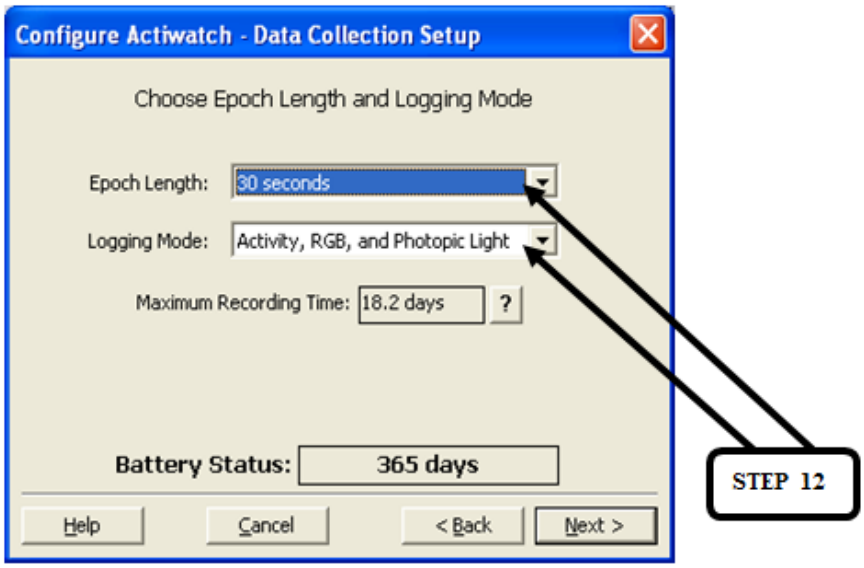


12) Configure the Data Collection Set Up.

- Select the Epoch Length to be **30 seconds**.
- Select the Logging Mode to be **Activity, RGB and Photopic Light**.

- Click **Next**.

Figure 10-C Configuring Data Collection



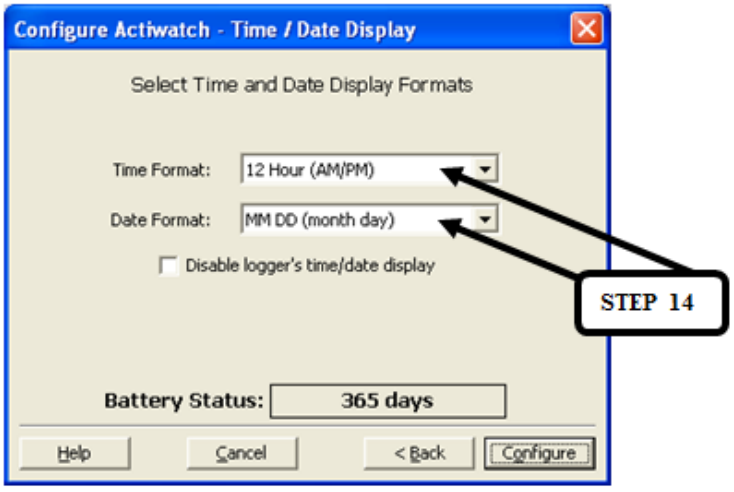
13) Configure the Start Time and Duration

- Uncheck the box next to 'Start collecting data as soon as possible'.
- Set data collection to start at the time of the scheduled Study Visit.
- Select the Data Collection Recording to be **Log Until Full**.
- Choose to change the time zone in which the data will be collected by clicking the **Time Zone** button. (This will also affect the time displayed on an Actiwatch Spectrum).
- Click **Next**.

14) Configure the Time/Date Display

- Select the Time Format to be **12 hours (AM/PM).**
- Select the Date Format to be **MM DD (Month Day).**

Figure 10-D Configuring Time/Date Display



15) Double check that battery status is sufficient for at least 15 days of recording.

16) Click **Configure** to proceed with configuration.

17) A new window will appear asking if you wish to configure now. Click **Continue** to proceed.

18) A prompt is displayed confirming that the configuration is complete. Click **OK**.

19) Allow the Communications Console to refresh by selecting **Refresh Status**.

20) Select the Actiwatch Spectrum device.

21) Click on the expansion arrow and confirm that that the watch information and collection start time is correct.

22) Remove the device from the Communication Dock.

10.3.2. Instructing the Participant in Actiwatch Spectrum Use

At the Study Visit, the participant will receive:

- Actiwatch Spectrum® actigraph
- Sleep Diary

1) Actiwatch Spectrum® Actigraph

The procedures for wearing the actigraph and completing the sleep diary should be explained to the participant and any questions should be answered. Items to be explained to the participant include:

a. Wearing the Actigraph

The actigraph should be worn on the non-dominant wrist. The non-dominant wrist is the one on the arm the participant does not write with. For a right-handed person, it would be the left wrist and for a left-handed person, it would be the right wrist. The actigraph should be securely fastened around the wrist. It should be worn just as a wrist watch would be worn. If the participant's skin is particularly irritable, a thin cloth wristband or some sort of padding can be worn underneath the actigraph so that it is not in contact with the wrist – the actigraph *must* still be securely fastened to the wrist. However, the watch should not be too tight either—a small finger should be able to be fit under the watch band. The actigraph should not dangle from the wrist or slide around. However, when engaged in contact sports (e.g., football) the watch should be removed to avoid damage. If the actigraph is fastened securely enough to record, it will display a circling black border around the time.

*If the actigraph is not fastened properly on the wrist, there will be a **flashing** black border on the display of the actigraph.*

b. Filling the Sleep Diary

Review the information on the first page of the sleep diary that describes actigraphy with the participant.

Next, turn to page 2 (labeled day 0). Complete the sleep diary information on this page with the participant by asking him/her to recall their sleep schedule on the previous day. Explain that information about the previous day should be completed in the diary each morning for the next 7 days. Emphasize that the questions are about the previous day. If the participant is typically awake at night, the diary should be completed after waking from the major sleep period of their day. If the participant forgets to complete the diary in the morning, they should still complete the diary if they remember later that day. However, if it has been more than 24 hours, they should leave that day blank and just move to the next day. The date and day of the week for each page should be filled out by the staff to aid in correct completion of the diary. You may want to suggest that the participant keep the sleep diary by their bed or other convenient place so that they remember to fill it out. The diary should be completed every morning after getting out of bed. If the participant refuses to complete the diary, they should still be given an actigraph to wear and should be encouraged to fill in as much data as possible.

c. Actigraph Event Marker

Participants should be instructed to press the event marker when getting in bed for the evening and when awoken in the morning. Additionally, participants should be instructed to press the event marker when they start and end napping. The event marker is the smaller button located on the right side of the actigraph while the button on the left side provides back lighting for the watch. To avoid confusion remembering which side is the event marker, participants should be instructed to press **both buttons** whenever they get into or out of bed (or any other location they are trying to sleep in). In order to mark an event, **the buttons should be pressed for approximately 3 seconds**, until Time Display blinks "- - - -" for a few seconds before returning back to original time display.

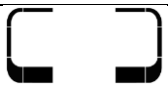
d. Removing the Actigraph

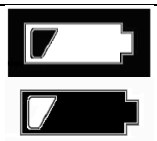
The actigraph does *not* have to be removed when bathing and/or during water sports. Participants should be encouraged to wear the actigraph when showering. It can be worn while showering, bathing, or swimming. When the actigraph or band does get wet, remove the watch and wipe the underlying skin dry to avoid possible irritation. Once skin is dry, the watch can be replaced on wrist and worn as normal.

e. When to Wear the Actigraph

The actigraph should be worn from the time the participant is given the watch until the day that it is returned to the clinic staff (a 7 day period). Study staff should confirm that the actigraph has already begun collecting data before ending the Study Visit. This can be done by making sure that there is a **circling** black border on the display of the actigraph. Participants should be told to continue to wear the actigraph until the time it is to be returned.

f. Appearance of the Actigraph

Visual Indicators	**Description**	**Visual Indicators**	**Description**
	Shows the time of day	 (flashing)	Indicates that the device is not fastened properly on your wrist. It might be too loose or too tight. Refasten the device to your wrist until the flashing stops.

	When you press the backlight button and hold it for 3 seconds, the date is shown as MM-DD.	(Backlight turns on)	Indicates that the backlight button has been pressed. The backlight button automatically turns off after 5 seconds.
 (circling clockwise)	The circling black border indicates that data collection has begun.		When these symbols appear, the Actiwatch Spectrum's battery is running low. Call study staff if this occurs.
(A pattern appears on the display and the backlight turns on briefly)	Indicates that you have successfully marked an event by pressing the Marker Button for 3+ seconds.	 (or blank screen)	Indicate the data collection is complete or that the device is in sleep mode. Call study staff if this occurs.

As long as the participant has the actigraph, they should continue to wear it. The study aims to collect a minimum of 5 days of valid actigraphy data for ALL participants. If less data is collected on the first contact occasion, attempt to have the participant repeat the recording. The participant may not repeat the recording twice, thus there may only be two contact occasions.

10.4. Retrieving data

10.4.1. Retrieving the Actigraph and Sleep Diary from Participant

The logistics of retrieving an actigraph from the participant should be customized at each site. The site can choose to directly pick up the actigraph and diary from the participant's home, use UPS, Fed-Ex or a courier, or have the participant return the device to the site. Instructions on how to return the watch and diary should be provided at the Study Visit. If the materials are to be mailed back, a padded and addressed mailer should be provided to the participant. When the actigraph is returned, log in the return date and note any problems with data retrieval as noted below.

10.4.2. Retrieving Data from Actiwatch Spectrum

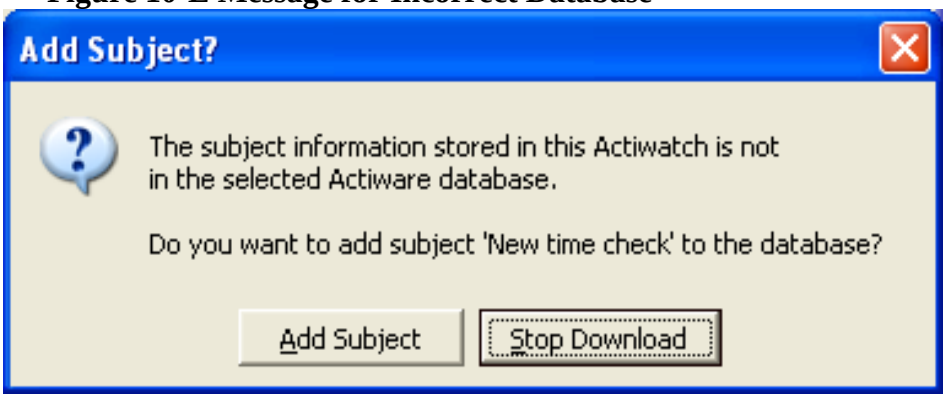
We strongly recommend that actigraph data be processed on a single computer. However, if your site is using more than one computer for actigraph data, please make sure the data is retrieved on the same computer on which the device was configured.

1) Place the Actiwatch Spectrum® securely on the communications docking station.
2) Select **Communications > Actiwatch Console** from the main menu bar.
3) Select the Actiwatch Spectrum device you are using from the Actiwatch Communication Console.
4) Make sure the checkbox next to **Launch Actigram** is selected.
5) Click **Retrieve** to continue. Depending on how large the file is, this may take several minutes.

- If you attempted to retrieve the data from an actigraph that was configured in a different database (see Figure 10-E)
  a. You will be prompted to add subject "HCHS Study ID" or "NEW time check" to database.
  b. Select **Stop Download**
  c. Open the database in which this actigraph was originally configured before attempting to retrieve again.

The retrieved data should be added into the database with the corresponding file name.

Figure 10-E Message for Incorrect Database



6) When retrieval is finished, save the data retrieved by clicking the **Save Data** button.

7) You now have three choices (below):

- **Continue the data collection.**
  DO NOT SELECT THIS OPTION.

- **Configure the device for a new subject.**
  Choose this option if the device is going to be immediately reconfigured and given to a new participant.

- **Put actigraph to sleep for later use.**
  Choose this option if the device is not immediately going to a new participant. This action causes the device to be put into low power sleep mode. The display turns off after a few seconds. Pressing the left marker button, or putting the device back into the dock wakes it up.
  a. After selecting this option, a new prompt will appear. Select **Put Actiwatch to Sleep.**
  b. Select **OK**.
  c. The actigraph display should turn off after a few seconds.

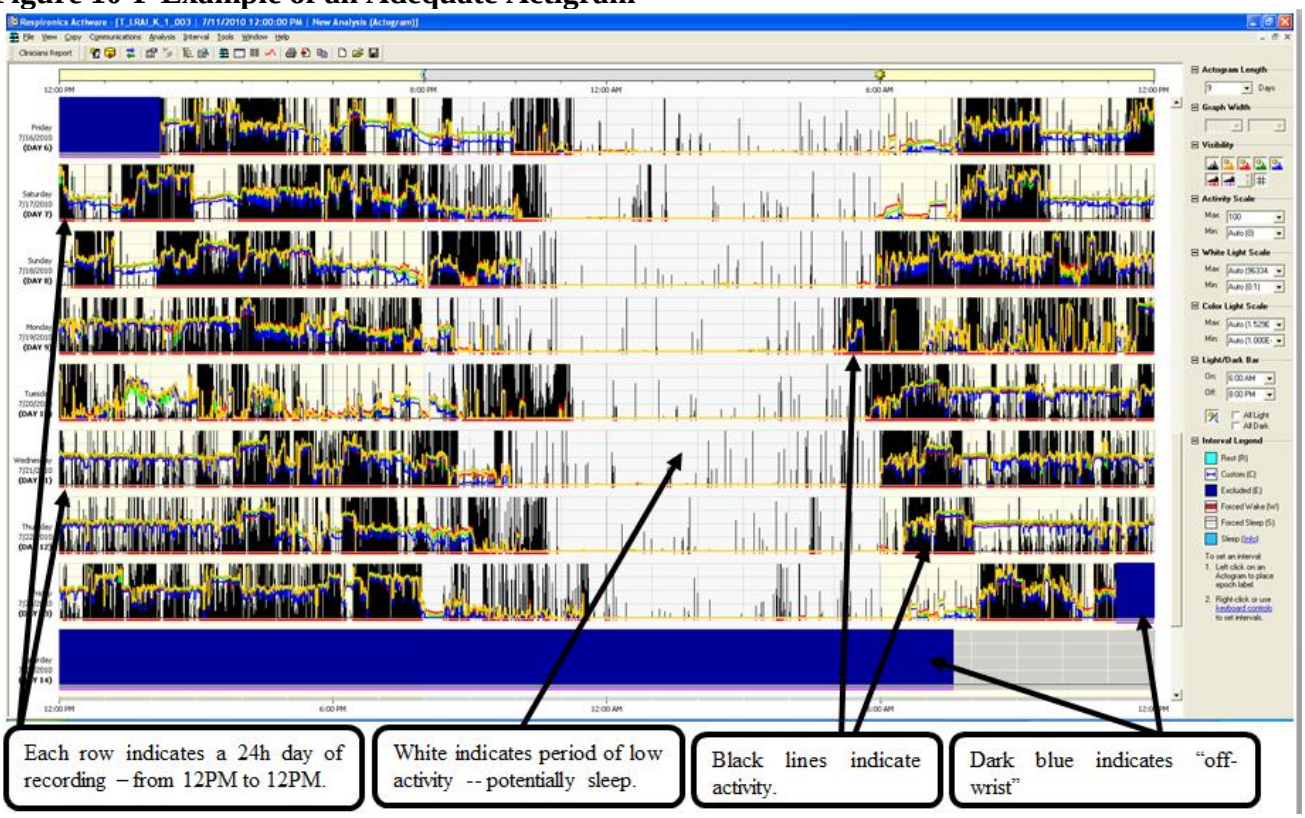
8) Choose one option and click Next.

10.4.3. Assessing Data Adequacy

Review participant's actigram recording.

- Confirm the following:
  a. There is a minimum of 5 nights recorded.
  b. There aren't any substantial periods of time that the actigraph was "off-wrist."

Figure 10-F Example of an Adequate Actigram



An adequate actigram (see figure 10-F)is defined as a study with at least 5 acceptable 24-hour periods of data collection. A 24-hour period begins and ends at noon of each day. **Data collection is acceptable for a 24-hour period if missing data (including off-wrist time) accounts for less than 4 hours of the 24-hour period, including no missing data for the entire main sleep period, immediately before sleep onset and immediately following sleep offset.** If it appears that less than 5 acceptable 24-hour periods (from 12pm to 12pm the next day) of data were collected, this should be noted in the actigraphy log and an email should be sent to the Reading Center alerting them to this problem. All data including the sleep log should always be sent to the Reading Center. The Reading Center will make a final determination as to whether the study is adequate or not.

10.4.4. Repeating Study if Necessary

If a study is determined to be of insufficient length and/or quality, the Reading Center will notify the Field Center by sending a partially completed Study Failure Form listing the reason for repeat. At this point, Field Center staff should re-contact the participant and request that he/she complete the actigraphy and sleep diary for another 7 days. The Field Center staff should also complete the Study Failure Form (see section 10.4.5 for details) listing participant repeat status and return the completed form to the Reading Center. If the participant agrees, a new study folder should be created labeled with the HCHS Study ID followed by the letter B to indicate second study. If this second study is also deemed, inadequate, no further attempts at data collection should be made. If the participant's actiwatch needs to be replaced at any point during the study due to a technical failure, the study with actigraphy data from the original watch should be labeled with the HCHS Study ID and the study with the replaced watch should be treated as the second study and labeled accordingly with the HCHS

Study ID followed by the letter B. All studies, regardless of duration, should be transmitted to the Reading Center.

10.4.5 Study Failure Form

When a first study is deemed inadequate, the Reading Center will send a partially completed Study Failure form per participant to a designated Field Center staff member listing the failure reason. Field Center staff members are expected to follow up with the participant and determine whether the participant is willing to repeat the study. Field Site staff should promptly return completed Study Failure Forms listing participant repeat status to the Reading Center. This form is located in the appendix in section V.C.

10.4.6 Sueño Study Email Account

When Study Failure Forms are received at the Reading Center as well as other relevant information pertaining to specific participants, they will be sent from the Sueño study email account: bwhsueno@partners.org. Completed Study Failure Forms should be sent to this email address.

Once data has been retrieved and saved, close out of Actiware software.

10.5. Transmitting Data to Reading Center

The frequency with which actigraphy and sleep diary files are sent to the Reading Center is up to the determination of the local Field Center but should be at least once per week. Any studies with likely insufficient data should be transmitted right away (with notification to the Reading Center by email or telephone) in order to obtain a timely determination of whether the study needs to be repeated.

Before transmitting the actigraphy data, the sleep diary needs to be converted into an electronic file.

- Review over participant's sleep journal and make sure all information is complete.
- Scan sleep journal into computer.
- Save as a .pdf file using the same naming convention as the Actigraph study folder –the HCHS Study ID followed by the letter A or B (to indicate whether it is the first or second attempt at data collection.
- Save the sleep journal in the participant folder in which the participant's actigraph data is located.

Whenever participant actigraphy data is collected of any length, there should always be a corresponding sleep journal labeled with an HCHS Study ID and letter (A or B) that matches the actigraphy file label. If there is no corresponding sleep journal because the participant lost or did not return a sleep journal, attach a blank sleep journal .pdf file. Never send an actigraphy file without a corresponding sleep journal.

The participant folder that will be encrypted, zipped, and sent to the Reading Center should be found in the **Sueño Actigraph Data** folder created in Section 5.

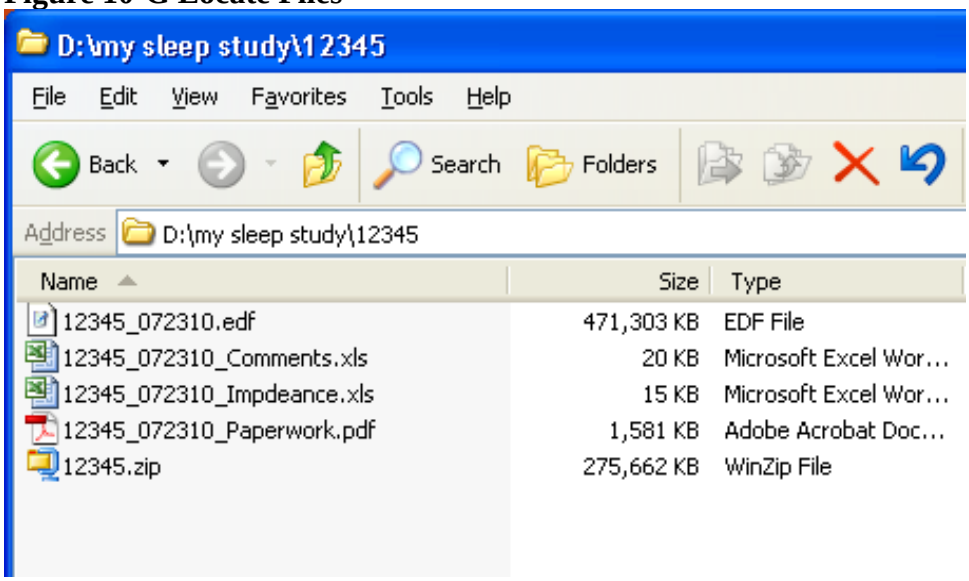
The encrypted zip file should include:

- The raw database file created for the participant with collected data.
- A PDF of the Participant's sleep journal.

10.5.1. Creating Zip Files using Windows Compressed Files

- Locate the files that are to be sent to the reading center.

Figure 10-G Locate Files



- Right-click on the files and select **Send To** > **Compressed (zipped) Folder**
  The selected files will be added to the zip file.

Figure 10-H Compress Files

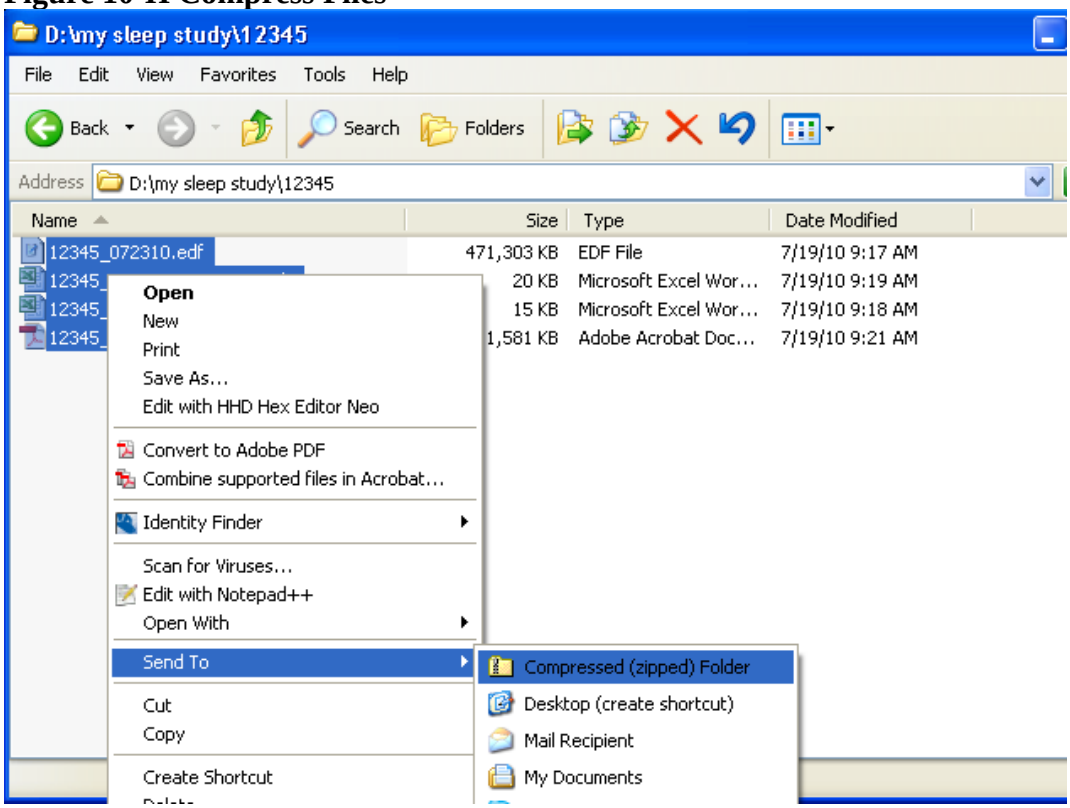
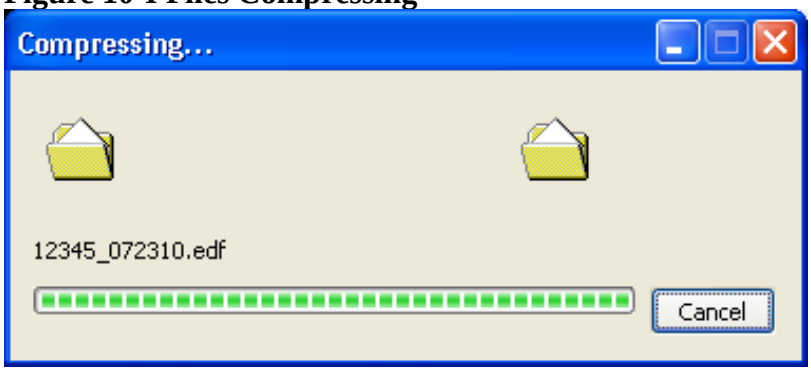
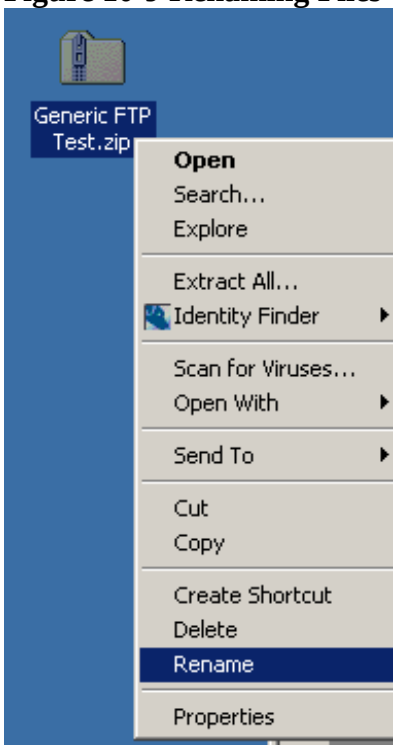


Figure 10-I Files Compressing



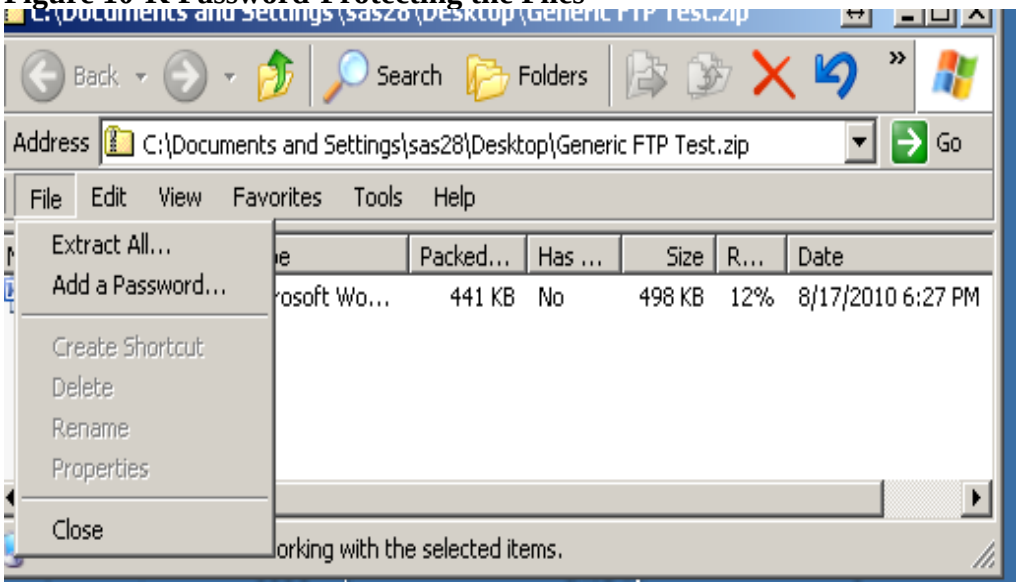
- Rename the file, if needed, to comply with naming conventions. Once the zip archive file appears in the directory, right click on the zip file name and "rename" (see Figure 10-H in the next page)Note the name of the zip file will be the same as the first file in the group selected, or if only one file is selected the zip file will be named after that file.

Figure 10-J Renaming Files



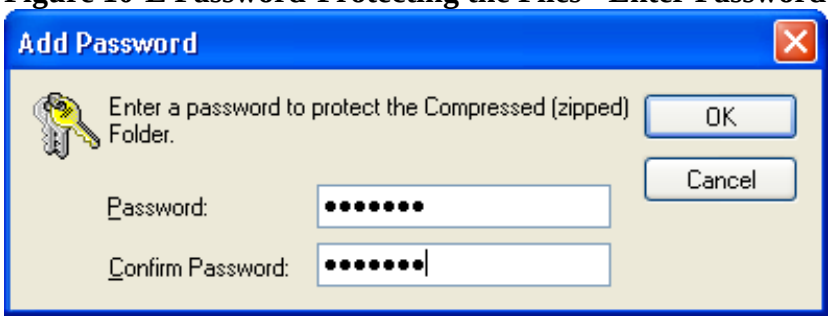
- Open the compressed zip file (double-click on the folder, or right-click and select Open) then select **File --> Add a Password**

Figure 10-K Password-Protecting the Files



- Enter the project encryption zip password and select **OK**.

Figure 10-L Password-Protecting the Files - Enter Password



You have now successfully added the password to the zip file and can close the zip file folder window. If you need to add a file to the encrypted zip file --- Open the zip file and drag the file you want to add into the zip folder.

It is important the folders and files sent to the reading center are named correctly to prevent loss or replacement of important raw data. The standardized naming conventions for data to be sent are as follows:

- ZIP file – **"HCHS Study ID A or B.zip"**
  The ZIP file should automatically have the same name as the folder being zipped.
- Folder [to be unzipped from ZIP file] – **"HCHS Study ID A or B"**
- Data Files [found in folder]:
  - Actigraph Database file – **"HCHS Study ID A or B.AW5"**
  - Sleep Journal – **"HCHS Study ID A or B.pdf"**

1) Username and Password

Each clinical site will receive a designated username and password that will be used for data upload. This password will be changed periodically to ensure security. Sites will be notified in advance when a change is to occur. The user name and password will be sent to the site Project Coordinator.

2) SFTP Software and Connection

Uploading of data to the Reading Center will be done via Secure (SSH) File Transfer Protocol (SFPT), which provides additional security for research data during transmittal. Sites uploading data will need FTP client software installed on the designated computer and may need to configure their firewall to allow outgoing traffic for SFTP on port 22. The site institution's IT personnel should be able to assist in this configuration.

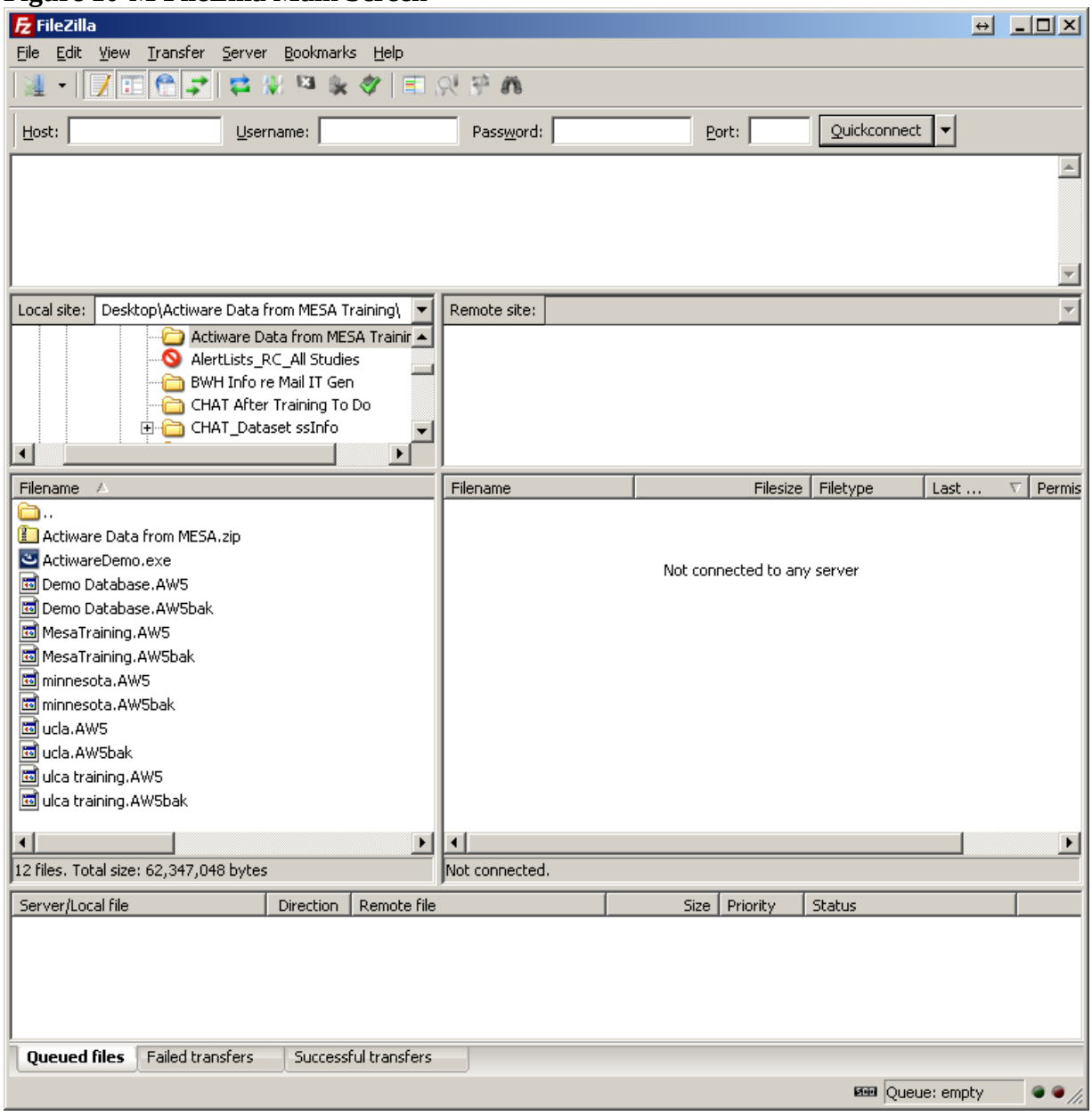
10.5.2. Using FileZilla to Upload/Transfer Data to BWH Reading Center

A number of FTP client software packages which support SFTP transfers are available free or for purchase. The Sleep Reading Center recommends downloading FileZilla which can be downloaded from the following website: http://filezilla-project.org/download.php.

Each clinical site will receive a designated username and password that will be used for data upload. This password will be changed periodically to ensure security. Sites will be notified in advance when a change is to occur. The user name and password will be sent to the site Project Coordinator. Each project will have a separate zip password that will be used for encrypting data files and this will also be sent to the site Project Coordinator.

- Click on the FileZilla icon to display the main screen

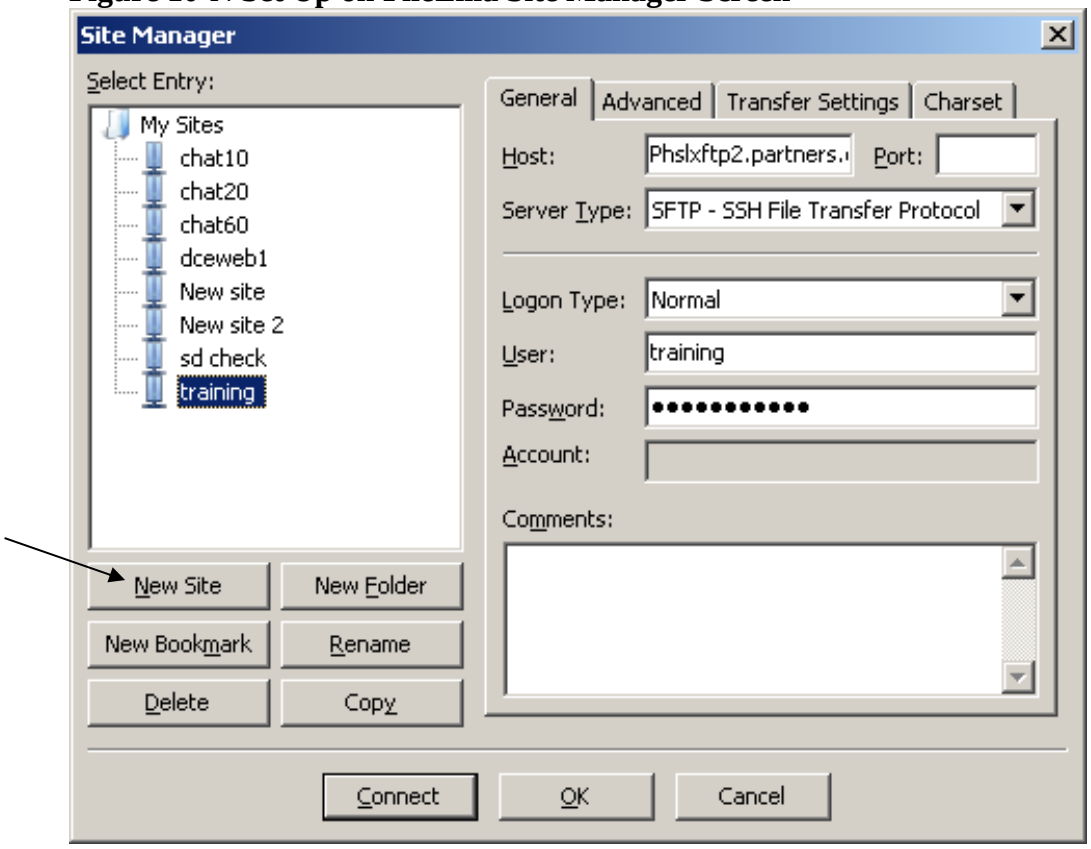
Figure 10-M FileZilla Main Screen



- Select File -> Site Manager to Display the Site Manager Setup screen. Select **New Site** and enter your Site Name. This name should be the same as your FTP username. Fill in the following information Under the **General** tab:

  Host: **Phslxftp2.partners.org**
  Port: **22**
  Server Type: Select **SFTP (SSH File Transfer Protocol)**
  Logon Type: Select **Normal** to receive options for **User** and **Password**
  User: *(the site FTP username provided by the Reading Center to the Coordinator)*
  Password: *(the site FTP password provided by the Reading Center to the Coordinator)*

Figure 10-N Set Up on FileZilla Site Manager Screen



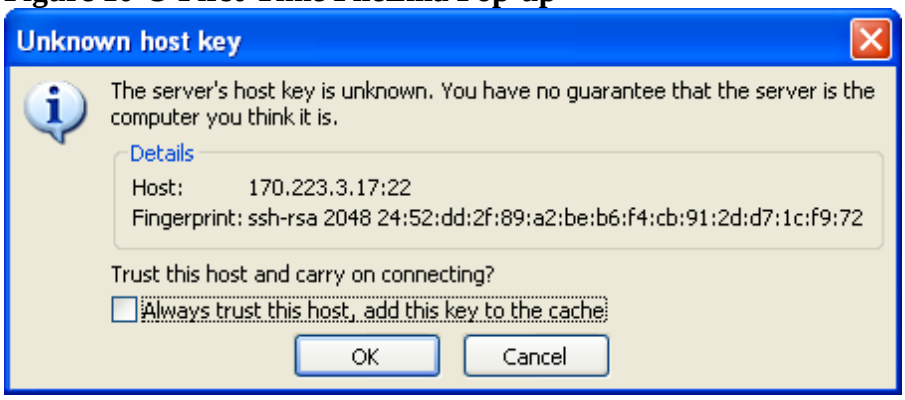
Once a new site is set up and appropriate information is filled in it can be used to connect whenever needed.

- **Select OK to save your settings** or select **Connect** which will also save your settings and connect you to the SFTP Server.

If this is the first time using FileZilla you may get the pop up shown on Figure 10-O. select "**Always trust this host, add this key to the cache**" then select OK. This Host IP number is the BWH/Partners SFTP Server. Once the FTP Client software is connected to the BWH SFTP server

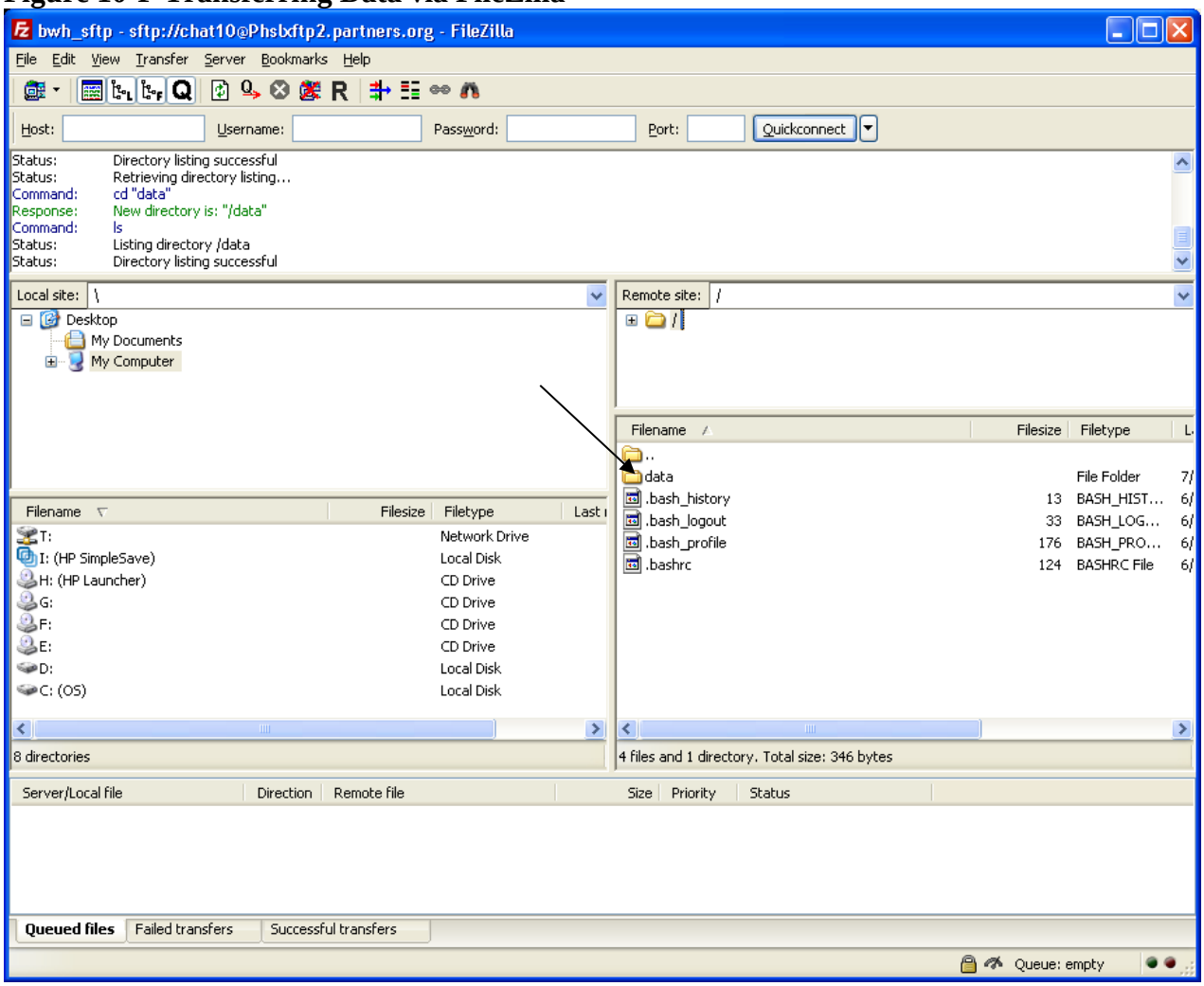
using the information provided, you will automatically be connected to a root folder specific to your site.

Figure 10-O First-Time FileZilla Pop-up



- OPEN the **data** folder on the server (Remote Site). You must be "inside" this folder before attempting the upload.

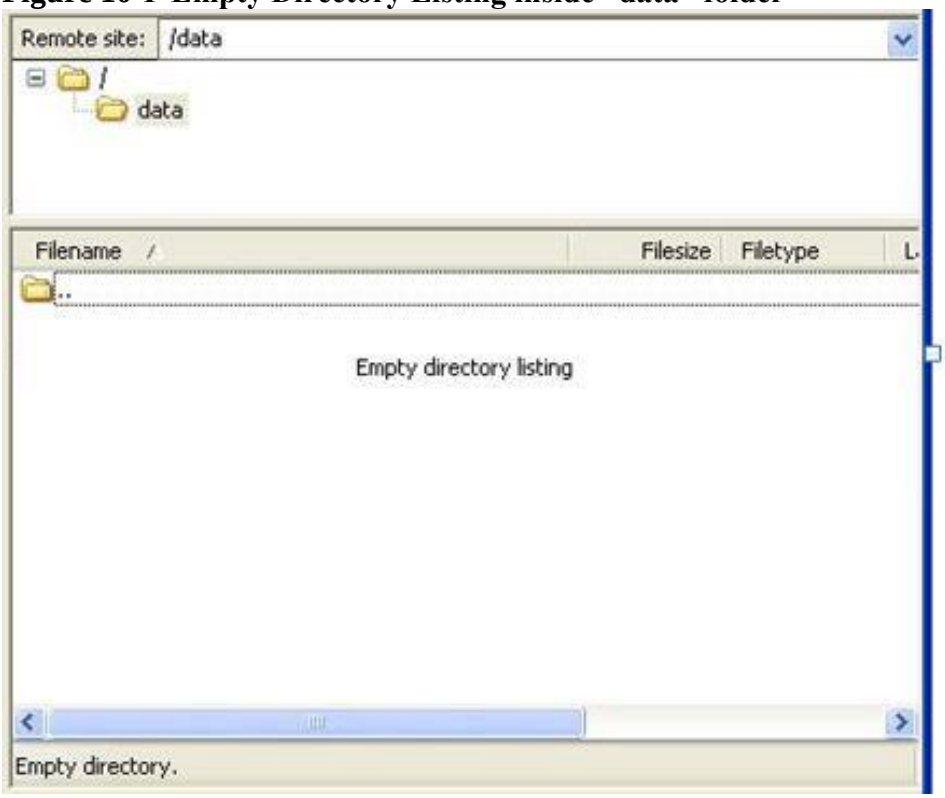
Figure 10-P Transferring Data via FileZilla



Note: The two Left Panes represent your local computer. The Top Left displays all your drives and the Middle Left displays the folder in which you currently are. You can navigate anywhere on your computer by using these two panes:

- Once inside it will read **Empty directory listing** or if you have placed other files there that have not been moved to the **Incoming** processing folder they will be displayed.

Figure 10-P Empty Directory Listing inside "data" folder



- Locate the encrypted zip file(s) to be uploaded on your local system (Figure 10-Q). On the left pane, double-click on the zip file(s) to be uploaded and transmission will start. Alternatively, right click on the file and select **Upload** (Figure 10-R). You will see the progress of the transfer in the bottom pane (Figure 10-S). At any time, select **Help** for additional information on using FileZilla.

Figure 10-Q Locate Encrypted File

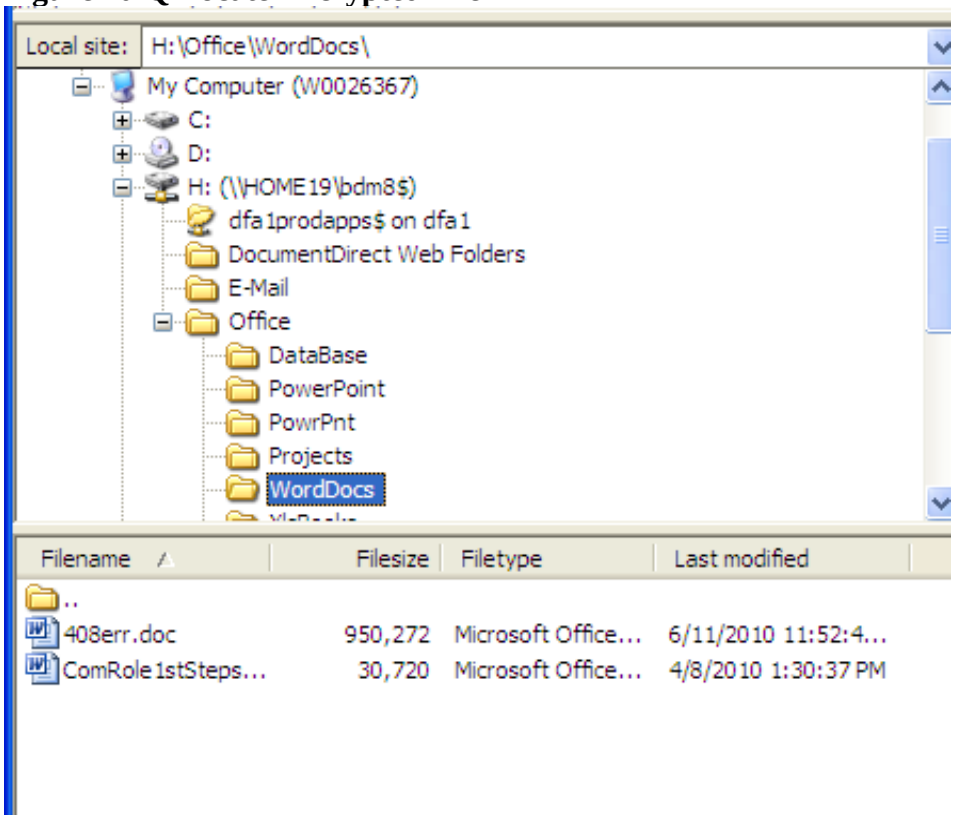


Figure 10-R Upload Encrypted File

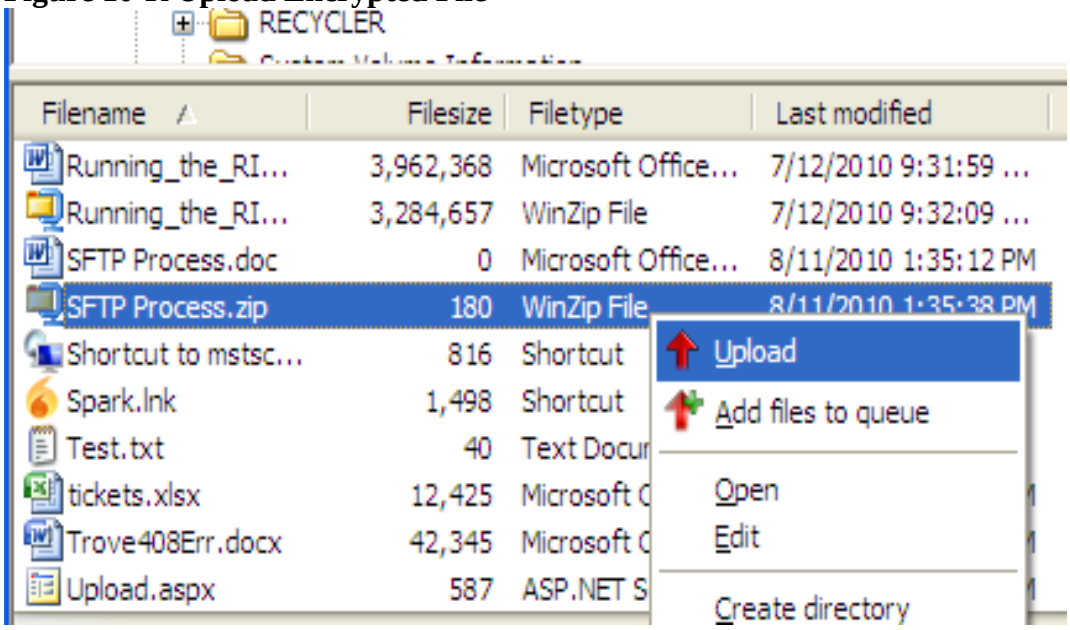
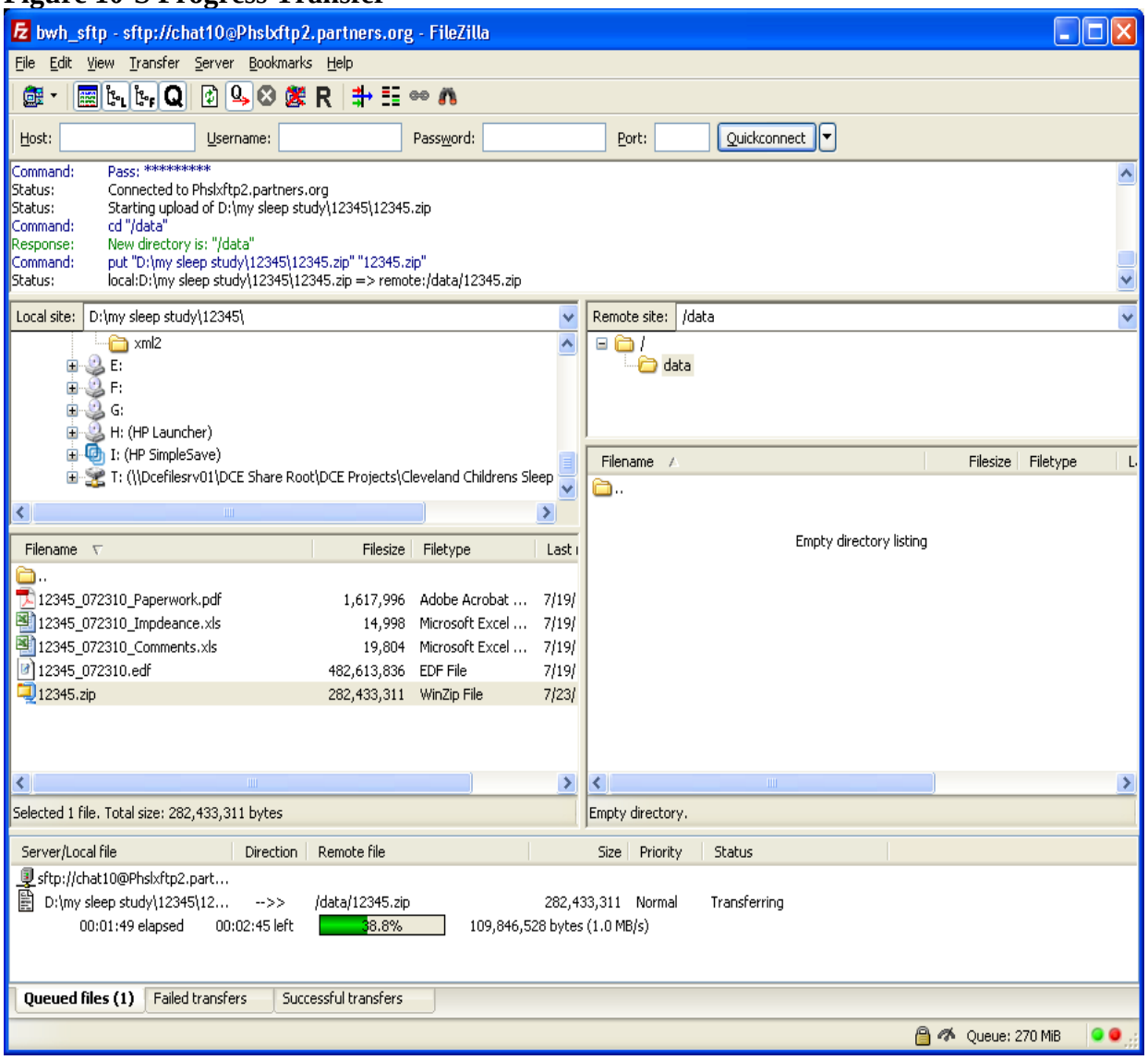
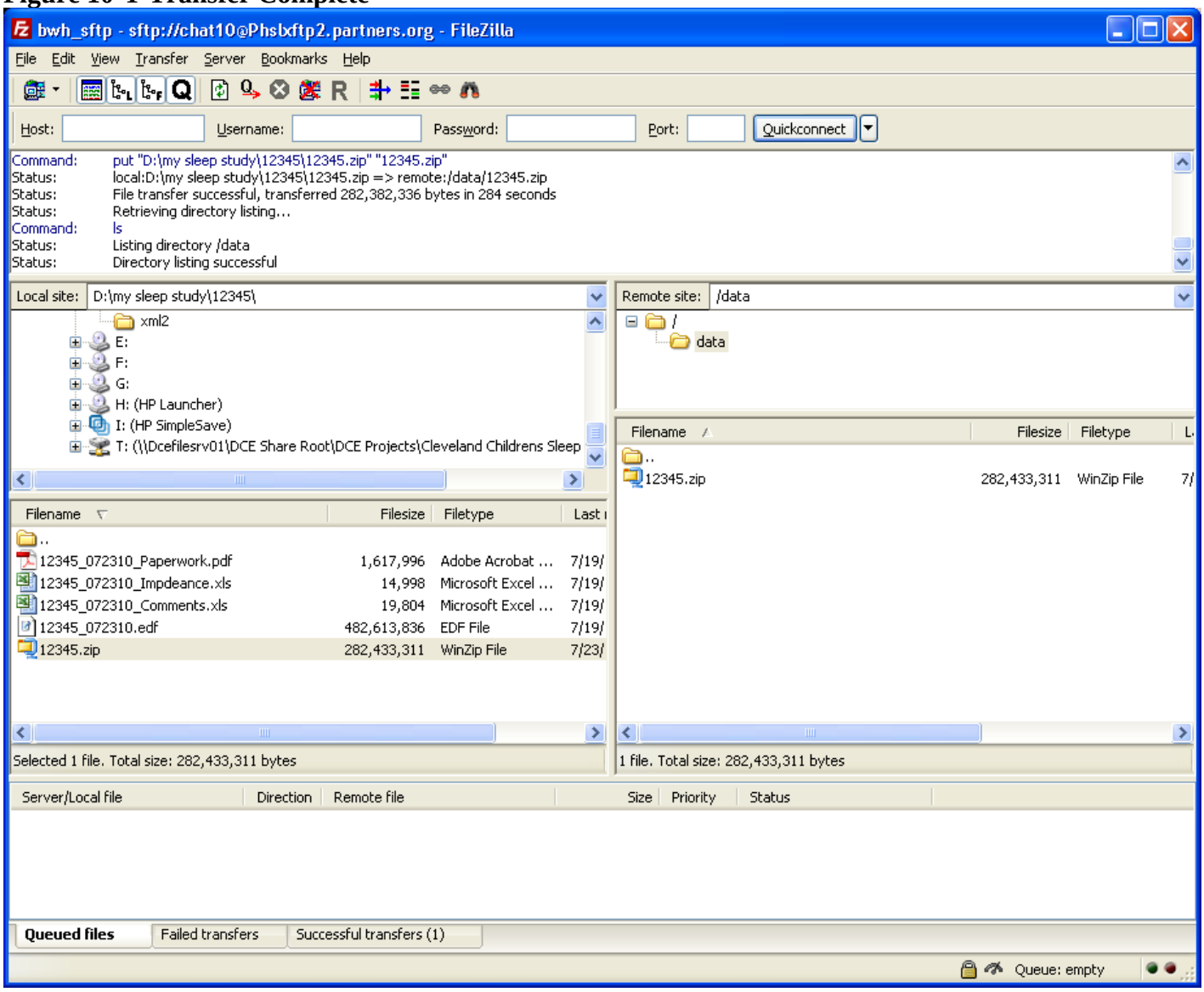


Figure 10-S Progress Transfer



- When the upload is complete the file will appear on the server (Figure 10-T)

Figure 10-T Transfer Complete



NOTE:
A program called Diplomat transfers files placed in your site directory to an Incoming directory for processing at the Reading Center two times a day (noon and 11:00 PM). Each site is to send the Sleep Reading Center the names and e-mail addresses of the individuals responsible for transmitting data. An e-mail will be sent to these individuals at the site when the transfer is complete stating whether it was successful or failed to transfer.

The most common reason for a failed transfer is forgetting to zip the file. If a file is not "zipped" it will fail to transfer.

Contacts:
If you have questions about uploading files or have difficulty connecting, please contact the Sleep Reading Center, either Susan Surovec (ssurovec@partners.org) at (216) 702-6050 or Nicole Bollinger (nbollinger@partners.org) at (857) 307-0343.

If you require your IT person to contact someone at Partners directly they can contact Brad McKenna (bmckenna@partners.org) at (617) 726-0331.

10.6. Equipment maintenance

A log should be maintained at the clinic so that the locations of the actigraph devices are known at all times. An example of this log is included in the study appendix, section V. A serial number (EX. A01785) for each actigraph can be found on the backside of each actigraph. This should be used as the **Actiwatch ID**.

10.6.1. Cleaning of Actiwatch Spectrum

After each participant, the actigraph should be cleaned before reconfiguring and given out to a new participant. This involves the following two steps:

1) Soak the actigraph in warm water and a mild detergent for 5 minutes.
2) Rinse and dry with a soft cloth.

Do not use abrasives or alcohol.

If the watch band is especially soiled, it may be wiped more vigorously with disinfectant wipes. The wipes may NOT be used on the watch portion of the device.

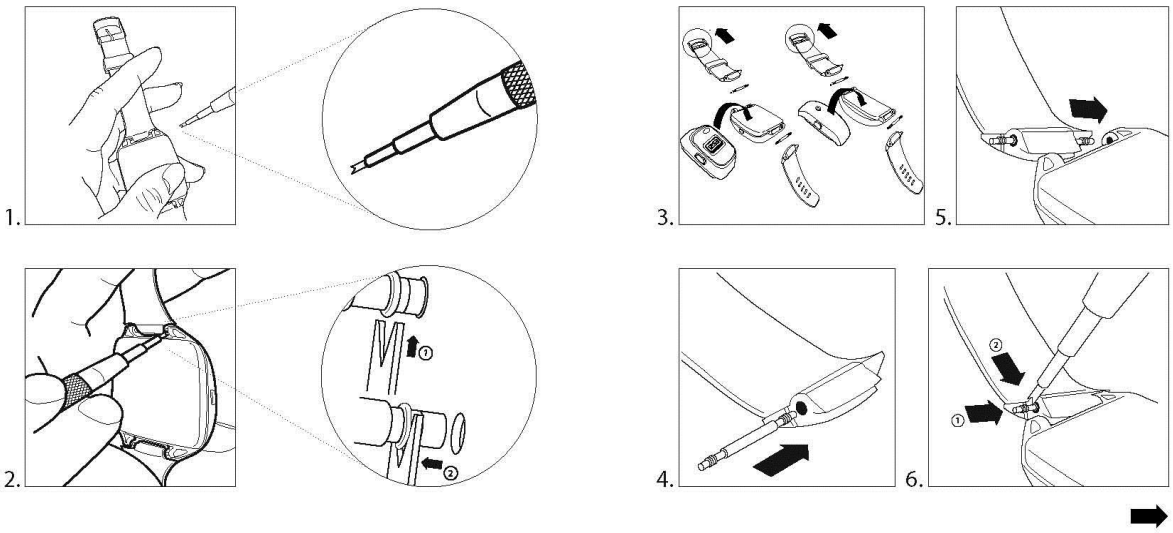
10.6.2. Battery management

The battery in the Actiwatch Spectrum® should last 1 to 2 years based on usage (1 year for continuous usage). In order to conserve the battery, the watch automatically shuts off if the back of the watch is not in direct contact with a conductive surface. Thus, do not store watches in such a way that the back of the watch is able to make contact to a surface. The battery cannot be replaced by the user and should be returned to Philips Respironics for replacement. If the battery status indicates less than 15 days of recording available, contact Philips Respironics and the Sleep Reading Center to arrange for battery replacement. Note that if the battery dies before data can be downloaded off the device, the data can still be downloaded. Contact the Sleep Reading Center to notify them of this need.

10.6.3. Replacing Actiwatch Bands

Bands should be replaced when they become damaged or permanently soiled. The Watchband Replacement Kit contains extra watchbands as well as a tool to remove and replace watchbands using the steps outlined in Figure 10-U.

Figure 10-U Replacing Actiwatch Bands



10.6.4. Shipping an Actiwatch Spectrum to Respironics

After approximately 12 to 14 months of use, each actigraph will be returned to Philips Respironics to have the battery replaced. A schedule will be set and provided to each site. In addition, malfunctioning watches—those not keeping time, failing to transmit data, or producing error codes, will also need to be returned to Philips Respironics after contacting the Reading Center and discussing the problem. Notify the Reading Center whenever a watch is to be returned to Philips Respironics so the Reading Center can monitor for watch problems across sites.

10.7. Quality assurance for the Actiwatch

Each research assistant charged with the responsibility of initializing, downloading or any other handling of the actigraph will be required to meet performance standards that indicate an understanding of the actigraph's battery life, use of communications dock and software, and explaining the actigraph and sleep diary completion to the participant. Only personnel who meet these standards will be certified and approved to handle the actigraph devices and instruct the participants.

Personnel will be required to attend a training session, or undergo local training by a certified technician. Training will consist of:

1) Overview of Actigraphy Operations Manual, including detailed use of actigraph, the software, and the communications dock.
2) Hands-on training for initializing and downloading/saving of files.
3) Overview of Actiware Spectrum® Software Manual

10.8. Certification

Each staff member handling the actigraph devices needs to successfully complete **2** initializations, downloading, file checking, and saving to the assigned folder including successful transmission to the Reading Center of at least 1 file. These should be done with a certified technician present. Actigraphy data for the certifications will be collected on healthy volunteers.

10.9. Troubleshooting solutions for an Actiwatch Spectrum

Error Message or Condition	**Solution**
'Disconnected' is displayed	a. Check the cable connections on the docking station and the computer. b. Connect the docking station to a different USB port on your computer. c. Verify installation of the software drivers: Select **Start > Control Panel > System > Hardware tab > Device > Manager**. Two items should be listed with the name, 'Actiwatch Spectrum Communications Dock'. If they are not listed, or if they're listed with yellow exclamation points, disconnect the communications doc, uninstall Actiware and reinstall it from the installation CD.
'Too many docks' is displayed	Caused when more than one Actiwatch Spectrum® communications dock is connected to the computer at the same time.
'Error' is displayed	Disconnect the Actiwatch Spectrum® communications dock then reconnect it.
Logger not found, insert logger into communications dock	a. The Actiwatch Spectrum® may not be docked properly. It may be upside down, not pressed securely into place or backwards. Verify that the Actiwatch Spectrum is installed exactly the same as the installation on the top of the communications dock. b. The Actiwatch Spectrum® may have a weak or dead battery.

NOTE:
Actiwatch devices that do not keep time correctly may still be recording movement correctly. If time is not being maintained correctly, transmit the data to the Reading Center and note this. Arrangements will be made to replace the watch.

11. REIMBURSEMENT AND SUMMARY LETTER

Subject participation in this Sueño will end after completion of the one week of actigraphy. The process for recovering the actigraph and sleep diary from participants will vary by site based on experience from the parent study. Upon return of the actigraph, the participant will be compensated $100 for their participation. The full amount should not be provided reimbursement until recovery of the actigraph has occurred. If an actigraph is lost, the Reading Center should be notified immediately with details in order to file appropriate insurance claims.

On a monthly basis, the Data Coordinating Center will transmit a file to each Field Center with summary data from the actigraphy on each participant identified by the Study ID. Field Center staff will need to re-identify this data and use it to complete the summary letter. This letter will summarize the subject's actigraphy results as well as contain general information and recommendations about healthy sleep habits. A template for the letter is attached in the study appendix, section VI. The site will then mail or have the subjects pick up the summary letters. For sites that choose to send reimbursements in the mail, the reimbursement check and summary letter may be combined in one mailing.

12. ADVERSE EVENT REPORTING

12.1 Defining adverse events

An **adverse event (AE)** is defined as any worsening of a subject's health status, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. Some subjects may have underlying health conditions. To qualify as an AE, there must be a worsening from the baseline level of health. If a subject has a known history of asthma and usually uses his/her inhaler twice a week on average, then needing to use their inhaler once during the week of their study participation would not be an AE. If they had to use their inhaler five times that week, this would be a worsening from their usual and so would qualify as an AE.

A **serious adverse event (SAE)** is any adverse event temporally associated with the subject's participation in research that meets any of the following criteria:

1. Results in death.
2. Is life-threatening (places the subject at immediate risk of death from the event as it occurred).
3. Requires inpatient hospitalization or prolongation of existing hospitalization.
4. Results in a persistent or significant disability/incapacity.
5. Results in a congenital anomaly/birth defect.
6. Any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

12.1.1 Unanticipated adverse events

An **unanticipated adverse event (UAE)** is defined as any adverse event occurring in one or more subjects participating in a research protocol, the nature, severity or frequency of which is **not** consistent with either:

1. The known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol-related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts.
2. The expected natural progression of any underlying disease, disorder or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

It is useful to consider the following 3 criteria in deciding whether something is a UAE. All 3 criteria must be met to qualify as a UAE.

1. Is the event an adverse event?
2. Is the event at least possibly related to study participation?
3. Is the event not an expected risk of study participation?

Some examples of UAEs include the following:

- A subject takes a bath wearing their actigraph and gets electrocuted.

- A subject is mugged and their actigraph and wallet are stolen. As part of the mugging, the subject is beaten.

The following would not be UAEs:

- The development of a rash from wearing an actigraph would not be considered a UAE because this is an expected potential risk as described in the Sueño Informed Consent form.
- A subject had a mammogram during the week she participated in the study and was found to have an abnormality that was diagnosed as breast cancer. In this case, the AE is not related to study participation so would not be a UAE.

It is up to the local Principal Investigator to decide whether an event constitutes a UAE. In general, if there is uncertainty, it is better to err on the side of declaring an event a UAE.

12.2 Reporting adverse events

All AEs and SAEs need to be reported to the Field Center's local IRB as per local IRB regulations. Typically, this is annually at the time of Continuing Review. In general, AEs and SAEs occurring at a local site do not need to be reported to the Coordinating Centers or other Field Centers.

All UAEs need to be reported not only to the Field Center's local IRB, but also to all other IRBs reviewing the project (those for the other Field Centers as well as the Sleep Reading Center and Data Coordinating Center). In addition, these need to be reported to NIH. This is because the occurrence of a UAE potentially changes the risk/benefit ratio of study participation and so a reevaluation of the study protocol and informed consent at each site may need to occur.

In order to facilitate information transfer about UAEs from one site to all other participating sites, UAEs need to be reported to the Sleep Reading Center using the *Sueño Unanticipated Adverse Event* form. The Reading Center will verify information and then distribute this information to all participating sites.

All UAEs need to be reported to the Sleep Reading Center **within 1 week**. The Sleep Reading Center will review information to ensure completeness and then distribute this information to all sites as well as NIH.

Information about UAEs needs to be reported to each site's local IRB according to local IRB regulations. The Office of Human Research and Protection (OHRP) suggests that all UAEs be reported to the local IRB within 2 weeks and that UAEs which are severe be reported within 1 week, but local IRBs often have more stringent requirements. The timeline for reporting begins from the time the local Field Center is made aware of the event. Thus a local UAE should be reported to the local IRB at the same time the Reading Center is notified. External UAEs (those occurring at other sites) should be done within 1-2 weeks of notification of the occurrence by the Reading Center to your site.

12.3 Sueño Unanticipated Adverse Event form

The *Sueño Unanticipated Adverse Event* form should be used to report UAEs to the Sleep Reading Center. This form can be obtained by going to the Sueño Study page on the HCHS/SOL website at http://www.cscc.unc.edu/hchs/utilities/docfilter.php?study=hchs&filter_type=manu.

For further information regarding some of the terms on this form, please see the additional description below:

12.3.1 Expected adverse events

There is a question on the *Sueño Unanticipated Adverse Event* form that asks "Is this type of event foreseen in the Informed Consent or study MOP?" Any event that is consistent with what is documented in the Sueño Informed Consent or study MOP would be considered an expected AE. If an AE is expected, then it is not a UAE and this form does not need to be completed.

12.3.2 Relatedness to study

There are three categories regarding the likelihood of relationship to participation in Sueño: definitely related, possibly related and not related. An event should be classified as "definitely related" if the event was clearly related to the study. An event should be classified as "possibly related" if the event may have been related to the study. An event should be classified as "not related" if the event was clearly not related to the study. If an AE is not related to the study, then it is not a UAE and this form does not need to be completed.

12.3.3 Severity of the event

An event would be considered mild if no intervention was required. An example of a mild AE would be if the participant developed a brief rash that cleared up on its own. An event would be considered moderate if some treatment or intervention was required. For example, if the participant developed a rash that needed to be medicated with a cream, this would be considered a moderate AE. An event would be considered severe (serious) if the event resulted in an emergency room visit, hospitalization (or prolonged a hospitalization), was associated with disability or incapacity or required intervention to prevent permanent impairment, was life-threatening or resulted in death. In addition, if the event was associated with a congenital anomaly or birth defect, it should be coded as severe (serious).

12.4 Protocol for reporting unanticipated adverse events

1. Complete the *Sueño Unanticipated Adverse Event* form.
2. Completed *Sueño Unanticipated Adverse Event* form should be labeled as **AE** followed by the **participant ID** (for example: AES9999999). Forms will need to be sent to the Reading Center and in order to do this they must be zipped using Windows Compressed Files or an equivalent zipping program such as WinZip or WinRAR. Please follow the instructions below in order to zip files using Windows Compressed Files:
    a. Locate the file to be sent to the Reading Center.
    b. Right-click on the files and select **Send To > Compressed (zipped) Folder**.
    c. Open the compressed zip file (double-click on the folder, or right-click and select Open) then select **File > Add a Password**.
    d. Enter the project encryption password **sueno321** and select OK.
3. FileZilla will be used to upload/transfer data to the Reading Center. FileZilla is the same program used to upload participant daily sleep logs and actigraphy files. Although FileZilla should already be downloaded on your computer, it can be downloaded from http://filezilla-project.org/download.php.
    a. After installation of FileZilla, click on the FileZilla icon to display the main screen. If FileZilla has already been installed on your computer, please skip to part 4.
    b. Select **File > Site Manager** to display the Site Manager setup screen.
    c. Select New Site and enter your Site Name. Once a new site is set up and appropriate information is filled out, it can be used to connect whenever needed.

Host: **Phslxftp2.partners.org**
Port: **22**
Server Type: Select **SFTP (SSH File Transfer Protocol)**
Logon Type: Select **normal** to receive options for User and Password
User: *(the site FTP username provided by the Sleep Reading Center to the Coordinator)*
Password: *(the site FTP username provided by the Sleep Reading Center to the Coordinator)*

4. In the main screen in FileZilla, open the **data** folder on the server (Remote Site on the right-hand side of the screen). **You must click inside this folder before attempting the upload.** Locate the encrypted zip file to be uploaded from your local system. Double-click on the zip file to be uploaded and transmission will start or right-click on the file and select **Upload**. When the upload is complete, the file will appear on the server.
5. A program called Diplomat transfers files to the Reading Center for processing twice daily (noon and 11 PM). An email will be sent to individuals at your site confirming whether the transfer was successful or failed.
6. Reading Center staff will verify and call if there are questions regarding the content of the *Sueño Unanticipated Adverse Event* form. **It is important that NO identifying information be present on the completed form received at the Reading Center.**
7. After verifying the details of the UAE and ensuring removal of all identifiable information, Reading Center staff will distribute copies of the *Sueño Unanticipated Adverse Event* form to the site PI and study coordinator at all Sueño sites including the Data Coordinating Center.
8. Once the *Sueño Unanticipated Adverse Event* form is received at your site from the Reading Center, this information needs to be reported to your local IRB as per your local IRB's guidelines.

Sueño – Sleep Habits in HCHS

Reading Center Procedures

Version 4.0
March 20, 2014

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A. RECEIVING FILES FROM FIELD SITES

Zipped files received from field sites should be unzipped and organized within the Sueño database (\\Rfa01\bwh-sleepepi\projects\src\sueno). It is important that all files received be carefully labeled according to the procedure below. Confirm that sites have properly labeled all files (original zipped file, Actigraphy file and Daily Sleep Log) with the same subject ID and contact occasion. If this is not the case, delete the received files and ask sites to resend the zipped file with proper labeling.

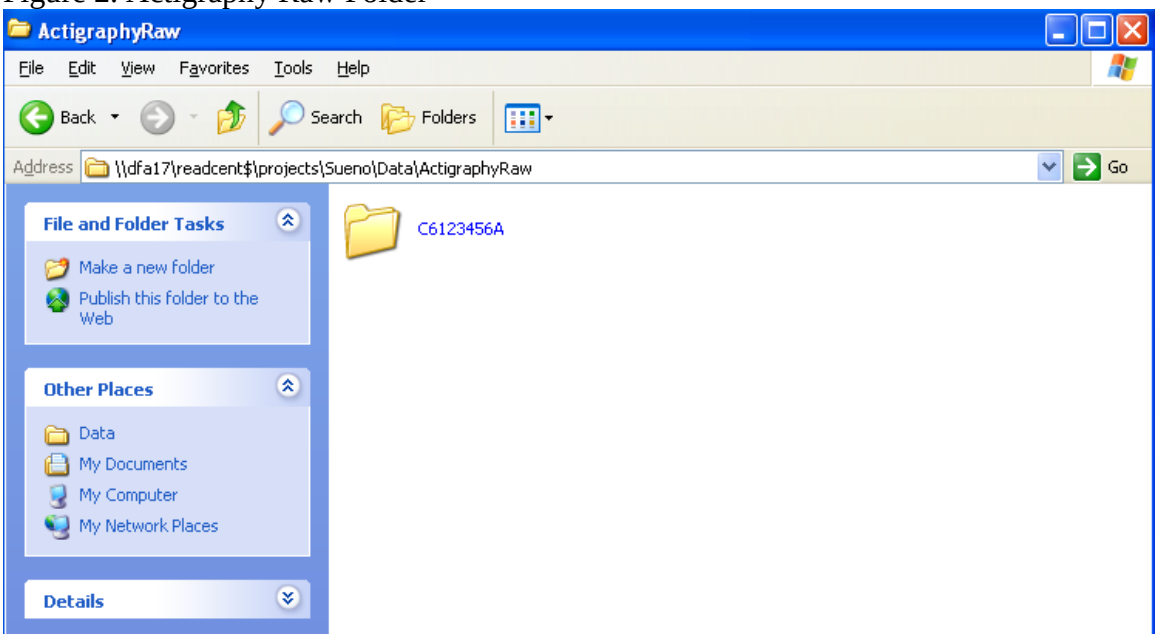
1. **Receiving Files:** Zipped files labeled with a subject ID number will be sent from Field Sites to the Reading Center.
    a. Open the folder labeled **Sueño > Data > Incoming**
    b. New zipped files will appear in the Incoming folder twice daily (noon and 11:00pm).
2. **Unzipping Files:**
    a. Make sure a copy of WinRAR, WinZip or another zipping program has been downloaded.
    b. Double click on the zipped file in order to open the file in a zipping program.
    c. Click on the **Extract to** icon. Click **OK**. Enter the encryption password **sueno321** and click **OK**. Unzipped contents should appear in the **Incoming folder**.

Figure 1. Unzipping Files

    d. The extracted Actigraphy file and the Daily Sleep Log should be placed in a folder labeled with the subject ID and the contact occasion (A or B) and this folder should be moved to the **ActigraphyRaw** folder. The zipped file should be moved to the **ActigraphyZipFiles** folder (see below).

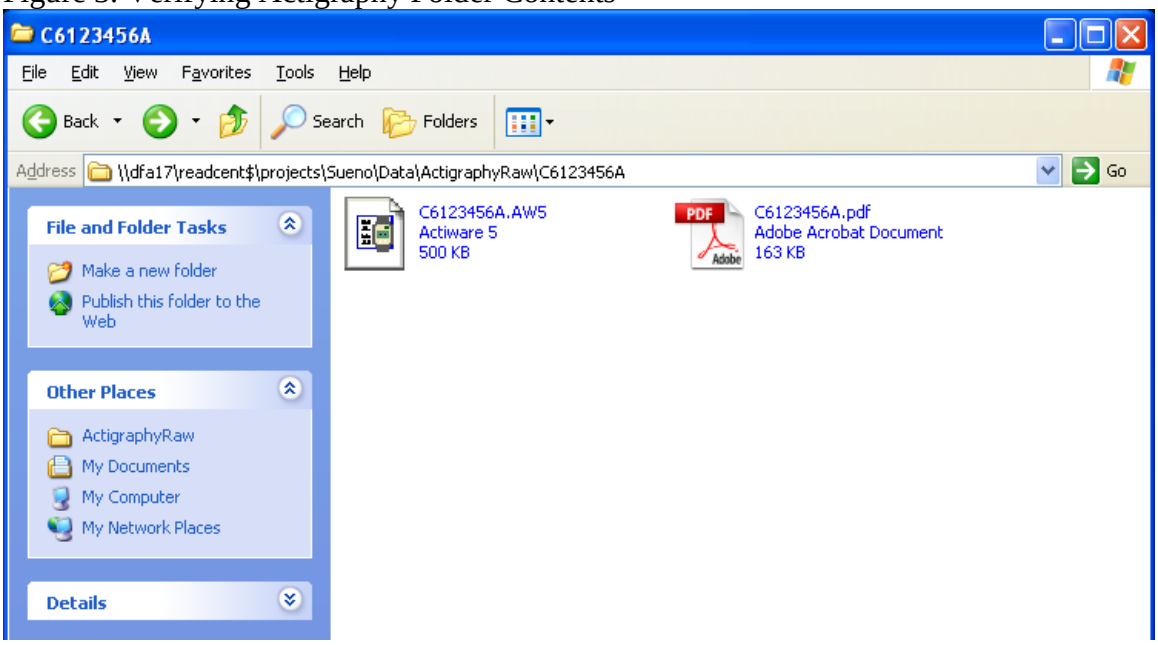
ActigraphyRaw Folder: This folder should contain a folder labeled with the subject ID and contact occasion (ex: C6123456A).

Figure 2. Actigraphy Raw Folder



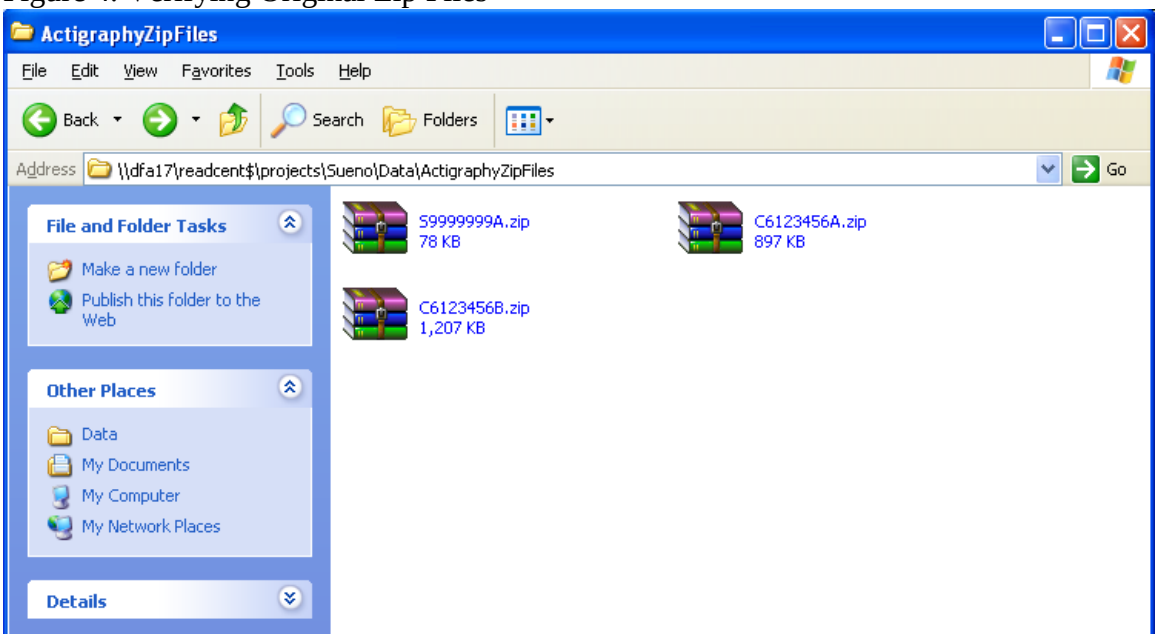
Subject ID + Contact Occasion Folder: This folder, within the ActigraphyRaw folder, should contain an .AW5 file (Actigraphy file) containing the actogram along with a scanned copy of the Daily Sleep Log.

Figure 3. Verifying Actigraphy Folder Contents



ActigraphyZipFiles Folder: This folder should contain the original zipped file received.

Figure 4. Verifying Original Zip Files



3. **Verify Match:**
    a. Each subject is given an ID that begins with the capitalized first letter of the site name followed by 7 digits (example: C6123456). The first letter should be B, C, M, or S (B: Bronx, C: Chicago, M: Miami, S: San Diego). Confirm that the files for the actogram and the Daily Sleep Log are labeled with the same subject ID and contact occasion.
    b. If files are not in this format (same subject ID and contact occasion), delete files and ask the field site to resend files clearly labeled with the same subject ID and contact occasion.
    c. If a subject failed to return a Daily Sleep Log or the log was left blank by the subject, there should be a blank Daily Sleep Log present. Encourage the Field Site staff to enter the participant ID, contact occasion and dates in the allotted portion of every page in the Daily Sleep Log.
    d. If there is no Daily Sleep Log present, delete files and contact the field site from which the zipped file was sent. Ask the site to resubmit the zipped file with both an actogram and a Daily Sleep Log. ***Do not*** assume that the absence of a Daily Sleep Log means the subject left the log blank.

B. QUALITY CHECK

The aim of this check is to quickly determine whether participants need to be contacted for a repeat study. Open the participant's Actigraphy file and adjust settings in order to determine whether the received Actigraphy file is of sufficient quality. Insufficient quality Actigraphy files are those that have **fewer than 5 days of valid data** either because there were fewer than 5 days recorded or because there were fewer than 5 included days after considering the exclusion criteria below (see B.2.a). A **day** is defined on the actogram based on the pre-set "Actogram Start Hour" under the "Analysis" menu, normally from 12:00:00 pm to 11:59:30 am. If the file is

determined to be of insufficient quality, contact the Field Center as soon as possible and follow procedures outlines in section B.3.

Note: The Start Hour is set to 12:00 pm except for the few cases when a 12:00 pm start time would create a ripple effect, invalidating days that would otherwise be valid because the main rest interval extends across 12:00:00 pm (noon). In these cases, assess if setting the start-hour in three-hour increments would remedy the situation. In most cases, the situation is remedied by setting the start hour to 3 pm, thus defining a day as the time from 3:00:00 pm- 2:59:30 pm. Any and all such exceptions are documented in the "Tracking Changes Log" under the "Start Hour Exceptions" tab with the Subject ID, Contact Occasion, new Start Hour, and specific reason with excluded day(s) that caused the exception.

Figure 5. Verifying/ Setting the Actigraphy Start Hour

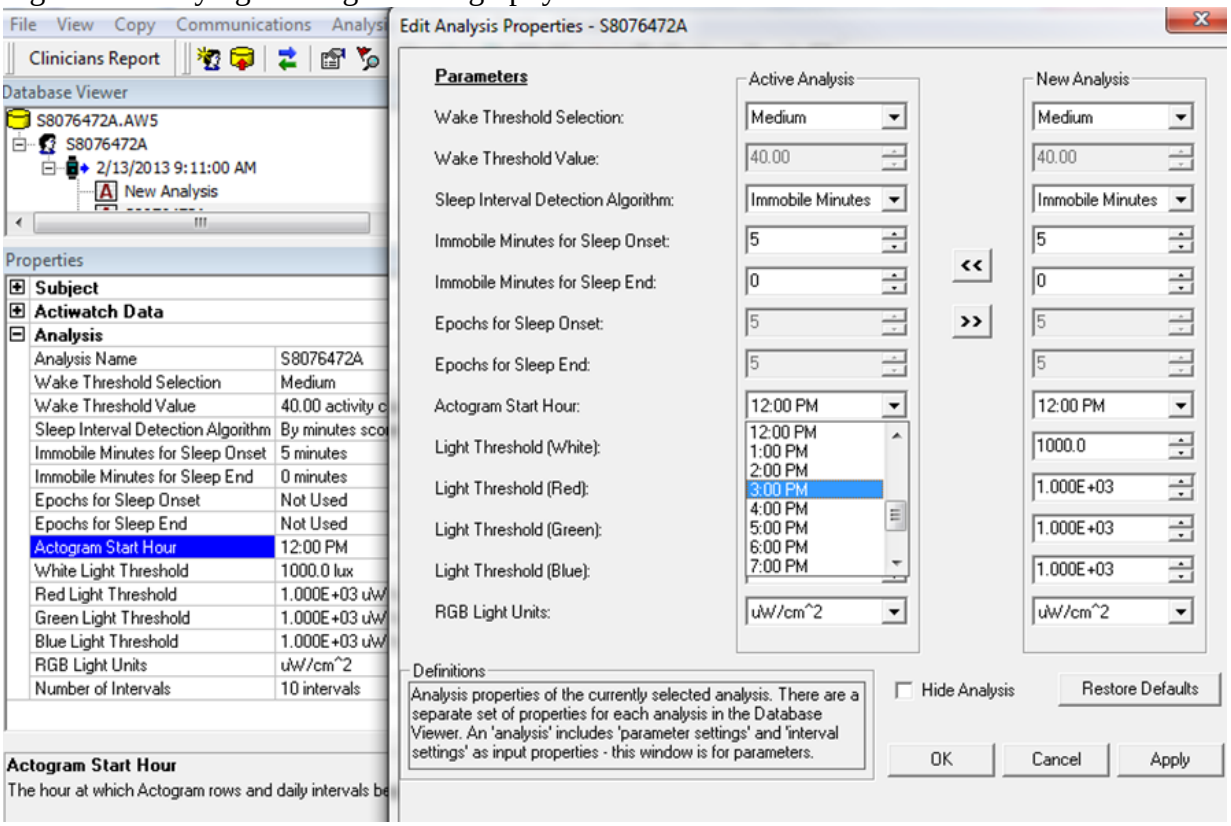


Figure 6. Actigraphy Start Hour Exceptions: Problem

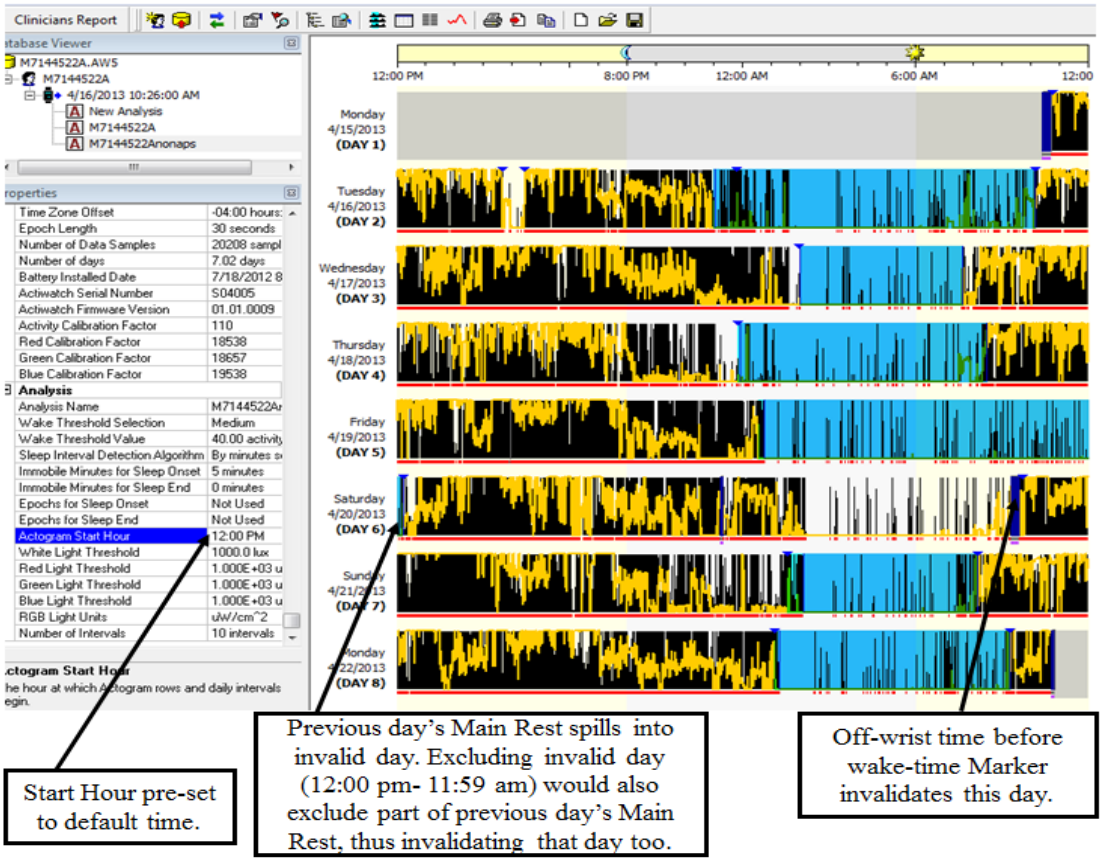
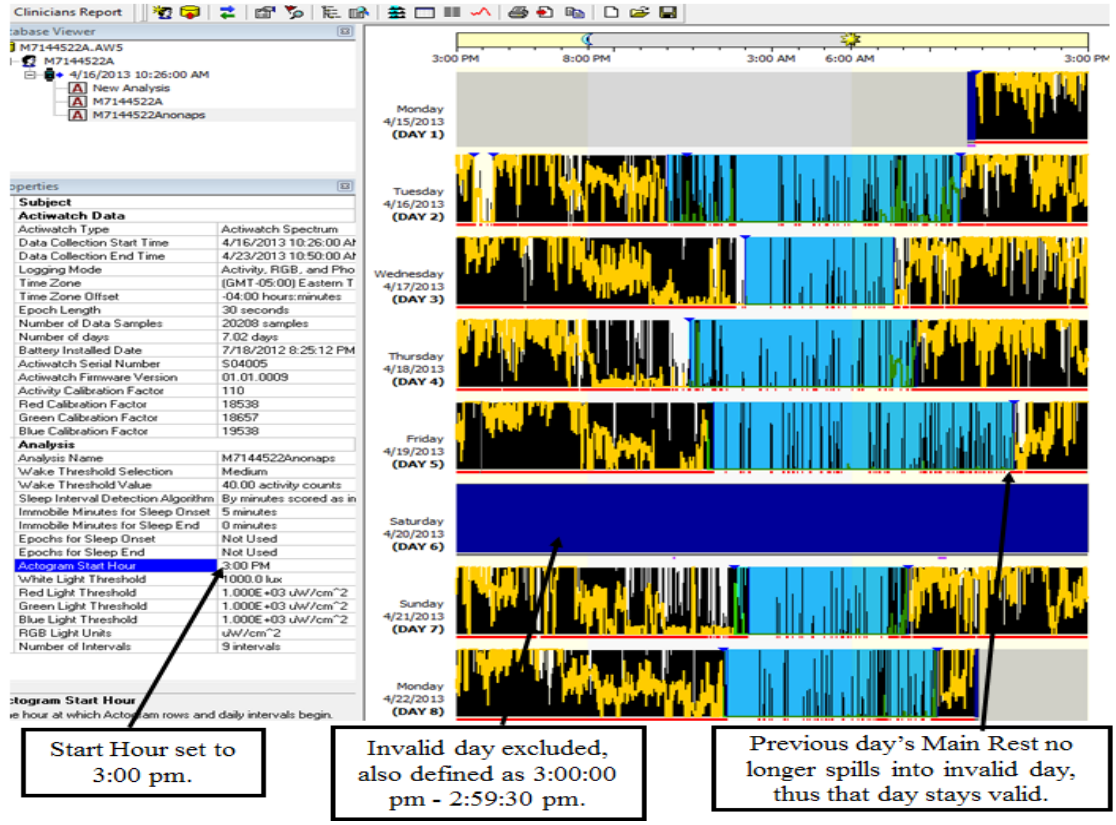


Figure 7. Actigraphy Start Hour Exceptions: Solution



1. **Adjust Settings in Actiware:**
    a. Open the desired database by opening **Respironics Actiware 5** and selecting **File > Database > Open** and search for the .AW5 file labeled with the appropriate subject ID and contact occasion. In the Database Viewer (on the left) select the subject file (has a picture of a head next to it) with the matching subject ID. Double clicking on this file will result in the appearance of a watch icon as well as the actual date and time the recording began. The rows beneath the watch icon display the data that can be viewed and edited. Select **New Analysis.** An actogram should be displayed in the Actigraphy Viewer. Each row in the Actigraphy window displays activity from 12:00:00 pm to 11:59:30 am of the next day.

Figure 8. **Database Viewer**

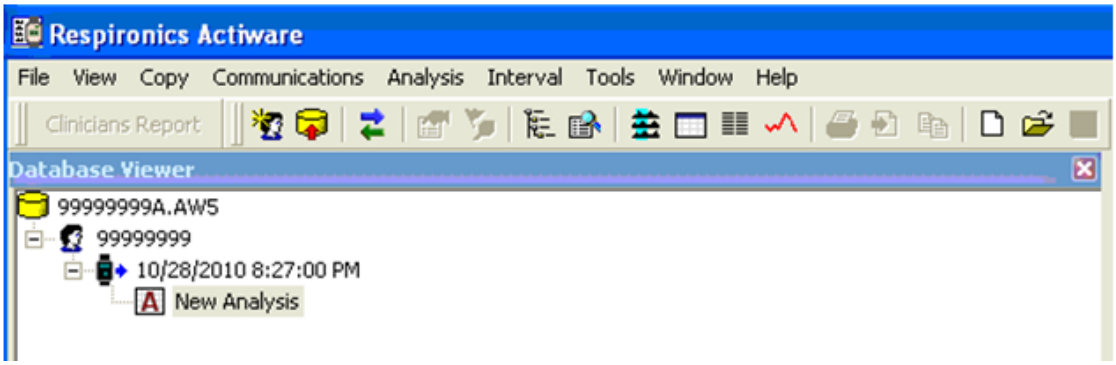
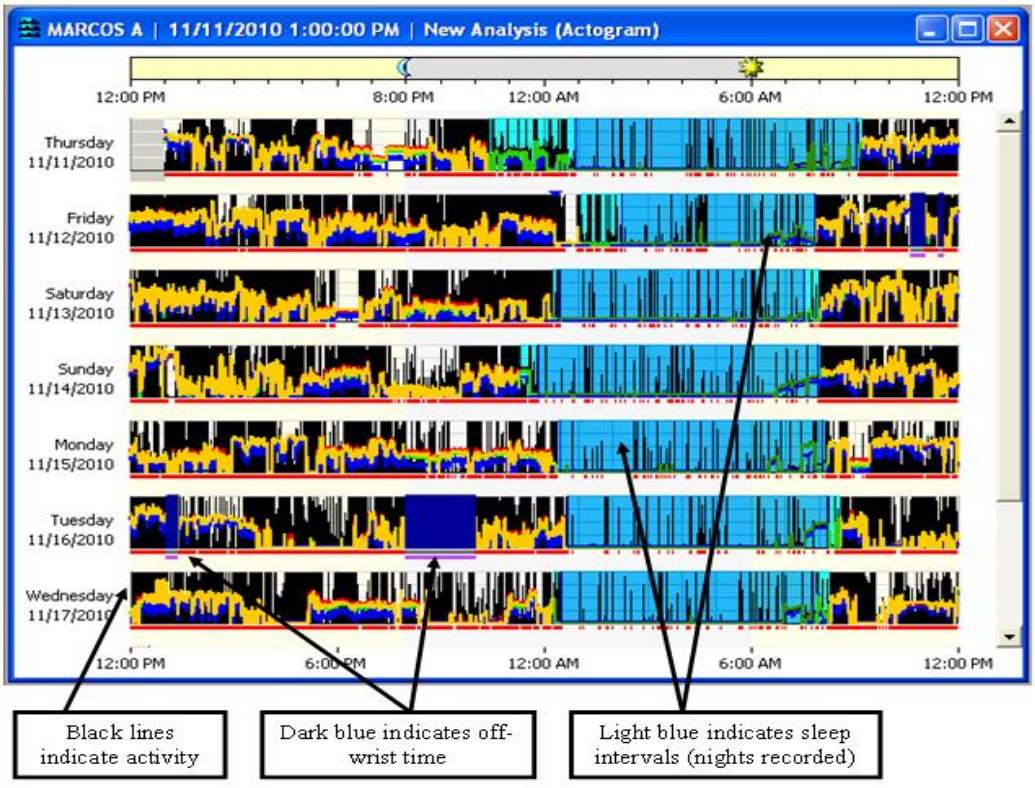
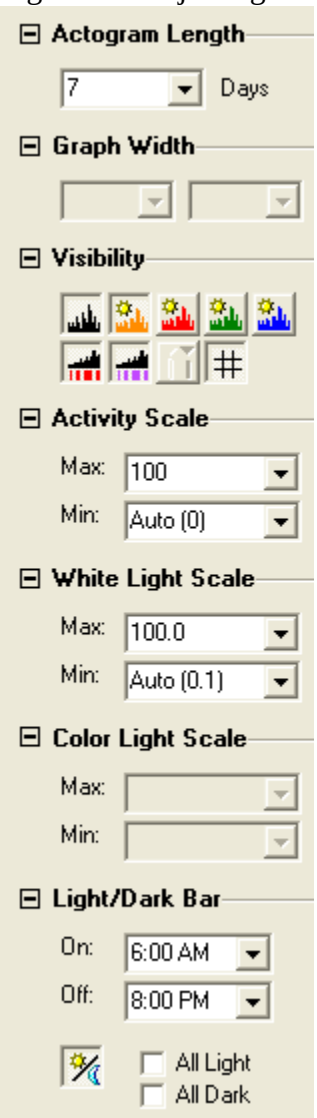


Figure 9. **Actigraphy Viewer:**



b. For ease of viewing, set the **Activity Scale Maximum to 100** and set the **Actogram Length** to the number of days with on-wrist data (on the right side of screen).
c. Under **Visibility**, deselect the colored light signals (red, green, blue) in order to get a clearer view of the Activity. Select and deselect the white light signal (orange). The white light signal provides useful information on the quantity of light. Set the **White Light Scale Maximum to 100**.

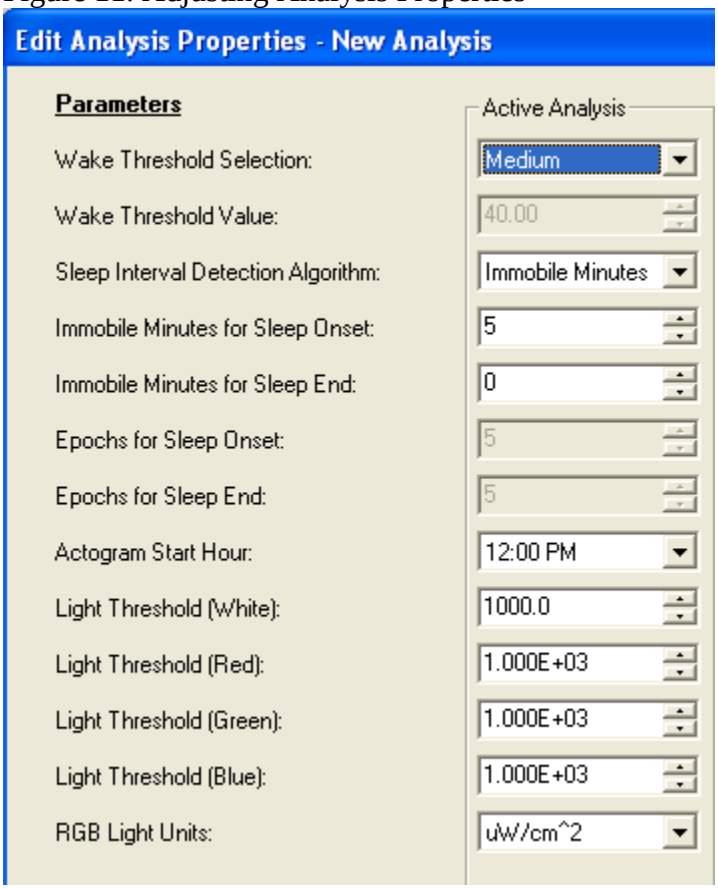
Figure 10. Adjusting Visibility Settings



d. Make changes to **Properties** by selecting **Analysis>Edit Analysis Properties** from the Respironics Actiware main menu. This will open the **Edit Analysis Properties** window. Under the **Active Analysis** column, make the following adjustments:
    i. Set the Wake Threshold Selection to **Medium**.
    ii. Set the Sleep Interval Detection Algorithm to **Immobile Minutes**.
    iii. Set Immobile Minutes for Sleep Onset to **5 minutes** and for Sleep End to **0 minutes**.

iv. Ensure the actogram Start Hour is set to the default of **12:00 PM** (or that it meets the exception rule to start at a different time as noted above).
v. Click on the button labeled **Apply** and then select **OK** (see below).

Figure 11. Adjusting Analysis Properties



2. **Brief Quality Check:**
   a. Look over the actogram and confirm:
      i. **There are a minimum of 5 days (12:00pm to 11:59am) recorded.**
      ii. **Out of the 5 days, there are at least 5 days with less than 4 hours of off-wrist, no data or data failure.**
      iii. **No off-wrist, no data or data failure during the beginning, middle or end of the sleep interval for the 5 days.**
   b. If it is not apparent simply from viewing the actogram whether there are 4 hours of off-wrist time within a day, select **View>Statistics Table**. In the statistics table window, select the **Daily** tab. Under the **Off-Wrist** column, the total number of off-wrist minutes will be displayed. If there are **240 minutes** or more of off-wrist time for a given day, then the day would be considered to have more than 4 hours of off-wrist time. *Note that only the off-wrist is displayed using this technique; time with no-data and time with data failure cannot be accounted for using this technique.*

Figure 12. Selecting Statistics Table

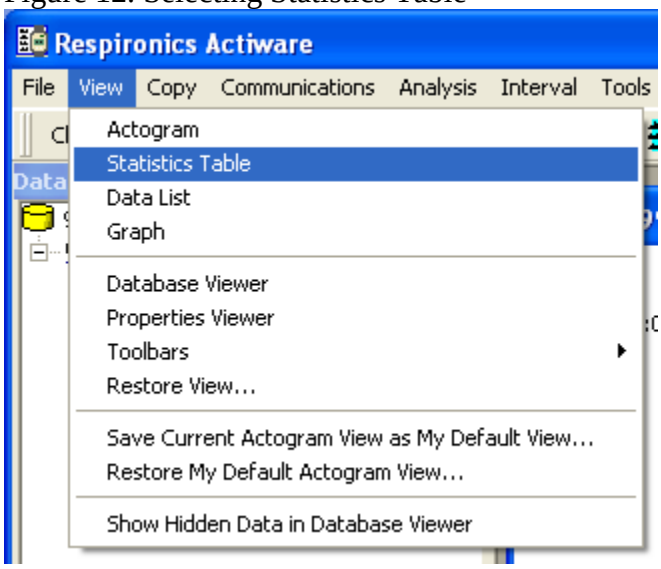


Figure 13. Statistics Table View

Rest | Active | Sleep | Custom | **Daily** | Summary | Clinicians Report

	Start Date	Start Day	Start Time	End Date	End Day	End Time	Duration	Off-Wrist
Day 1	11/1/2010	Mon	12:43:00 PM	11/2/2010	Tue	12:00:00 PM	1397.00	0.00
Day 2	11/2/2010	Tue	12:00:00 PM	11/3/2010	Wed	12:00:00 PM	1440.00	0.00
Day 3	11/3/2010	Wed	12:00:00 PM	11/4/2010	Thu	12:00:00 PM	1440.00	0.00
Day 4	11/4/2010	Thu	12:00:00 PM	11/5/2010	Fri	12:00:00 PM	1440.00	0.00
Day 5	11/5/2010	Fri	12:00:00 PM	11/6/2010	Sat	12:00:00 PM	1440.00	328.00
Day 6	11/6/2010	Sat	12:00:00 PM	11/7/2010	Sun	12:00:00 PM	1440.00	0.00
Day 7	11/7/2010	Sun	12:00:00 PM	11/8/2010	Mon	12:00:00 PM	1440.00	177.50
Day 8	NaN	NaN	NaN	NaN	NaN	NaN	NaN	NaN
Day 9	NaN	NaN	NaN	NaN	NaN	NaN	NaN	NaN
Day 10	NaN	NaN	NaN	NaN	NaN	NaN	NaN	NaN
n	*	*	*	*	*	*	7	7
Minimum(n)	*	*	*	*	*	*	1397.00	0.00
Maximum(n)	*	*	*	*	*	*	1440.00	328.00
Average(n)	*	*	*	*	*	*	1433.86	72.21
Std Dev(n-1)	*	*	*	*	*	*	16.25	130.76

More than 4 hours (240 min) off-wrist

3. **Contacting Sites:** If the study is determined to be of <u>sufficient</u> quality (5 or more days meet the criteria in B.2.a), GO TO SECTION C. If the study is determined to be of <u>insufficient</u> quality (fewer than 5 days meet the criteria in B.2.a), the field site from which the Actigraphy file was sent should be *immediately* told to contact the subject to try to obtain another round of Actigraphy if this is the first round of Actigraphy for the participant (contact occasion A or 1). *Do not* contact sites if this is the participant's second round of Actigraphy.
    a. The form entitled **Study Failure Form** should only be completed for first time studies (contact occasion A or 1) that were determined to be of insufficient quality. This form should not be completed for repeat studies (contact occasion B or 2) regardless of the quality of the study. The first half of the form is to be

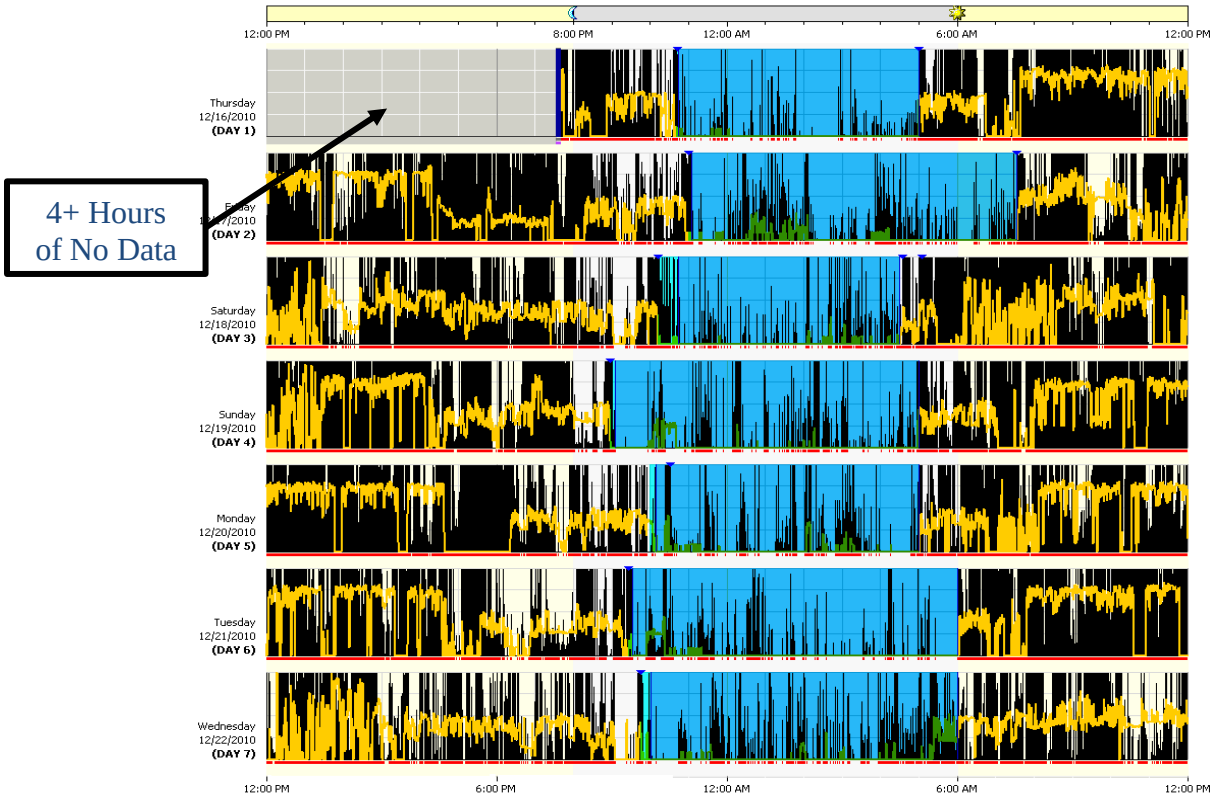
completed by the Reading Center staff and the second portion is to be completed by the Field Site staff.

i. In the Sueño database \\Rfa01\bwh-sleepepi\projects\src\sueno, select **Data>Study Fail Form** and open the file **Study Fail Form**.
ii. Enter today's date in the **Date Failed** section.
iii. Enter the participant's ID in the **ID Number** section.
iv. Enter the scorer's initials.
v. Note that only **Contact Occasion** 1 (first contact) or -1 (confusion) can be entered. Contact occasion 2 cannot be selected because this form should NOT be completed for those studies.
vi. Enter the **Failure Reason**. If the study failed because fewer than 5 days were recorded or fewer than 5 days were of sufficient quality, enter **Fewer than 5 days of valid data**. Alternatively, if the study failed because data could not be properly retrieved, enter **Data corruption/ technical failure**. For all other reasons, enter **Other**. If this option is selected, make sure to detail the failure reason in the notes section below. The **Notes** section should also be used for providing feedback to the field site about ways to eliminate this failure in future studies.
vii. After the first half of the form has been completed, the next line in the form will state **To be completed by Field Site Staff**. At this point save a copy of the form under **Data>Failed Studies>Pending**. Label the form with the participant ID and the contact occasion. *Additionally*, print a copy of this form and place it in the binder labeled **Sueño Pending**.

b. **Sueño Email Submission:** Send the Study Failure Form to field sites *immediately* from the BWH Sueño Sleep Study email account (bwhsueno@partners.org). In order to access this account, open Internet Explorer and enter the address: https://phsexchweb.partners.org/exchange/bwhsueno@partners.org. In the BWH Sueño Sleep Study email account, send an email to the Field Center staff with the participant's partially completed **Study Failure Form** as an attachment. Field Center staff is expected to return the fully completed form to the Reading Center. Once the completed form is returned, save the completed version OVER the original saved file in **Data>Failed Studies>Pending** and MOVE the completed form from the **Pending** folder to the **Complete** folder. *Additionally*, MOVE the incomplete Study Failure form from the Sueño Pending binder to the Sueño field site binder (ex: both forms would be placed in the Sueño Site 1 Albert Einstein binder in the case of a file received from the Bronx). PRINT a copy of the completed Study Failure form and add this form to the Sueño field site binder.

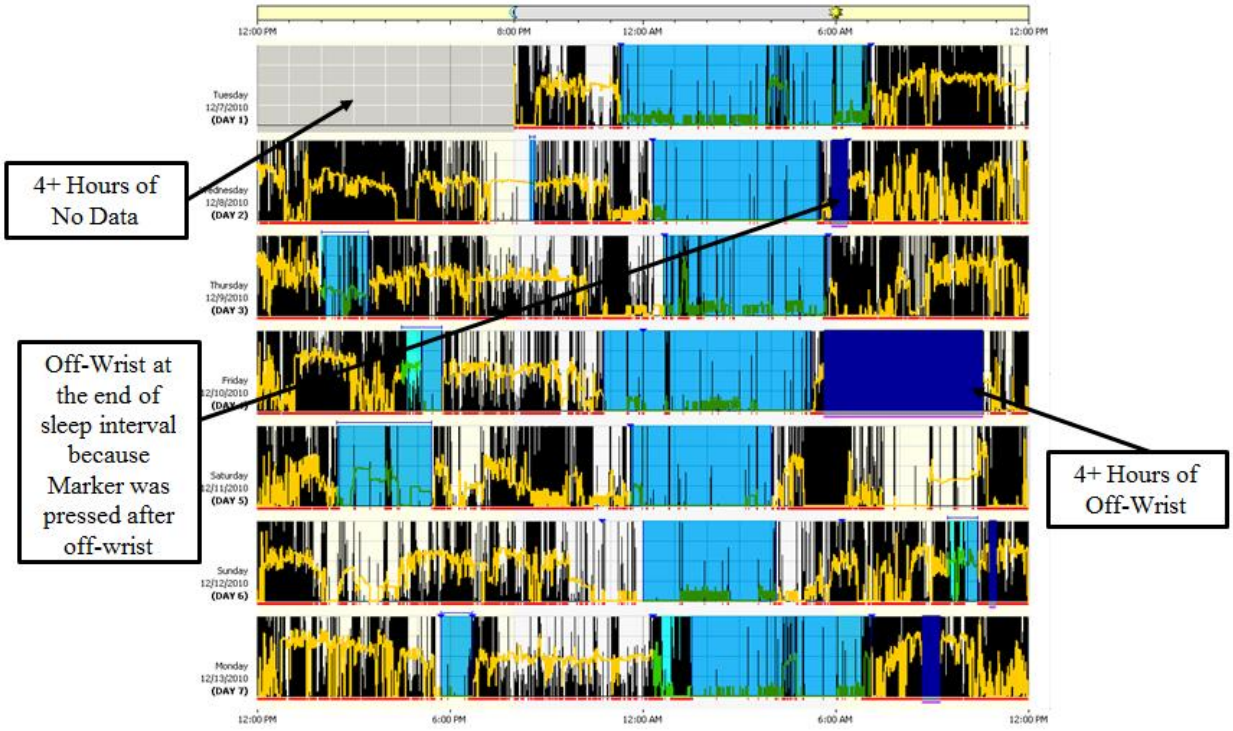
Example of a Quality Actogram: A minimum of 5 days were recorded. Out of the 7 days recorded, one of the corresponding days had more than 4 hours of no data time. There were no off-wrist, no data or data failure episodes during the beginning, middle or end of the sleep intervals that would have prevented confident estimations of sleep interval timing and duration. Therefore, 6 days had quality data.

Figure 14. Example of a Quality Actogram



Example of an Insufficient Quality Actogram: A minimum of 5 days were recorded. Out of the 7 days recorded, the first day had more than 4 hours of no data. The second day had off-wrist time at the end of the sleep interval. Since one of the parameters, the Marker, was pressed after the off-wrist episode, the end of the sleep interval as well as the duration could not be determined with confidence. The fourth day had more than 4 hours of off-wrist time. Therefore, out of the 7 days recorded, only 4 of the days had quality data. Since fewer than 5 days had quality data, a repeat trial is desirable. *Please see next page for an example of an insufficient quality actogram (Figure 15).*

Figure 15. Example of an Insufficient Quality Actogram



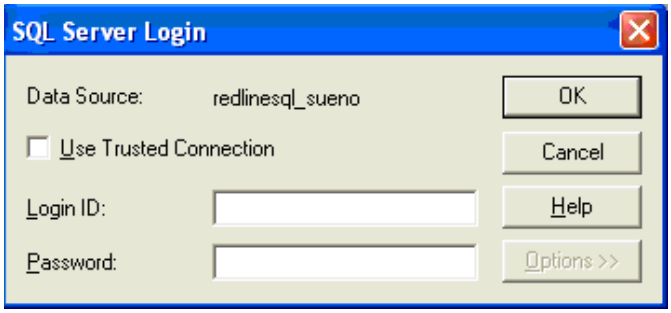
C. DAILY SLEEP LOG DATA ENTRY

Information from the Daily Sleep Log (Diary) should be entered into the Access file: **sueno sleep diary.mdb**. Entering this data will provide an electronic way to keep track of participant logs as well as provide a copy of the data from the original log. It is important to realize that the Sleep Log is a subjective recording by the participant of their sleep habits and is prone to human error. Keep the participant's Actiware file open when entering log data in order to determine when a participant's entry does not make sense based on the actigraphy recording. In this case, make sure to note that the data entered by the participant does not make sense. This will help to minimize the amount of human error present in the log data. For more information about what to do when a log entry does not make sense, see entry C.1.k.

1. Entering Daily Sleep Log Data:

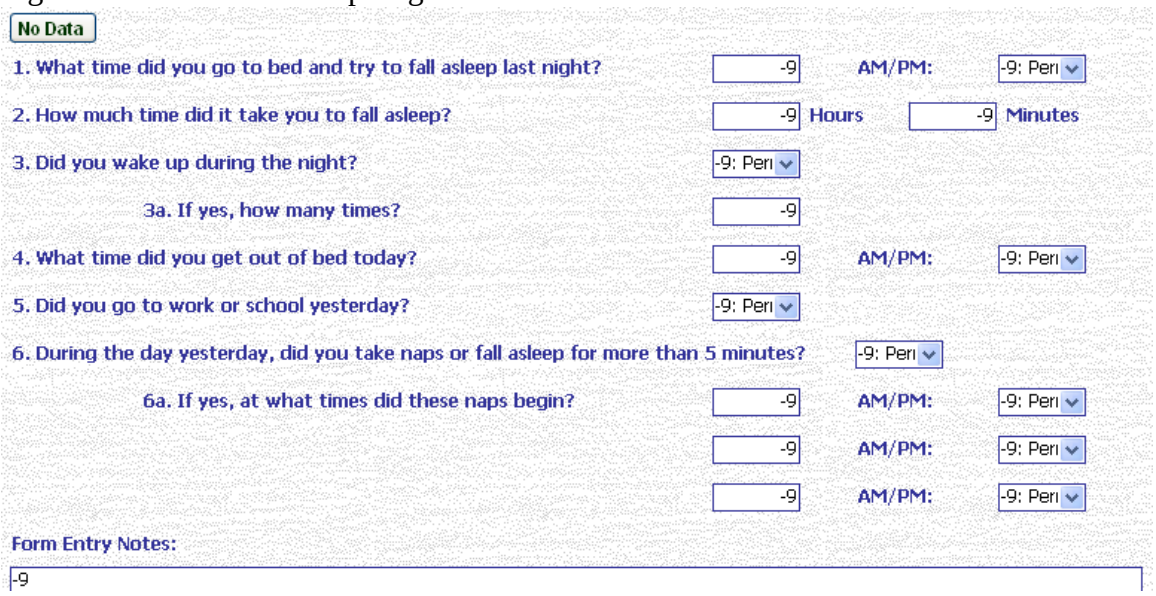
a. Select **sueno sleep diary.mdb > open.** Enter the assigned SQL **Login ID** and **Password** and click **OK**.

Figure 16. Login to Sleep Log Data



b. Select the button labeled **New** in the upper right hand corner in order to start a new form.
c. Confirm that the dates of the Daily Sleep Log entries are consistent with the dates displayed on the actogram. *Note: the Daily Sleep Log should be offset from the actogram by 1 day because the log is completed the morning after.*
d. ***Do not*** enter data from Day 0 of the Daily Sleep Log. Enter data starting with **Day 1** of the log.
e. The **Contact Occasion** should be entered as **1** if this is the first time the subject has participated, **2** if this is the subject's second time participating and **-1** if it is unclear as to the contact occasion.
f. If the subject did NOT complete a Daily Sleep Log as indicated by receipt of a blank Daily Sleep Log, select the button **No Data**. Selection of this button will result in the answer to every question on the form automatically being filled in as **permanently missing** or **-9** (see below). In instances where the dates on the diary cannot be obtained, enter the dates on the actogram and make a note in the entry that this is what you did.

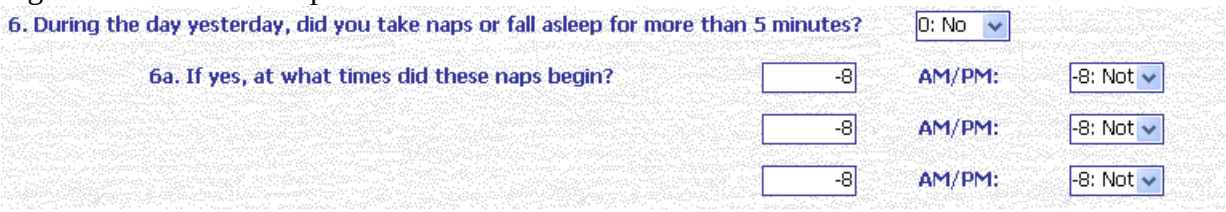
Figure 17. Blank Data Sleep Log



g. If specific items on the Daily Sleep Log were left blank by the subject, select **-9** from the drop down menu or type **-9**.
h. If it was unclear as to what the subject had intended to record, select **confusion** or **-1**.

i. If the subject did not perform a particular action, select **Not Applicable** or **-8** indicating that the question being asked is not relevant for the subject.
j. Certain inputs will result in certain fields automatically becoming filled. *For example, if a participant entered "no" in response to question 6, then all fields for question 6a will automatically be filled in with -8.*

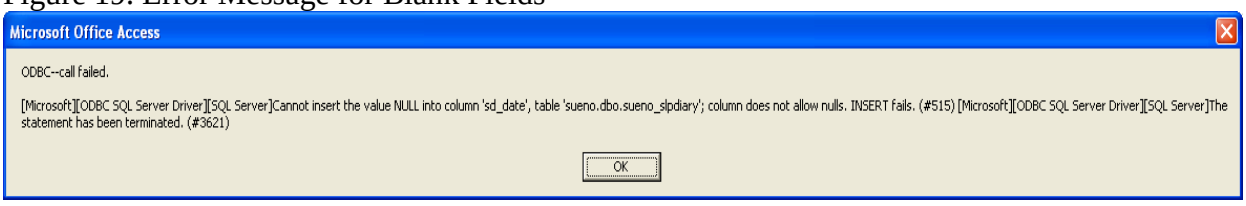
Figure 18. Automatic Inputs



k. Enter comments in the **Form Entry Notes** section as needed. ***Important note:*** *unlike the Actigraphy data, the Daily Sleep Log is a subjective recording of the participant's perception of when they went to bed and woke up. This log is prone to human error and when an entry does not make sense, use your best judgment as to what the participant intended to record. Make a note of the nonsense information in the log in this section. For example, if the participant recorded that they went to bed at 12 pm and woke up at 7 am, it is likely and can be confirmed in the actogram that the participant actually went to bed at 12 am. 12 am would be entered into the log as the answer to question 1 and this correction would be noted in the form entry notes.*

2. **Daylight Savings:** If a watch is worn over the transition to or from daylight savings, the Daily Sleep Log entries will differ from the Actigraphy data by 1 hour. It is important to make a note of this discrepancy. Please note that watches worn before or after the daylight savings transition will not exhibit this 1 hour discrepancy.
   a. For each day following a change to or from daylight savings there will be a discrepancy of 1 hour between the Daily Log and the actogram data. This discrepancy should be noted in the **Form Entry Notes** section for EVERY day following the daylight savings transition.
   b. The original time entered in the Daily Sleep Log should be entered into Access. However, the 1 hour discrepancy should be accounted for when placing sleep intervals (see section D).
3. **Saving Daily Sleep Log Data:** After the form for a specific day has been completed, select the button labeled **Submit** in the upper right hand corner and the completed form will automatically be saved in the Subject Database. *Note: It is important that all fields are filled in. If fields are left blank, an error message will appear when "Submit" is selected.*

Figure 19. Error Message for Blank Fields



a. Forms should be completed and saved for all 7 days of the Daily Sleep Log regardless of whether the subject completed all pages.
b. In the main window, confirm that all 7 daily log entries are present.
c. Exit the Sleep Diary Program in Access.

D. SETTING ACTIGRAPHY SLEEP INTERVALS

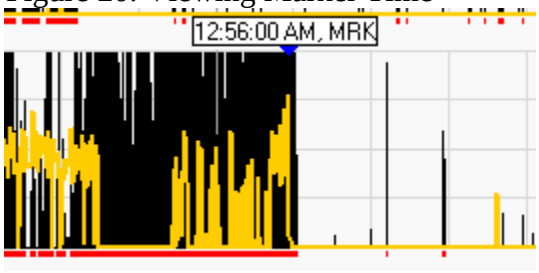
Rest intervals should be manually set in the participant Actigraphy file with the goal of capturing when the participant intended to sleep. Sleep intervals correspond to the time the Actiware software estimates that the participant was actually sleeping as opposed to lying in bed awake. These intervals are automatically generated within rest intervals. Therefore, the focus of this chapter is the accurate placement of rest intervals (periods when the participant intended to sleep). Placement will be dictated by 4 parameters: the Marker, the Daily Sleep Log, the Light Quantity and the Activity. The Marker, the Light Quantity and the Activity are recorded in the Actiware program. The Daily Sleep Log file should be referenced alongside the participant Actigraphy file. Keep in mind that the Daily Sleep Log is a subjective estimate of when the participant remembered they intended to sleep and is more prone to human error compared with the Actigraphy parameters.

Important note about Rest Intervals: Each **Rest Interval** is defined by a start and end time – the times the subject began and ended trying to sleep. These start and end times are called the bed time and wake time respectively. *Note* that these times differ from sleep onset and sleep offset, which are the times the subject first actually fell asleep and last woke up within the Rest Interval.

There are **4 Parameters** that can be used to determine when a person is sleeping: the Marker, the Daily Sleep Log, the Light Quantity and the Activity.

The presence of a **Marker**, displayed as an upside down dark blue triangle above the Actigraph, shows when the participant intended to sleep or wake up. The Marker is pressed in real time and therefore tends to be a more accurate estimate of bed/wake time in comparison to the Daily Sleep Log. The time when the Marker was pressed by the subject can be viewed on the actogram placing the mouse on top of the Marker. A time will appear followed by MRK.

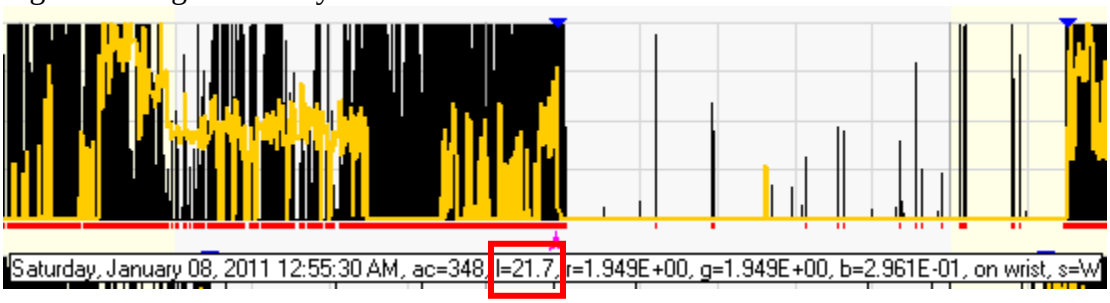
Figure 20. Viewing Marker Time



The **Daily Sleep Log** is completed by the subject for a given day the morning after. The log shows the subject's recalled bed/wake time. These bed time and wake times can be viewed in the Daily Sleep Log under questions 1 and 4. Account for the amount of time the participant recorded it took them to fall asleep (question 2).

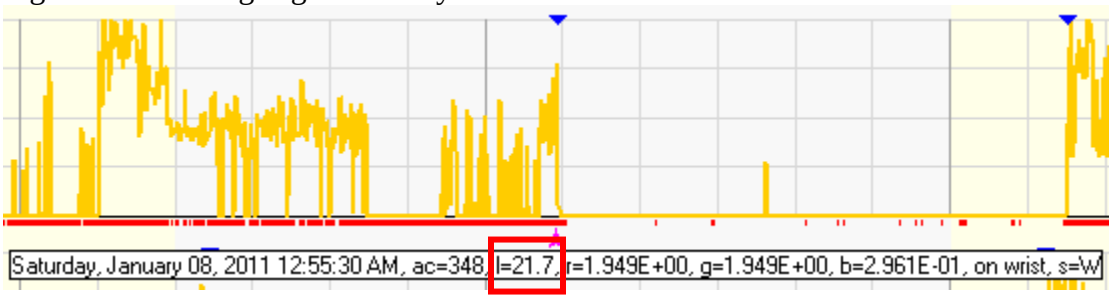
A change in the white **Light Quantity**, displayed as a yellow-orange trace in the actoram, serves to indicate bed time and wake time in addition to the Marker and the Log. A sustained decrease in the quantity of light may indicate that the lights were turned off thereby serving to indicate bed time. A sustained increase in the quantity of light may indicate the lights were turned on thereby serving to indicate wake time. Light quantity can be viewed multiple ways. In the main actigraphy window, light is shown as a yellow trace. The exact value in lux for every 30 second period can be viewed by clicking on the actogram. A caption will appear beneath the area on the actogram clicked listing the Light Quantity, l. In the figure below, this value is displayed inside a red box.

Figure 21. Light Intensity



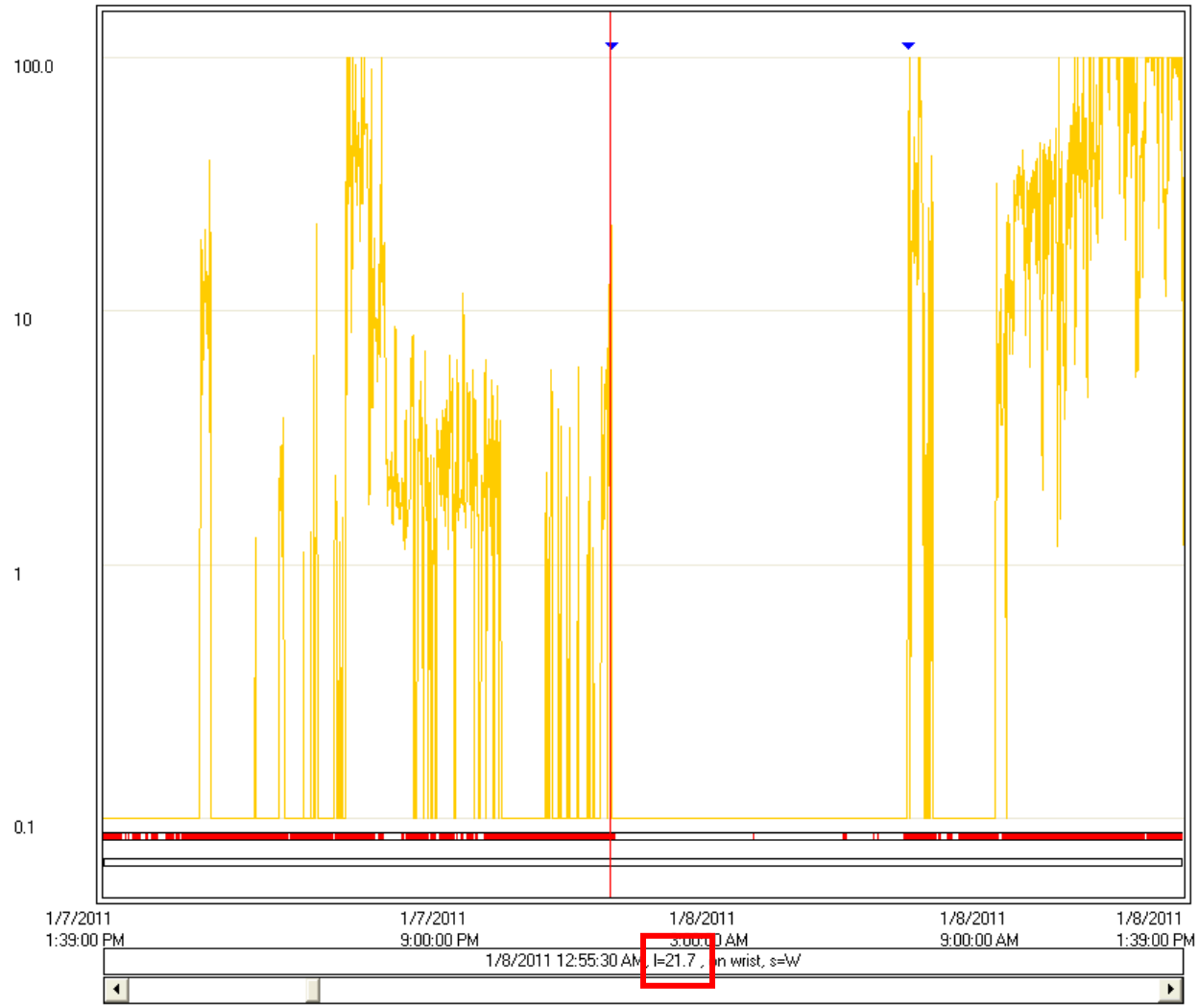
By deselecting the Activity, shown as a black trace under the Visibility section to the right of the actogram, only the light quantity will be displayed on the actogram.

Figure 22. Isolating Light Intensity



In order to get a different view of the light data, double click on the actogram on the region associated with the interval of interest. A new window entitled “Graph” will pop up. Note that in the Graph view the time scale is compressed. Of note, this view typically provides a greater visual contrast between the time in a 24 hour period when the light levels are high and the time when they are low. Therefore, it tends to be easier to see the transition in light levels between sleep and wake in this view (Figure 23).

Figure 23. Graph View of Light Intensity



In order to determine the time when the lights went off, indicating intent to sleep, find the time with the greatest sustained drop in light intensity. For bed time, the light quantity parameter would be recorded as the time the light quantity drops to less than 1 lux and remains at this level a sustained period of time, usually over 2 hours. If light does not drop to below 1 lux for bedtime, choose the time at which light intensity drops to the minimum level recorded that day. For wake time, the light parameter would be recorded as the time when the light quantity increases to more than 1 lux and remains over 1 lux for a sustained period of time. If there is a gradual increase in light intensity associated with wake time, choose the time point with the greatest increase/contrast.

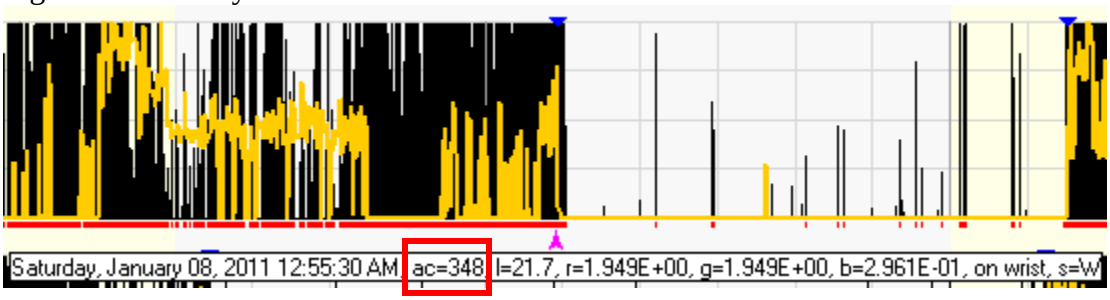
Another visual contrast that may aid in interval placement is when light goes from a constant value from epoch to epoch to a varying level, which can be an indication that the participant is moving their wrist. In some cases, contrast rather than absolute light levels will provide an indication of when the participant woke up.

A change in **Activity**, displayed as a black trace in the actogram, serves to indicate sleep onset and sleep offset, NOT bed time and wake time. Thus, a drop-off in activity may indicate sleep

onset. Similarly, an increase in activity may indicate sleep offset. ***Note:*** because sleep onset and NOT bedtime is determined by a drop in activity, it becomes impossible to determine Sleep Latency (the time from bed time to sleep onset) if the start of the sleep interval is placed at the time activity drops off.

On the main actigraphy window, activity is shown as a black trace. The activity count value for every 30 second period can be viewed by clicking on the actogram. A caption will appear beneath the area on the region of the actogram clicked listing the light activity count, ac. In the figure below, this value is displayed inside a red box.

Figure 24. Activity Count

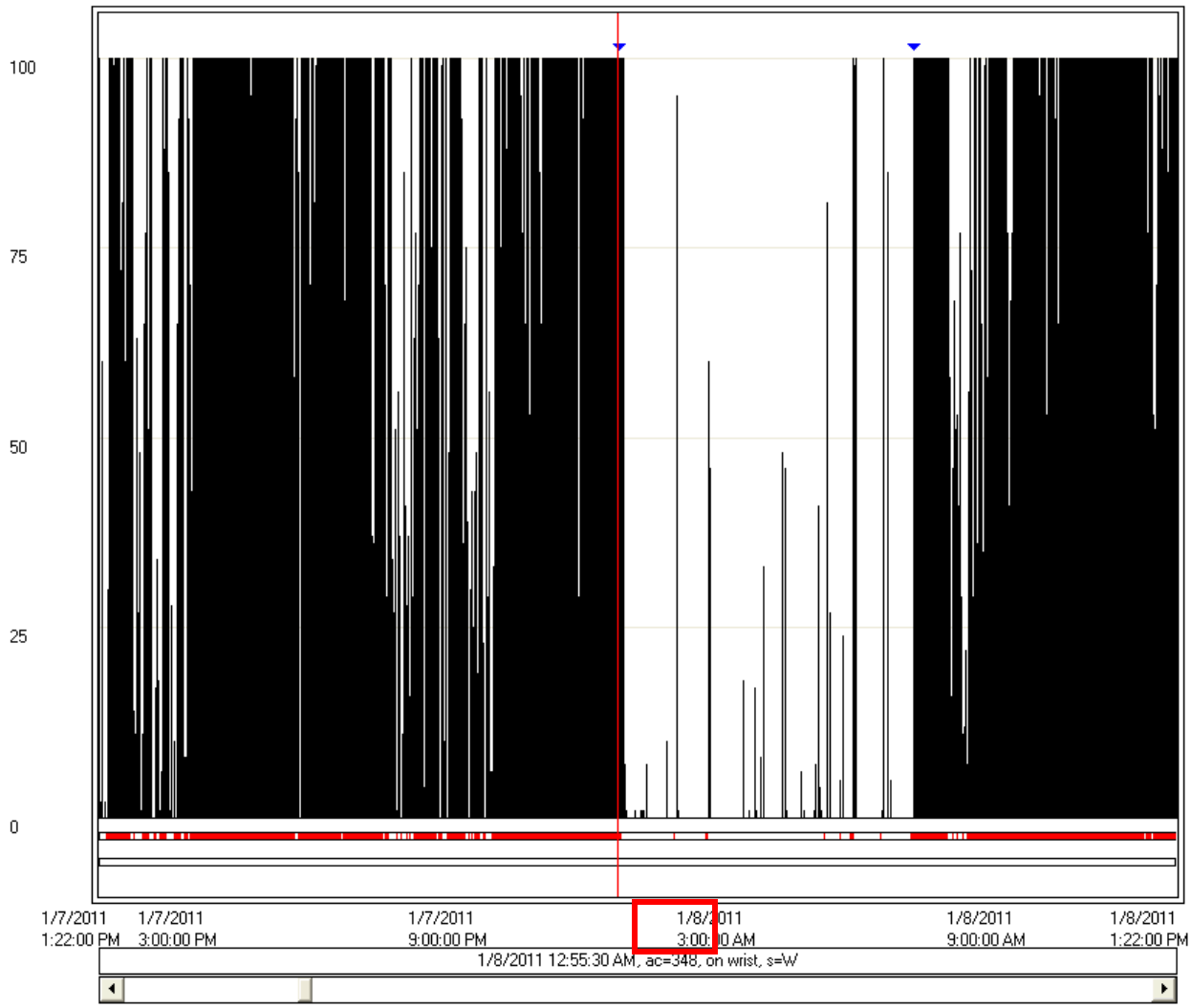


By deselecting White Light, shown as an orange trace under the Visibility section to the right of the actogram, only the activity will be displayed on the actogram.

Figure 25. Isolating Activity Count

In order to get a different view of activity, double click on the actogram on the region associated with the sleep interval of interest. Of note, this view typically provides a greater visual contrast between the times when there is a lot of activity and when there is low activity. Therefore, it tends to be easier to see the transition in activity levels between sleep and wake in this view.

Figure 26. Graph View of Activity Count

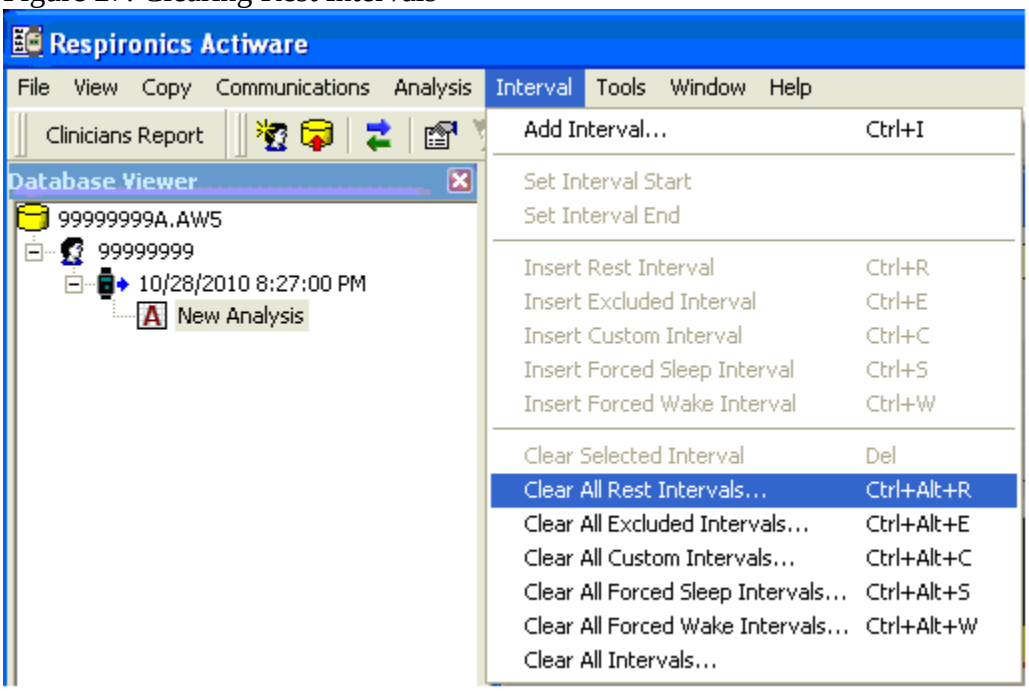


In order to determine the time the activity level drops likely indicating sleep onset, determine where on the actogram there is a transition from mostly black lines (activity) to mostly white lines (no activity). At this transition, find the time when the activity count drops to zero (ac=0) for a sustained period of time (multiple 30 second intervals where ac=0). The activity time that should be recorded is the time of the first ac=0 in the sequence of zero activity counts. In order to determine the time the activity level increases, likely indicating the subject woke up, determine where there is a transition from mostly white lines (no activity) to mostly black lines (activity). At this transition, find the time when the activity count increases from zero for a sustained period of time (multiple 30 second intervals where the majority of activity counts are substantially greater than zero). The activity time that should be recorded is the time of the first nonzero activity count in a series of mostly nonzero activity counts.

In conclusion, a pressed marker, a recorded sleep time and/or a drop in the amount of light serve as indicators that the participant tried to fall asleep. Likewise, a pressed marker, a recorded wake time and/or an increase in the amount of light serve as indicators that the participant got out of bed. In contrast, a drop in activity serves to indicate that a participant fell asleep (onset) whereas an increase in activity serves to indicate that the participant woke up (offset).

1. **Setting Sleep Intervals:** Rest intervals should only be set for **the main sleep period**, which is defined as the subject's longest period of continuous time in bed with the intent to sleep. Setting time in bed/out of bed will be based on 4 parameters: the Marker, the Daily Sleep Log, the Quantity of Light and the Activity.
    a. In the Actigraphy window select **Interval > Clear All Rest Intervals**.

Figure 27. Clearing Rest Intervals



    b. Examine each of the regions on the actogram associated with getting into bed and getting out of bed.
    c. Determine which parameters are **present** for the period of bed time and wake time for each main sleep period.
    d. Determine which parameters appear to be reliable indicators of intent to sleep and wake up. A **reliable** parameter is one that unambiguously indicates intent to sleep/wake up and seems reasonable considering the other parameters. If a parameter is unreliable, do not account for this parameter when setting an interval. *Note: Light Quantity is often unreliable as a wake time parameter because light often gradually increases as the sun rises. Activity is rarely considered unreliable.*
    e. Bed time and wake time should be determined by the set of present and reliable parameters. If no parameters are present, set a 30-second rest interval starting 12:00:00 am. If some parameters are present, but none are reliable, set a 30-second rest interval at the least unreliable parameter.
    f. Using **only present and reliable parameters**, examine the following situations to determine how to place intervals based on your set of parameters.

Important: Interval placement should be based on determining how many parameters are consistent with one another. Parameters that fall within 15 minutes of one another are considered to be consistent. For example, if the light quantity substantially changes within 15 minutes of the

marker, these parameters would be considered to be consistent with one another. Parameters are considered to fall within 15 minutes of one another if each of the parameters falls within 15 minutes of any other parameter(s). Therefore, even if a parameter does not fall within 15 minutes of every single other parameter, if it falls within 15 minutes of another parameter that is within 15 minutes of every other parameter, all of these parameters are considered to fall within 15 minutes of one another. *For example, if the Marker was pressed at 11:20 pm, 11:30 pm was recorded in the Daily Sleep Log and the Light Quantity decreased at 11:45 pm, all of these parameters are considered to fall within 15 minutes of one another even though there is a 25 minute difference between the Marker and the Light Quantity parameters.*

i. **Situation 1: All of the parameters fall within 15 minutes of one another.** If so, place sleep interval at the time corresponding to the highest priority parameter. Follow this order of priority:
    1. Marker
    2. Daily Sleep Log
    3. Light Quantity
    4. Activity

ii. **Situation 2: A single subset has parameters within 15 minutes of one another.** If so, determine sleep interval time using the subset of parameters that fall within 15 minutes of another present and reliable parameter. Follow this order of priority:
    1. Marker
    2. Daily Sleep Log
    3. Light Quantity
    4. Activity

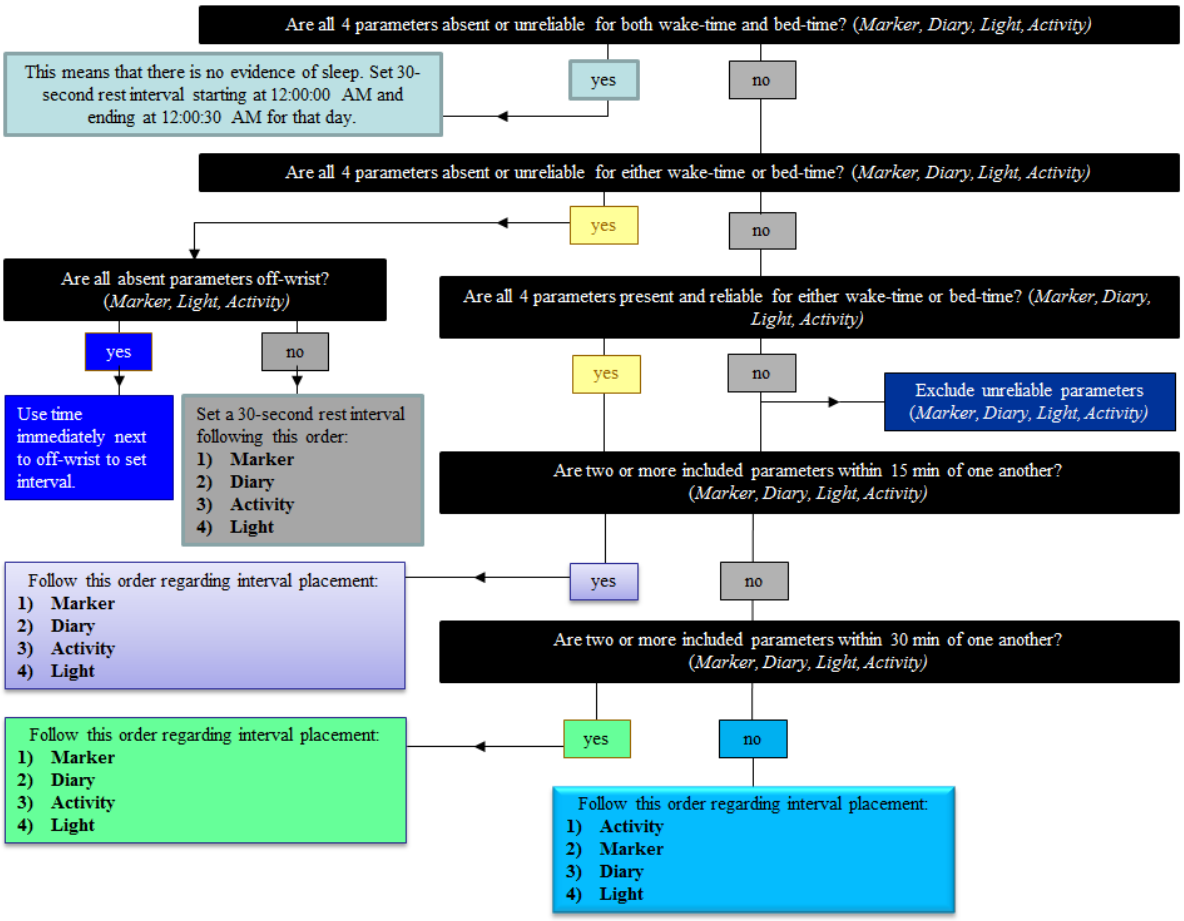
iii. **Situation 3: Multiple subsets have parameters within 15 minutes of one another.** If there is no majority of present and reliable parameters that fall within 15 minutes of one another, but rather there are multiple sets of parameters, follow the instructions below:
    1. If the Marker and the Daily Sleep Log fall within 15 minutes of each other, set the interval at the Marker time.
    2. If the Marker and the Daily Sleep Log are present and reliable, but are not within 15 minutes of one another, determine whether a change in light falls within 15 minutes of the Marker. If so, set interval at the Marker time. Alternatively, if light is within 15 minutes of the Daily Sleep Log entry time, set interval at the Log time.

iv. **Situation 4: None of the parameters fall within 15 minutes of one another.** Determine whether any of the parameters fall within 30 minutes of one another.
    1. **All or some of the parameters fall within 30 minutes of one another.** If so, determine interval placement using the same reasoning that was used when parameters fell within 15 minutes of one another. Refer to situations 1 through 3 above substituting 30 minutes for 15 minutes.
    2. **None of the parameters fall within 30 minutes of one another.** If all of the parameters are more than 30 minutes apart, set interval

based on Activity (the time when Activity visibly decreased or increased).

3. **None of the parameters fall within 30 minutes of one another and there is no activity drop associated with the interval.** If all of the parameters are more than 30 minutes apart, but the interval cannot be set based on Activity, follow this order of priority:
    a. Marker
    b. Daily Sleep Log
    c. Light Quantity

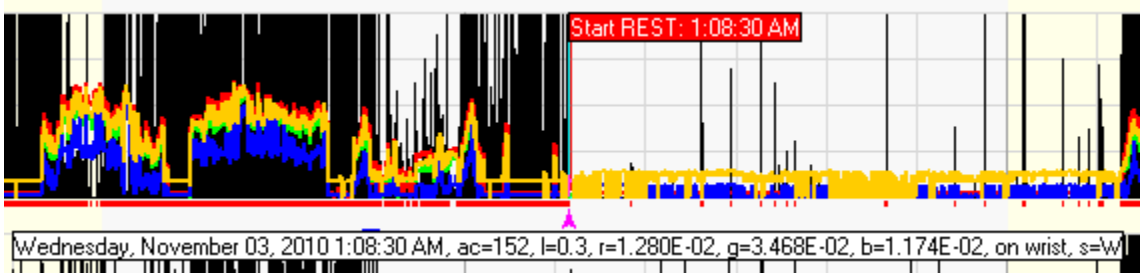
Figure 28. Setting Rest Intervals Flowchart



g. After the placement of the main sleep period has been determined, set the time in bed by clicking on the actogram in the desired location. Clicking on the actogram will result in the appearance of a pink arrow beneath the activity plot. In order to make adjustments to the placement of the arrow, tap the right and left arrow keys. This will result in the pink arrow moving to the right or left in 30 second intervals.

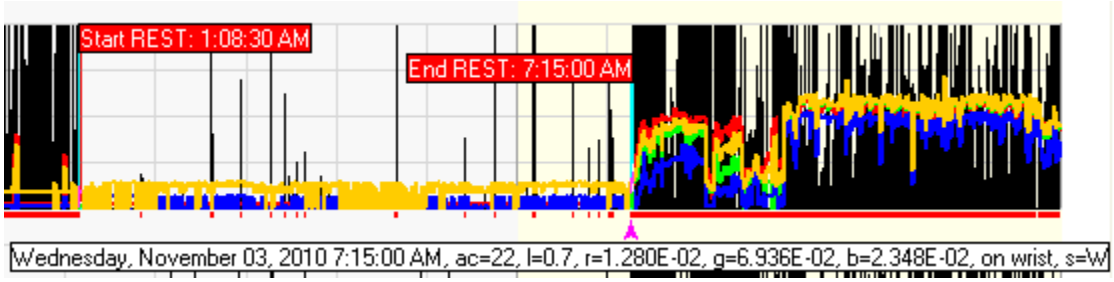
h. When the arrow has been placed at the desired start of rest time, type **r**. This action will result in the appearance of a red flag stating **Start REST**.

Figure 29. Starting a Rest Interval



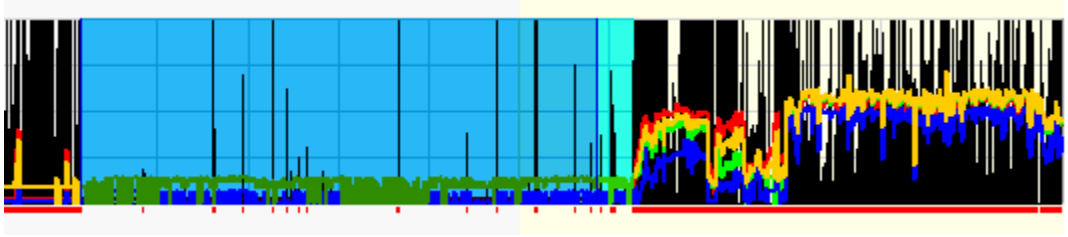
i. Next, when the arrow has been placed at the desired end of rest time type **Shift + r**. This action will result in the appearance of a red flag stating **End REST**.

Figure 30. Ending a Rest Interval



j. In order to set the rest interval, type **Ctrl + r**. A light blue color should appear indicating the presence of a **Rest Interval**. The appearance of a medium blue color indicates the presence of a **Sleep Interval** (see Interval Legend in the lower right hand corner of the Actigraphy window). Note that in some cases the set rest interval will appear as mostly or all light blue in color. Sometimes the set rest interval will appear as mostly or all medium blue. In either case, this interval is still considered to be a rest interval regardless of the relative proportion of light versus medium blue color.

Figure 31. Setting a Rest Interval



k. **Brief Quality Check:** determine whether there was any off-wrist, no data or data failure that prevented the ability to set intervals confidently. Following this check, if there are now fewer than **5 valid days**, and the file is for *contact occasion 1 or - 1*, repeat steps in section B.3.a-b.

2. **Setting Nap Intervals:** Naps are considered periods of sleep outside the main sleep period. Normally, there is one main sleep period per day and the remaining sleep periods

are considered naps. Napping can occur during the day or at night. Nap intervals should ONLY be set if there is a Marker and/or Daily Sleep Log entry. Nap intervals should NOT be set for periods of low activity outside the main sleep period that are not associated with a Marker and/or Log entry.

a. Examine each of the regions on the actogram associated with a Marker and/or Daily Sleep Log entry.
b. Determine which parameters are present and reliable. In many cases, light quantity will not be a reliable indicator of napping. Use **only present and reliable parameters** to set nap intervals.

Important: Participants record naps for a given day the following morning. When a participant records a nap, they are often estimating when their naps took place many hours later. Therefore, estimates of nap times as recorded on the Log tend to be less accurate compared with estimates of bed time and wake time. Therefore, a period of low activity within **4 hours** of the time recorded in the daily sleep log is considered to be associated with the log entry time. *Note: do not set a nap interval if the Daily Log entry time coincides with a main sleep period and there is no drop in activity within 4 hours of the entry that is outside of the main sleep period. Do not set a nap interval if the participant indicated in the Log that they took a nap but no nap time was recorded and no other supportive evidence for this nap was present making it impossible to place a nap interval. Another important note is that when participants take naps in the morning, they often record these naps on the wrong day. They record them for the previous day because they are filling out their diary the morning of their nap. Use your best judgment in deciding which day to classify these naps under.*

i. **Situation 1: A Marker and/or Diary are present and fall within 15 minutes of each other or of a significant change in Activity or light.** Set the nap interval at the time corresponding to the highest priority parameter. Follow this order of priority:
    1. Marker
    2. Activity
    3. Light Quantity
    4. Daily Sleep Log

    If the marker was pressed, and any of the remaining three parameters are within 15 minutes of the Marker time, set the nap interval start time at the Marker time. If only one Marker is present for the nap interval, set the nap start or end time (whichever one is not associated with a Marker) using the remaining three parameters in the following order: Activity, Light, and Diary.
ii. **Situation 2: A Marker and/or Diary are present and associated with a significant change in Activity or Light, but only Light and Activity fall within 15 minutes of each other.** If the decrease in light and activity for bed time are within 15 minutes of each other, start the nap interval at the time corresponding to the significant change in Activity. Likewise for an increase in light and activity at wake time.
    Reminder: parameters are considered to be associated with each other if they fall within 4 hours of one another.
v. **Situation 3: A Marker and/or Diary are present and associated with a significant change in Activity or light, but no parameters fall**

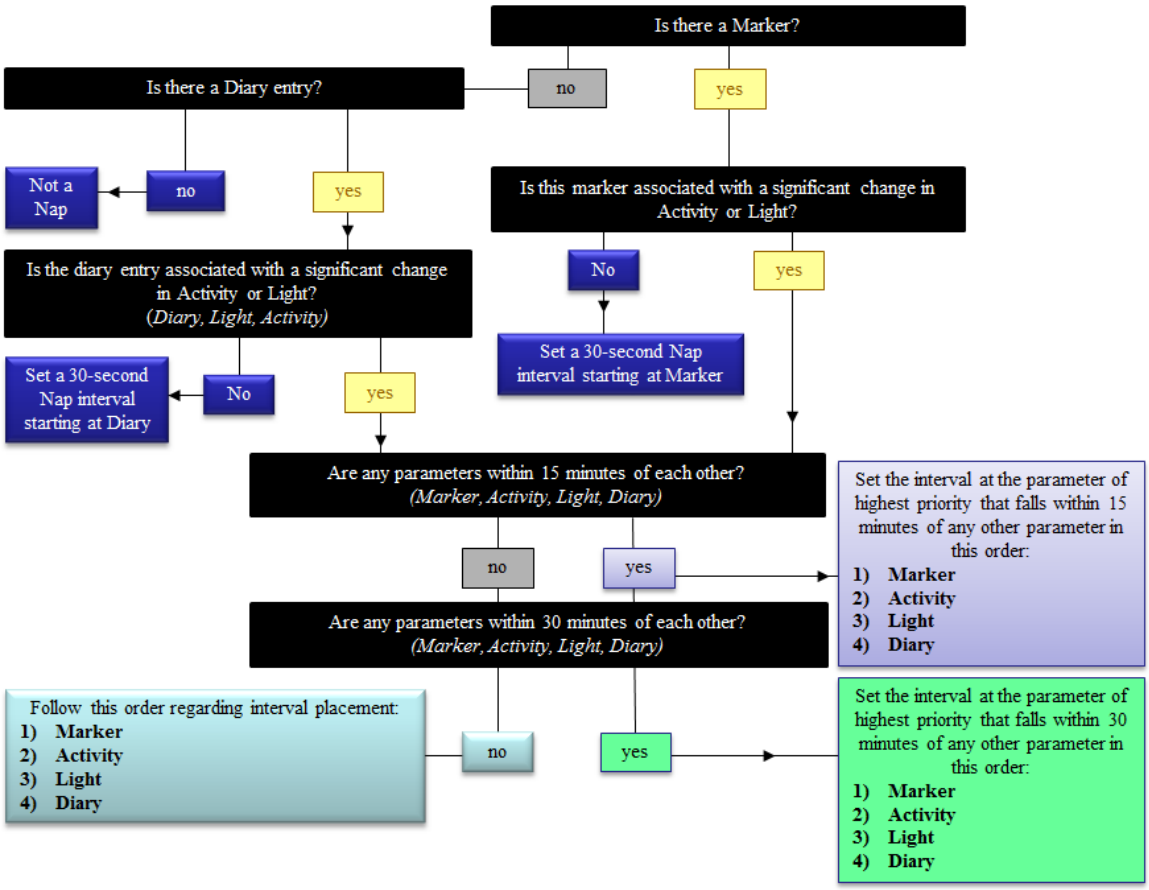
within 15 minutes of each other. Determine whether any of the parameters fall within 30 minutes of one another.

1. **All or some of the parameters fall within 30 minutes of one another.** If so, determine interval placement using the same reasoning that was used when parameters fell within 15 minutes of one another. Refer to situations 1 and 2, substituting 30 minutes for 15 minutes.
2. **None of the parameters fall within 30 minutes of one another.** If all of the parameters are more than 30 minutes apart, set interval based on Activity (the time when Activity visibly decreased or increased).
3. **None of the parameters fall within 30 minutes of one another and there is no activity drop associated with the interval.** If all of the parameters are more than 30 minutes apart, but the interval cannot be set based on Activity, follow this order of priority:
    a. Marker
    b. Light Quantity
    c. Daily Sleep Log

ii. **Situation 4: Neither a Marker nor a Daily Sleep Log entry, if present, is associated with an unambiguous decrease in the quantity of light or a drop in Activity.** In this case, set the nap start time at the Marker time if the Marker is present. Set the nap end time 30 seconds after the nap start time. If the Marker is absent, set the nap start time at the time recorded in the Daily Sleep Log. Set the nap end time 30 seconds after the nap start time.

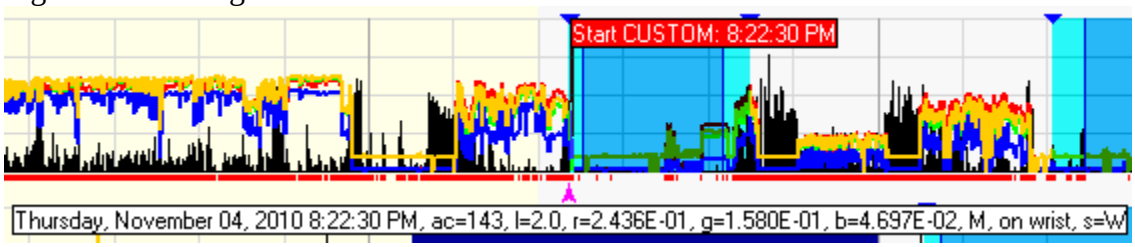
For further instruction regarding rules for setting the onset of nap intervals, refer to the flow diagram in Figure 32 (next page).

Figure 32. Setting Nap Intervals Flowchart



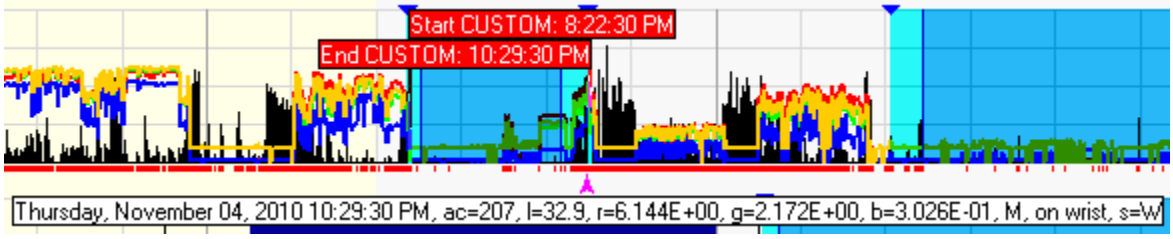
c. Set the start of the nap interval and the end of the nap interval using the same keys that were used to set the in/out of bed times (D.1.i-k).
d. In addition to setting rest intervals in the actogram in order to indicate sleep intervals, **custom intervals** should be placed over nap intervals in addition to rest intervals. Every nap should be marked by a rest interval **AND** a custom interval. The custom interval should occur over the identical interval (same start and end time) as the rest interval. Marking naps as custom intervals allows the software to distinguish sleep time in the main sleep period from sleep time in naps.
e. After the rest interval has been placed over a nap, move the pink arrow to the same time as the start of the rest interval. When the arrow has been placed at this time, type **c**. This action will result in the appearance of a red flag stating **Start CUSTOM**.

Figure 33. Starting a Custom Interval



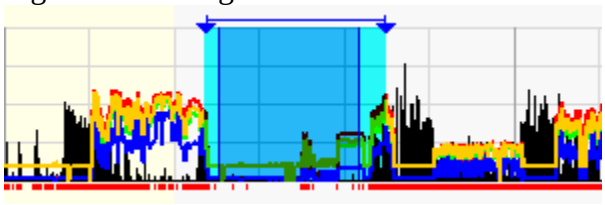
f. Follow the same steps in order to place the pink arrow at the end of the rest interval. When the pink arrow has been placed at this time, type **Shift + c**. This action will result in the appearance of a red flag stating **End CUSTOM**.

Figure 34. Ending a Custom Interval



g. In order to set the custom interval, type **Ctrl + c**. A horizontal blue bar will appear **above** the rest interval previously set. The presence of both the rest interval and the custom interval indicates the presence of a nap (a rest interval outside the main sleep period).

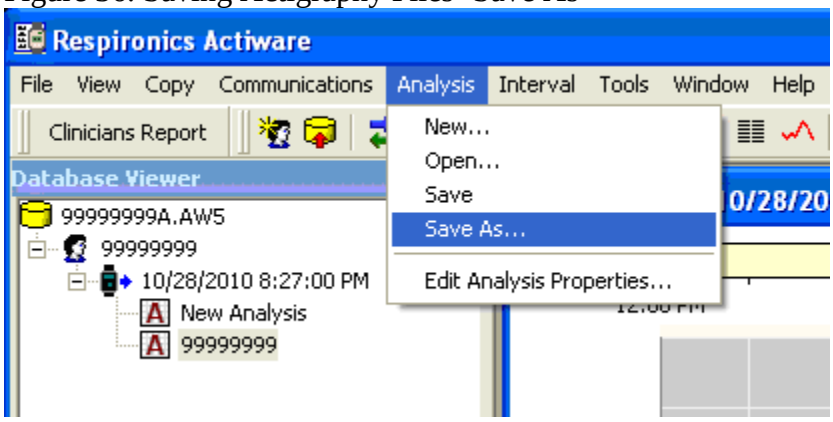
Figure 35. Setting a Custom Interval



h. **Brief Quality Check:** determine whether there was any off-wrist, no data or data failure that prevented confident placement of the nap intervals. Following this check, if there are now fewer than **5 valid days**, and the file is for *contact occasion 1 or -1*, repeat steps in section B.3.a-b.

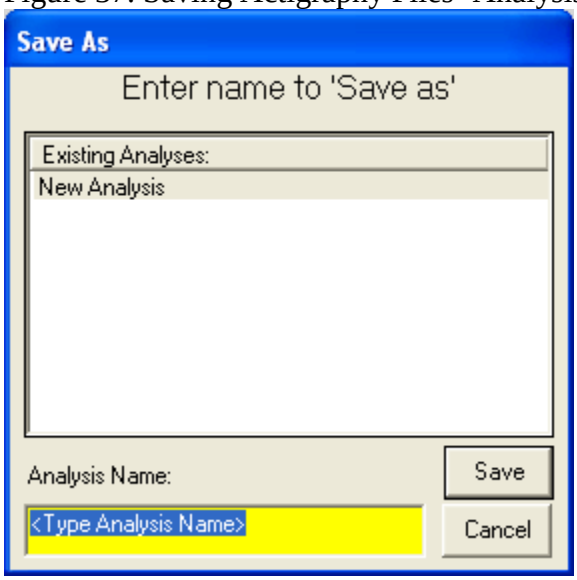
3. **Saving Actigraphy Files:**
   a. Select **Analysis > Save As.**

Figure 36. Saving Actigraphy Files- Save As



b. Enter the **subject ID** under **Analysis Name** and click **Save**. *For example: C6123456.*

Figure 37. Saving Actigraphy Files- Analysis Name



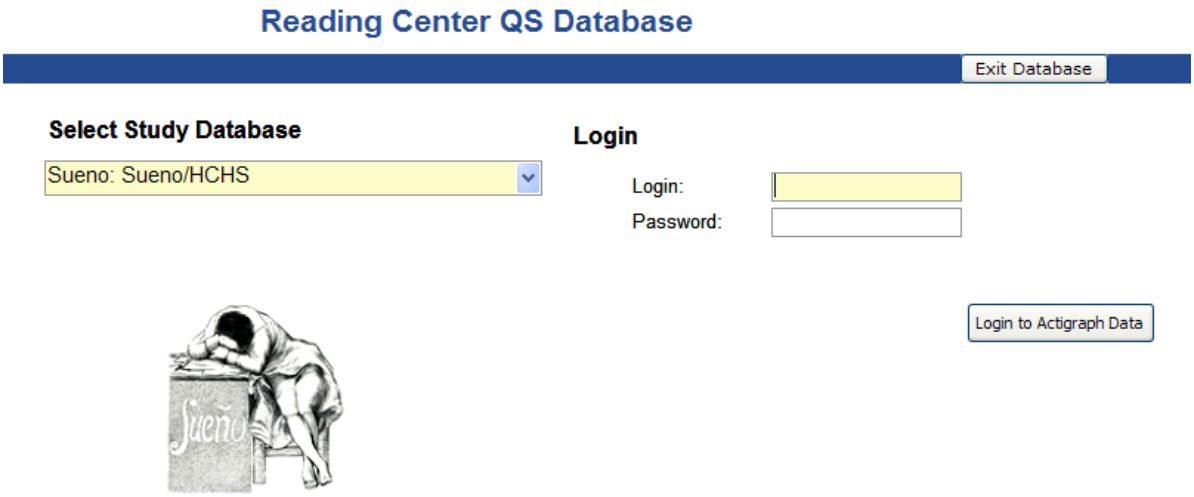
4. **Printing Actogram:** Print this report by selecting **File>Print Report**. The printed report should be placed in the Sueño binder labeled with the field site the participant's file was sent from. *For example, if the Actigraphy file was from the Bronx, place the report in the binder labeled: Sueño Site 1 Albert Einstein.*

E. DOCUMENTING QUALITY

The quality of the received sleep data will be documented using the **Actigraphy Quality Form**. The general purpose of this form is to indicate the level of confidence that the intervals placed are an accurate reflection of the participant's actual sleep habits for the time the Actiwatch was worn.

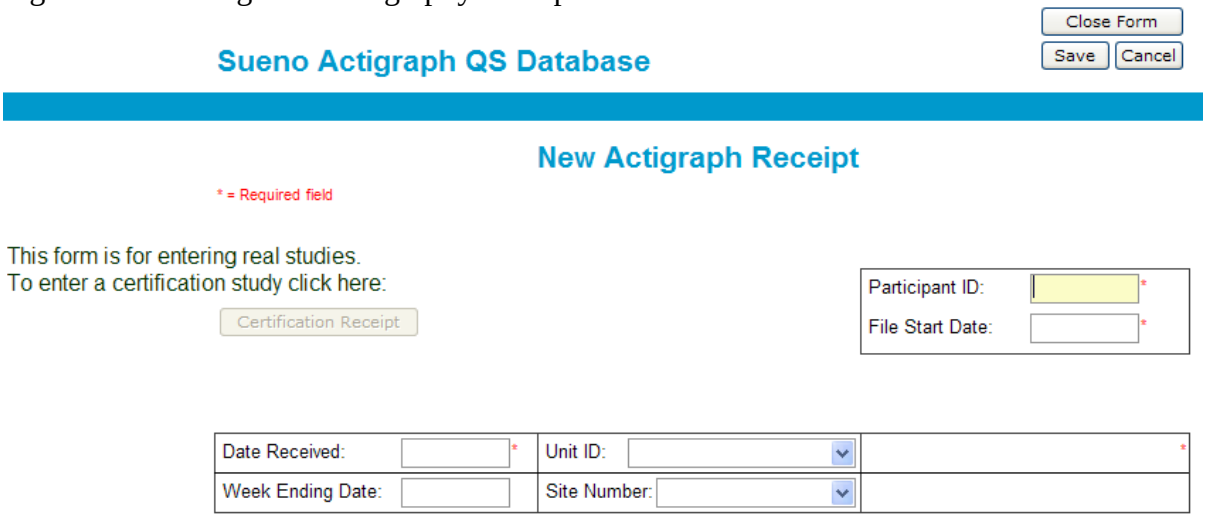
1. **Start the Actigraphy Receipt form:**
    a. Select **RC_bwh.mdb**. A window in Microsoft Access will open.
    b. Under **Select Study Database**, select **Sueno: Sueno/HCHS** from the dropdown menu.
    c. Under **Login**, enter **SQL username/password**. Then press the **Login to Actigraph Data** button.

Figure 38. Login to Reading Center QS Database



d. Select **New Receipt** from the upper left hand corner.
e. In the **New Actigraph Receipt**, enter the **Participant ID** (first letter of the field site + 7 digits).

Figure 39. Entering New Actigraphy Receipt



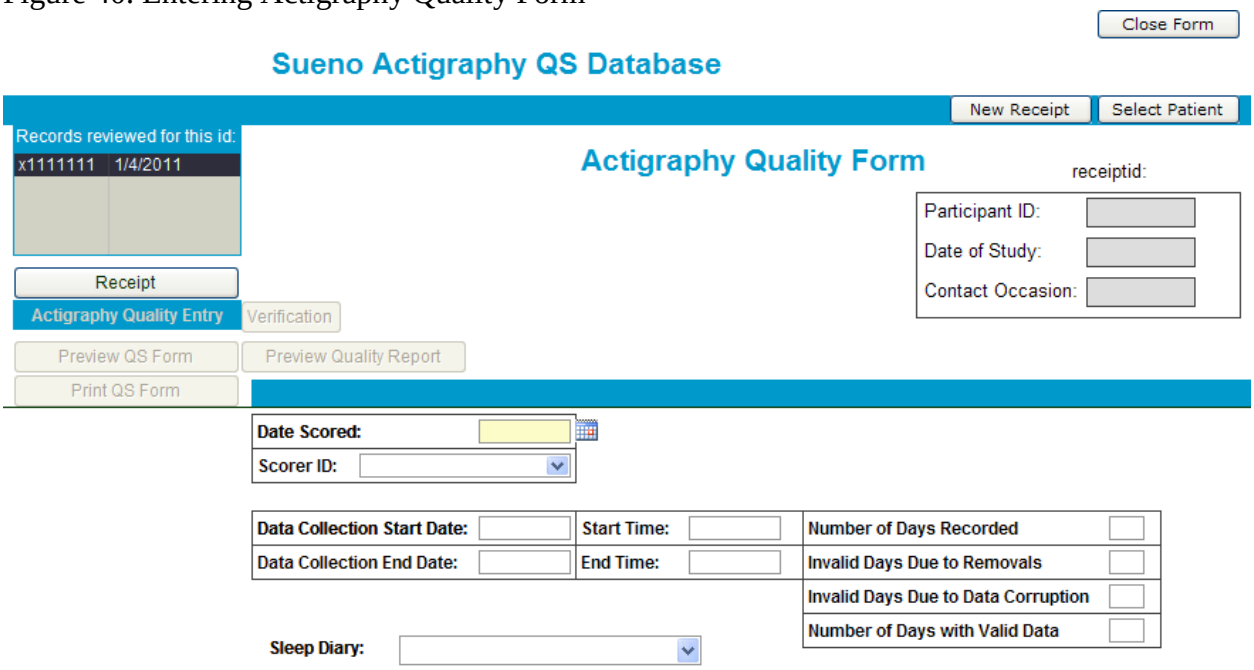
f. Enter the **File Start Date**, which is the date of the first on-wrist episode. Reference the participant's actogram for this information.
g. Enter the **Date Received**, which is the date the file was received at the Reading Center. Reference received Diplomat emails.
h. Enter the **Week Ending Date**. This value corresponds to the Friday after the study was *received* unless the study was received on a Friday. In this case, enter the date the study was received on.
i. Select the **Unit ID** from the dropdown menu. The unit ID corresponds to the last 4 digits of the Actiwatch serial number. The serial number can be located in the participant's printed **Actiware Print Report** in the upper right hand corner under **Actiwatch SN**. The serial numbers begin with the letter "S" followed by 5 digits. Confirm that the last 4 digits are consistent with the origin site of the watch. Enter

-9 or missing only if the serial number of the watch cannot be retrieved. Enter -1 or confusion if there is conflicting data as to what the serial number is.

j. Enter the **Site Number** (Site 1: Bronx, Site 2: Chicago, Site 3: Miami, Site 4: San Diego, Site 99: Boston). Confirm that the site number is consistent with the unit ID. Enter -9 or missing only if the site from which the data was sent is unknown. Enter -1 or confusion if there is conflicting data as to the identity of the site from which the data was sent. In some instances, watches originally from the Boston site will be sent to a different site as temporary loaner watches. In these instances, the Unit ID should correspond to the original site (Boston) and the site number should correspond to the site the Actigraphy and Daily Sleep Log data was sent from.

2. **Save New Actigraph Receipt:** click on the **Save** button in the upper right hand corner of the New Actigraph Receipt form. Close this form and return to the main window where the participant's record should be displayed under **Select Record**. Confirm that the record is present.
3. **Complete Quality Form:** It is important to complete *every* field on this form. Make sure to select an answer for every dropdown item. The purpose of the quality form is to provide a record of the degree of confidence that the sleep intervals manually set in the participant actogram correspond to the times the participant actually intended to sleep and wake up.
    a. Under **Select Record**, select the participant's record. In the **Actigraphy Receipt Form**, *do not* complete the rest of the receipt. Instead, select the **Open QS Form Entry** button located in the leftmost column. This action will result in opening the **Actigraphy Quality Form** window.

Figure 40. Entering Actigraphy Quality Form



b. Enter the **Data Collection Start** and **Data Collection End Dates** based on the Actigraphy file. *Note: the data collection start date is the date of the first **on-wrist***

episode *and the end date is the date of the last on-wrist episode. In order to find the date and time of the first on-wrist episode, click on the actogram near the start of the first on-wrist time. A pink arrow with a white caption listing the date and time will appear beneath the actogram. Adjust the arrow placement by using the right and left arrow keys. The time when the first activity count (ac) occurs is the first on-wrist episode. Record the date displayed in the white caption as the Data Collection Start Date. In order to find the date and time of the last on-wrist episode, click on the actogram near the last on-wrist time. Position the pink arrow to the last activity count (ac) and record the date displayed in the white caption as the Data Collection End Date.*

c. Enter the **Data Collection Start** and **Data Collection End Times** based on the Actigraphy file. It is important to enter times in **MILITARY TIME**. Therefore, 8:00 am would be entered as 0800 and 8:00 pm would be entered as 2000. If these times end in ":30" or 30 seconds, do not record the extra 30 seconds on this form. Do not round up. *Follow the steps in E.3.b to find the exact times of the first and last on-wrist episodes.*

d. Enter the **Number of days recorded,** which corresponds to the number of days (12:00:00 pm to 11:59:30 am) with on-wrist data including day 1 onward. For details regarding how day 1 is determined, see E.8.

e. **Invalid Days Due to Removals** are days when the Actiwatch was off-wrist for more than 4 hours and/or during the main sleep period making it impossible to confidently estimate the sleep interval time and duration or both. Additionally, if there were more than 4 hours of NO DATA for a given day, this would be considered an invalid day due to removal.

f. **Invalid Days Due to Data Corruption** are days when there was a Data Failure for more than 4 hours and/or during the main sleep period making it impossible to confidently estimate the sleep interval time or duration or both.

g. The **Number of Days with Valid Data** is the number of days recorded minus the number of invalid days.

h. The **Daily Sleep Log** is considered reliable if it aided in the confidence of the placement of the sleep intervals in the actogram. Enter "-9 Permanently missing" if the sleep log is blank or otherwise missing. Enter "-1 Confusion" if the log is unclear.

4. In/Out of Bed Grades: Grades are assigned to both the Time in Bed and Time Out of Bed separately. The grade assigned to the Time in Bed for a given sleep interval should not influence the grade assigned to the Out of Bed Time and vice versa. The Time in Bed/ Out of Bed should be filled in as a grade ranging from 0 to 3. This grade is a measure of the level of confidence that the time the sleep interval was set matches the actual time that the participant intended to sleep. A grade of 1 or unreliable indicates that the time set was a guess/approximation. In contrast, a grade of 3 or mostly reliable indicates that the interval set is likely the actual time the participant intended to sleep.

a. A grade of **3** or **Mostly Reliable** is assigned when it is likely that the time the sleep interval was set corresponds to the actual time the participant intended to sleep. Most of the present and reliable parameters indicate that sleep occurred at the time the interval was set with only minor inconsistencies. Conversely, it seems unlikely there is an alternative sleep time.

b. A grade of **2** or **Somewhat Reliable** is assigned when it is probable that the time the interval was set corresponds to the actual time the participant intended to

sleep, but there is also a reasonable alternative time at which the sleep interval could have been placed.

c. A grade of **1** or **Unreliable** is assigned when the time the interval was set is at best a guess or approximation of the actual time the participant intended to sleep. In most cases, there are major inconsistencies between parameters preventing a robust prediction of the time sleep actually occurred.

d. A grade of **0** or **No Evidence of Sleep** is assigned when there is no indication that the participant intended to sleep on a given day. This grade is typically assigned when there is a brief on-wrist episode on the last day the participant wore the watch. *For example, if the participant permanently took their watch off at 2:00 pm, there would be two hours (12:00:00 pm to 2:00:00 pm) of on-wrist data for the last day the watch was worn. If there was no evidence that sleep occurred over the two hours the watch was worn, the Time in Bed and Time Out of Bed grades for this day would receive a grade of 0.*

e. A grade of **-1** or **Confusion** is assigned when some or all of the parameters are missing due to invalid, excluded, and/or off-wrist data. This grade is typically assigned when there is an off-wrist episode during the in-bed or out-bed transition or between any of the four parameters at either transition. *For example, if the participant marked a bed-time of 11:00 pm on the Sleep Log, took the watch off between 11:15 pm-11:17pm, and then pressed the marker and went to bed at 11:20, the transition will be at 11:20 pm, but the In-bed score will receive a grade of -1.*

5. **In/Out of Bed Parameters:** In addition to entering a grade for each In/Out of Bed episode, the parameter (Marker, Diary, Light Quantity, Activity) that was used to place the In or Out of Bed interval should also be indicated. Only the parameter that had the exact same time as the time entered for the interval placement should be entered as "1" or "Checked" in the Quality Assessment Form. Therefore, a single parameter should be checked for each of the In/Out of Bed episodes per day. All other parameters listed should be filled in as "0" or "Not Checked." If a grade of "0" was assigned, enter "-8" for all parameters.

6. **Napping Grades:** The grade assigned in response to the question "did napping occur?" for a given day should be based on how confident the scorer is that naps actually took place. The grades assigned range from 0 to 3. Reference both the subject's Actigraphy file as well as Daily Sleep Log when assigning a grade. The napping grade assigned should be based on ALL of the naps taken for a given day. **Important:** the grade assigned should be based on the grade given to the LEAST reliable nap. Remember that any periods of low activity that are not associated with a Marker and/or Daily Sleep Log should not be counted as naps.

    a. A grade of **3** or **Mostly Reliable** is assigned when all of the naps for a given day reported by the participant in the form of Diary and/or Marker entries are likely to have occurred based on associated distinct drops in activity.

    b. A grade of **2** or **Somewhat Reliable** is assigned when there is some evidence that the least reliable nap reported by the participant occurred. All Marker and Log entries should be associated with some supportive evidence that the least reliable nap occurred such as a drop in the quantity of light or a brief drop in activity.

    c. A grade of **1** or **Unreliable** is assigned when the least reliable nap reported by the participant did not have an associated drop in light and/or activity or it seems very

unlikely this nap actually occurred. A napping grade of 1 should be assigned to days where default 30 second nap intervals are present.

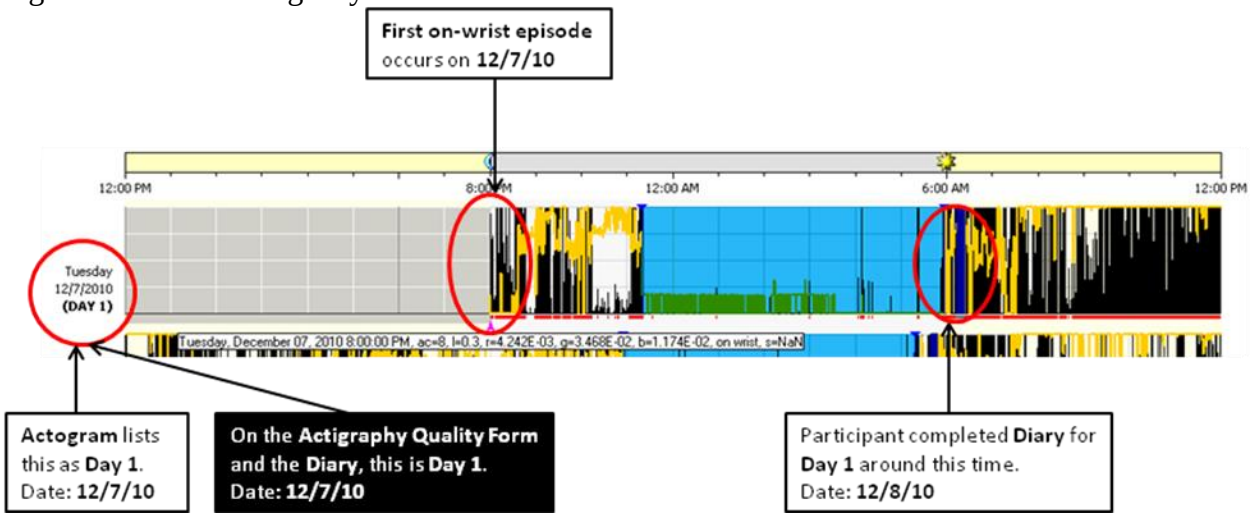
d. A grade of **0** or **No Evidence of Sleep** is assigned when there is no Daily Log entry or Marker indicating the presence of naps for a given day.
e. A grade of **-1** or **Flag/Confusion** should be assigned when there is no way to determine where a default 30 second nap interval should be placed. This can occur if the nap recorded by the participant overlapped with a main sleep period or if the participant recorded the nap as having taken place when the device was off-wrist. Alternatively, if the only evidence the participant took a nap for a given day is in the form of "yes" in response to the Daily Sleep Log question "during the day yesterday, did you take a nap or fall asleep for more than 5 minutes?" but the actual nap time was not entered and there was no other conclusive evidence, then it would be appropriate to assign this grade. If any of the naps for a given day received the grade of -1, the grade assigned for the entire day should be -1.

7. **Napping Parameters:** Nap intervals can only be set if there was a Marker and/or a Daily Sleep Log entry indicating the presence of a nap. Check the parameter(s) that served as evidence that napping occurred (Marker, Daily Log or both). If a grade of "0" was assigned, enter "-8" for all parameters. If there are multiple naps on a given day, check the parameter(s) that were used to set all nap intervals. *For example, if the Marker was used as evidence of the first nap interval and the Diary was used as evidence of the second nap interval, both the Marker and the Diary should be checked off in the Quality Assessment form for that day.*
8. **Entering Grades and Parameters Properly:**
    a. The day entered as **Day 1** in the Actigraphy Quality form should satisfy the following conditions:
        i. Day 1 recorded in the Actigraphy Quality form should always match day 1 in the Daily Sleep Log. *Note: the <u>date</u> of day 1 in the log will be off by one day compared with the date on the actogram because participants complete the log the morning after.*
        ii. The ***<u>date</u>*** of day 1 in the Actigraphy Quality form should always match the **Data Collection Start Date**. The data collection start date is defined as the date of the **first on-wrist episode**. For instructions as to how to find this date, see E.3.b. *<u>Do not</u>* simply record the date listed to the left of the actogram for the day on-wrist begins as the data collection start date. Instead, click on the actogram and move the pink arrow to the start of first on wrist.
        iii. Day 1 in the Actigraphy Quality form may or may not match the ***<u>day</u>*** listed as day 1 directly to the left of the actogram.

For additional information on how to designate **Day 1 in the Actigraphy Quality form**, refer to the following examples:

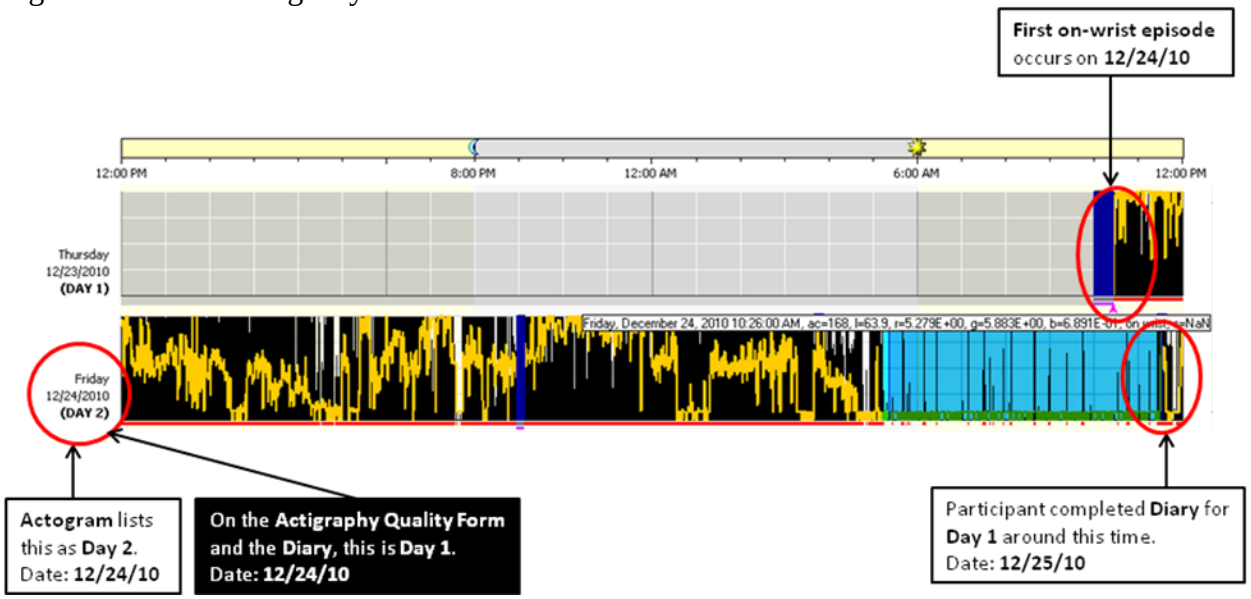
Determining day 1 when first on-wrist episode is <u>at or after</u> the preset start time (in most cases 12:00:00 pm)**:** the day the **actogram** lists as day 1 should match day 1 in the **Daily Sleep Log**. This is also the same day that should be entered into the **Actigraphy Quality Form** as day 1. The date of the first **on-wrist episode (data collection start date)** is the same date as that of day 1 in the Actigraphy Quality Form.

Figure 41. Determining Day 1 with Data at or after Pre-set Start Time



Determining day 1 when first on-wrist episode is <u>before</u> the preset start time: The day the actogram lists as day 1 is <u>NOT</u> the same as day 1 in the **Daily Sleep Log**. The day that should be entered into the **Actigraphy Quality Form** as day 1 should match day 1 in the Daily Sleep Log. The date of the **first on-wrist episode (data collection start date)** is the same date as that of day 1 in the Actigraphy Quality Form. *Note: on the actogram, the first on-wrist episode will appear to be listed on a separate day and date compared with day 1 in the Actigraphy Quality form. By actually clicking on the region of the actogram associated with the first on-wrist episode and moving the pink arrow to the first on-wrist episode, the white caption that appears under the arrow will list the same date for the first on-wrist episode (data collection start date) as the date for day 1 in the Actigraphy Quality Form.*

Figure 42. Determining Day 1 with Data before Pre-set Start Time



b. **Entering all Grades and Parameters:** Grades should be entered in the leftmost field in the Time in Bed, Time Out of Bed and Napping columns. Parameters should be checked in the rightmost field in all three columns. If a parameter was not checked, select "0" or "unchecked" in the dropdown menu for this parameter

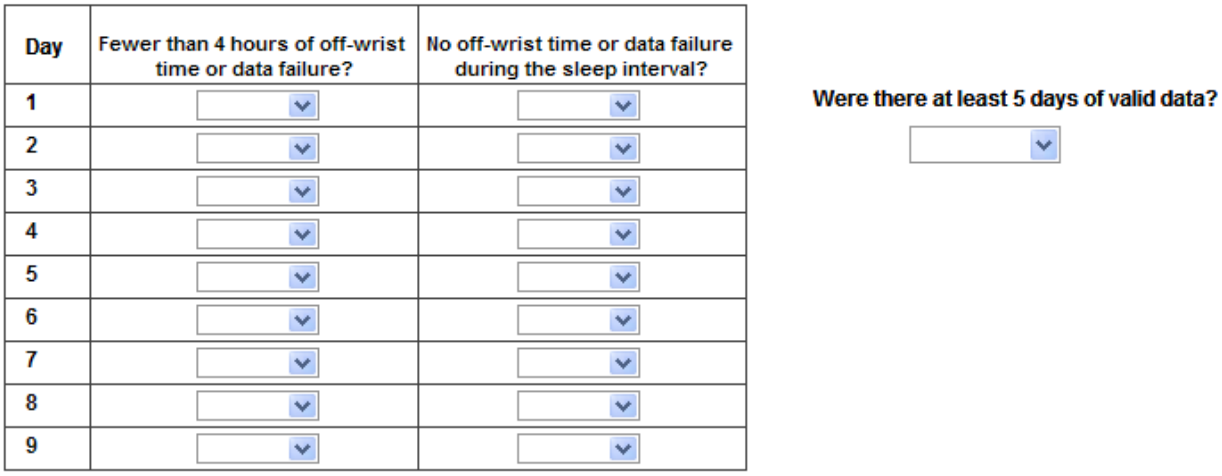
rather than leaving the field blank. If a grade of zero was assigned, all of the parameters corresponding to this grade should be filled in as "-8" or "Not Applicable." Make sure that every field of this form is complete. If there are fewer than 9 days of on-wrist data, enter a grade of "-8" for all fields for the remaining rows. Figure 43 (below) shows a blank version of the Actigraphy Quality Form.

Figure 43. Entering Grades and Parameters Used in Quality Form

Day	Time in Bed		Time Out of Bed		Did Napping Occur?	
1		Marker		Marker		Marker
		Diary		Diary		Diary
		Light		Light		
		Activity		Activity		
2		Marker		Marker		Marker
		Diary		Diary		Diary
		Light		Light		
		Activity		Activity		
3		Marker		Marker		Marker
		Diary		Diary		Diary
		Light		Light		
		Activity		Activity		
4		Marker		Marker		Marker
		Diary		Diary		Diary
		Light		Light		
		Activity		Activity		
5		Marker		Marker		Marker
		Diary		Diary		Diary
		Light		Light		
		Activity		Activity		
6		Marker		Marker		Marker

9. **Determining How Many Days of Valid Data:** Enter data for this section in the table below on the Actigraphy Quality Form:

Figure 44. Determining the Number of Valid Days



a. **Fewer than 4 hours of off-wrist time or data failure:** This value should be the sum total of all of the off-wrist, no data and data failure time for a given day. Off-wrist intervals are indicated by dark blue bands (excluded intervals). Note that a day starts at 12:00:00pm and ends at 11:59:30am. Check "yes" if there were fewer than 4 hours or 240 minutes of off-wrist time, no data and data failure cumulatively. Check "no" if there were 4 or more hours of off-wrist time, no data and data failure combined for a given day. For further instruction, see B.2.b.

b. **No off-wrist time or data failure during the sleep interval:** If there was no off-wrist time or data failure during the beginning, middle or end of sleep (including all naps), check "yes." If dark blue bands (excluded intervals) or grayed regions of no data or data failure are present at the beginning, middle or end of sleep (including all naps), check "no."

c. **At least 5 days of valid data:** Initially determine how many main rest intervals are present. If there are fewer than five, check "no." Then determine how many days had no checked for the question "Fewer than 4 hours of off-wrist time or data failure?" and/or the question "No off-wrist time or data failure during the sleep interval?" Days that had "no" as inputs for either or both question(s) are considered to be invalid. Determine how many valid days remain. If there are fewer than 5, check "no" for this question. If there are still 5 or more valid days, check "yes." If "no" was selected, make sure that a **Study Failure Form** has been sent to the original field site. Additionally, make sure that the answer to this question is consistent with the **Number of Days with Valid Data** previously entered.

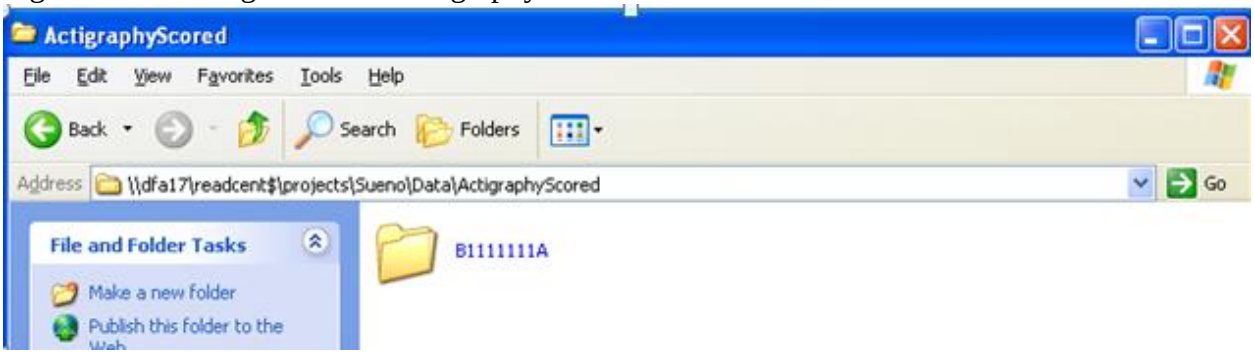
10. **Study Comments:** Enter comments as needed. Enter "-8" or "Not Applicable" if no comments are necessary.

Figure 45. Study Comments Field

11. **Saving Quality Form:** After all fields have been completed in the Actigraphy Quality Form, click on the **Save** button in the upper right hand corner.
12. **Moving Files in the Sueño Database:** Move the folder labeled with the subject ID and contact occasion that contains the Actiware file, the Daily Sleep Log and the Quality Assessment form from the **ActigraphyRaw** folder to the **ActigraphyScored** folder. Make sure the folder labeled with the subject ID and contact occasion is no longer in the ActigraphyRaw folder. See below:

ActigraphyScored Folder: This folder should contain a folder labeled with the subject ID and contact occasion (ex: B1111111A).

Figure 46. Labeling of Scored Actigraphy Folder



Subject ID + Contact Occasion Folder: This folder should contain the subject's Actigraphy file, Daily Sleep Log and the completed Quality Assessment form. This folder should be saved in the **ActigraphyScored** folder.

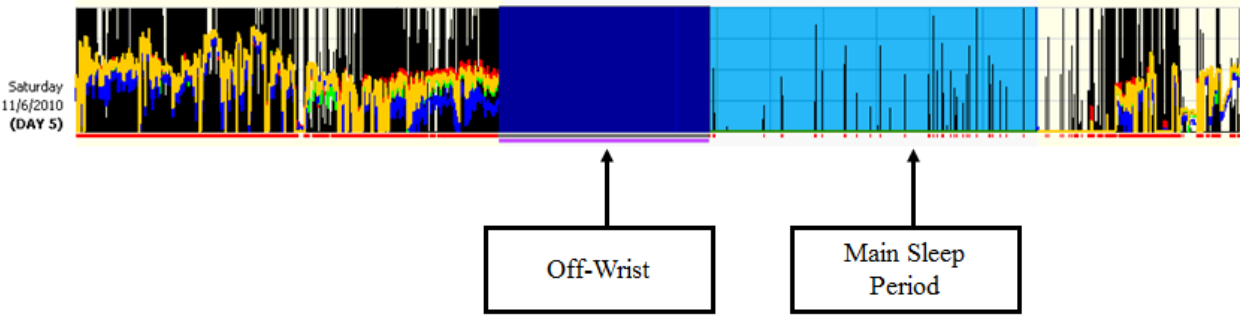
Figure 47. Verifying Contents of Scored Actigraphy Folder

F. CREATING "NO NAPS" ACTIGRAM

The modified "no naps" actogram is created so that there is an actogram only containing valid main sleep intervals. The original file containing naps provides a record of all of the data present in the file including naps, whereas the "no naps" file provides a record of only the valid main sleep periods. Both of these files will be useful in terms of statistical analysis.

1. **Open Participant Actogram:** In the actogram window, open the saved Actiware file for the subject by going to the Database Viewer and selecting the actogram labeled with the **subject ID** instead of New Analysis.
2. **Remove Naps:** Click on each nap interval and press the **Delete** key. Successful removal will be indicated by the disappearance of the **rest** and **custom** intervals. Alternatively, right click on the rest interval and select **Clear Interval**. Then right click on the custom interval and select **Clear Interval** as well.
3. **Set Default Intervals:** Every day must have a rest interval. For days lacking rest intervals, set a rest interval from 1:00:00 pm to 1:00:30 pm for these days. If there was off-wrist at this time, select an alternative location to place the default interval. *Note: days begin at 12:00:00 pm and end at 11:59:30 am.*
4. **Set Excluded Intervals:** For main sleep periods (not naps) where the duration of the rest interval is unclear, exclude the entire day (12:00:00 pm to 11:59:30 am). *Example: when the subject had the Actiwatch off-wrist during the time they went to bed (see below).*

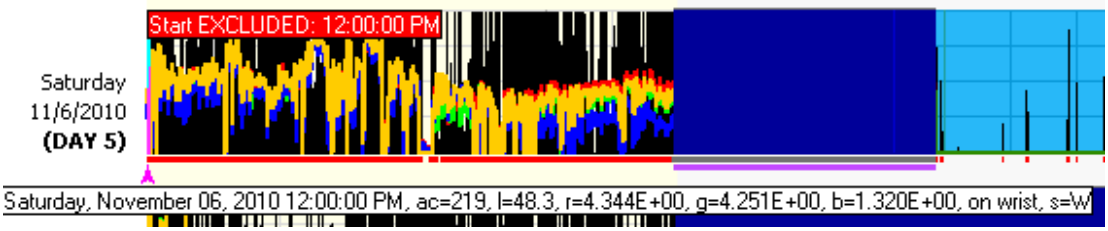
Figure 48. Excluding Invalid Day Due to Unclear Sleep Duration



Important: The exclusion criteria are <u>not</u> the same as the criteria for determining whether an actogram is of sufficient quality (B.2.a). Days should only be excluded when there is off-wrist time or data failure during the beginning, middle or end of main sleep periods, making it impossible to determine the duration of sleep periods. If there is off-wrist time or data failure in a nap, the entire day should <u>not</u> be excluded on this basis alone.

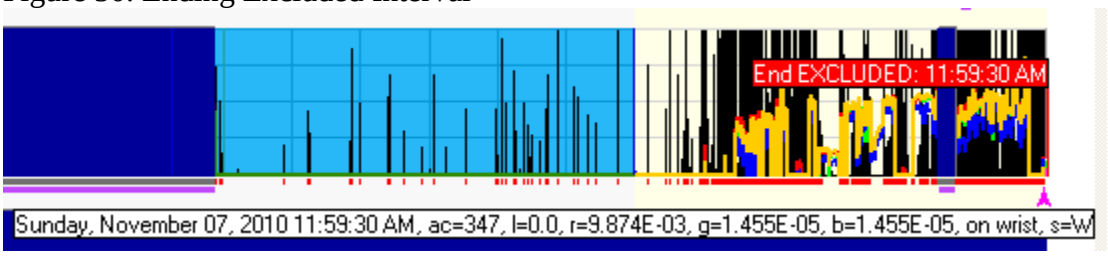
a. Position the pink arrow at the Start Hour, normally 12:00:00pm, of the day containing the unclear rest interval and type **e**. This action will result in the appearance of a red flag stating **Start EXCLUDED**.

Figure 49. Starting Excluded Interval



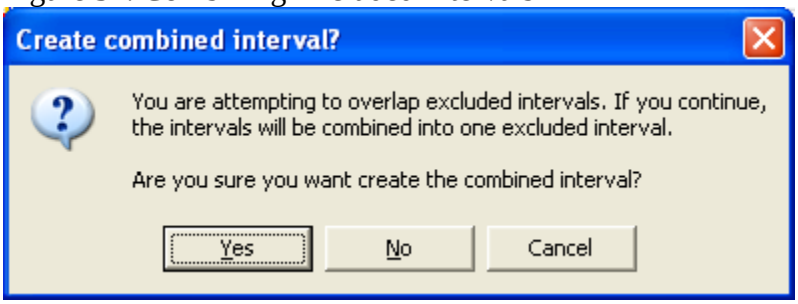
b. Position the arrow the end of the actigraphy day, (in most cases 11:59:30 am), and type **Shift + e**. This action will result in the appearance of a red flag stating **End EXCLUDED**.

Figure 50. Ending Excluded Interval



c. Set the Exclusion interval by typing **Ctrl + e**. A dark blue band should appear indicating the presence of an Excluded interval (see Interval Legend). Make sure to delete all **rest** and **custom** intervals for the excluded day. *Note: if there is an excluded interval already present, a message will appear asking to combine intervals. Select yes*

Figure 51. Combining Excluded Intervals



The entire day from Start Hour to End Time, should be marked as excluded (dark blue). **Important:** If a sleep period is considered invalid and extends past 11:59:30 am, create a 24-hour excluded interval that includes the invalid sleep period portion after 11:59:30 am.

Figure 52. Setting Excluded Interval

5. **Saving "No Naps" Actogram:** The modified actogram should be saved as **subject ID + nonaps** in the Actigraphy file. Select **Analysis>Save As**. ***Do not*** save over the original file with naps included labeled with just the **subject ID**.

Important note: even if no modifications were necessary, save a second copy of the actogram following the "no naps" naming system.

6. **Confirming Sleep Intervals:** Check that the intervals were set correctly by selecting **View > Statistics Table > OK**. Under the **Rest** tab, look up and down intervals and confirm that the number of rest intervals is consistent with the number of main sleep periods.

Figure 53. Selecting Statistics Table View

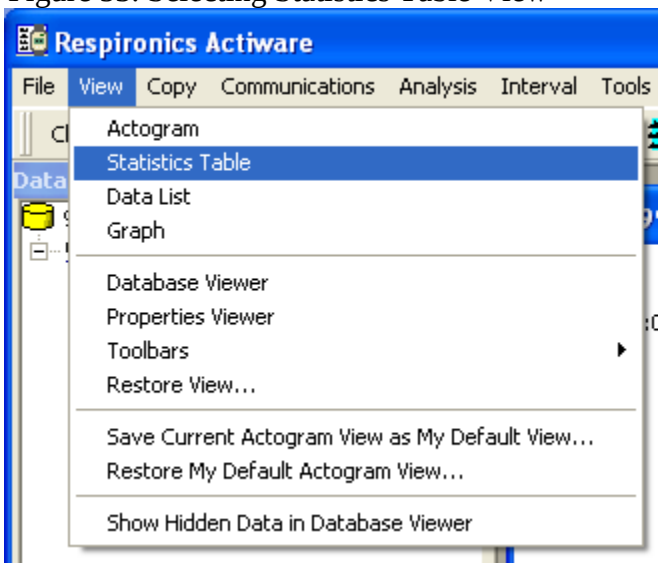


Figure 54. **Statistics Table**

Rest | Active | Sleep | Custom | Daily | Summary | Clinicians Report

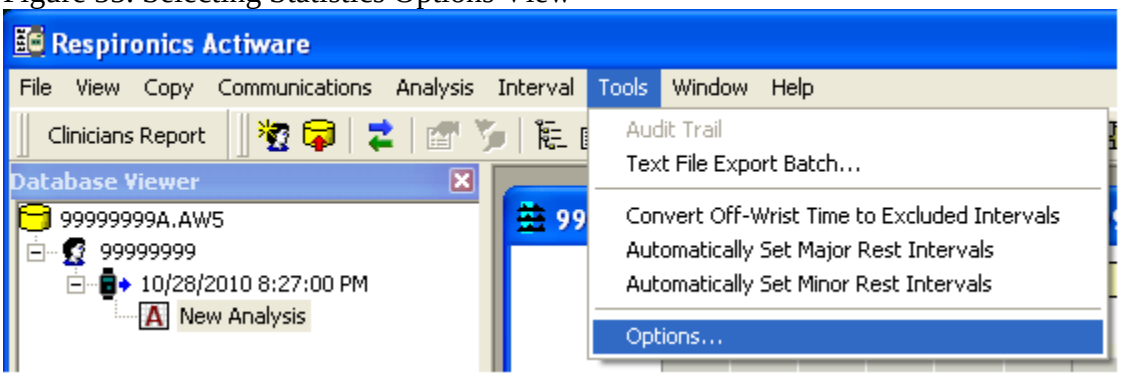
	Start Date	Start Day	Start Time	End Date	End Day	End Time	Duration	Off-Wrist	%Off-Wrist	Total AC
Interval 1	10/28/2010	Thu	11:00:00 PM	10/29/2010	Fri	6:00:00 AM	420.00	0.00	0.00	3514
Interval 2	10/29/2010	Fri	10:40:00 PM	10/30/2010	Sat	5:45:00 AM	425.00	0.00	0.00	5217
Interval 3	10/31/2010	Sun	12:55:00 AM	10/31/2010	Sun	7:10:00 AM	375.00	0.00	0.00	2591
Interval 4	10/31/2010	Sun	9:40:00 PM	11/1/2010	Mon	6:10:00 AM	510.00	0.00	0.00	5856
Interval 5	11/1/2010	Mon	11:20:00 PM	11/2/2010	Tue	5:00:00 AM	340.00	0.00	0.00	6955
n	*	*	*	*	*	*	5	5	5	5
Minimum(n)	*	*	*	*	*	*	340.00	0.00	0.00	2591
Maximum(n)	*	*	*	*	*	*	510.00	0.00	0.00	6955
Average(n)	*	*	*	*	*	*	414.00	0.00	0.00	4826.60
Std Dev(n-1)	*	*	*	*	*	*	63.97	0.00	0.00	1765.15

G. EXPORTING ACTIGRAPHY FILES

Both the original file containing naps marked with custom intervals labeled with the **subject ID** and the "no naps" file labeled with the **subject ID + nonaps** should be exported as .csv files. The original file containing naps marked with custom intervals will be saved in the **Naps** folder and the "no naps" file will be saved in the **No Naps** folder.

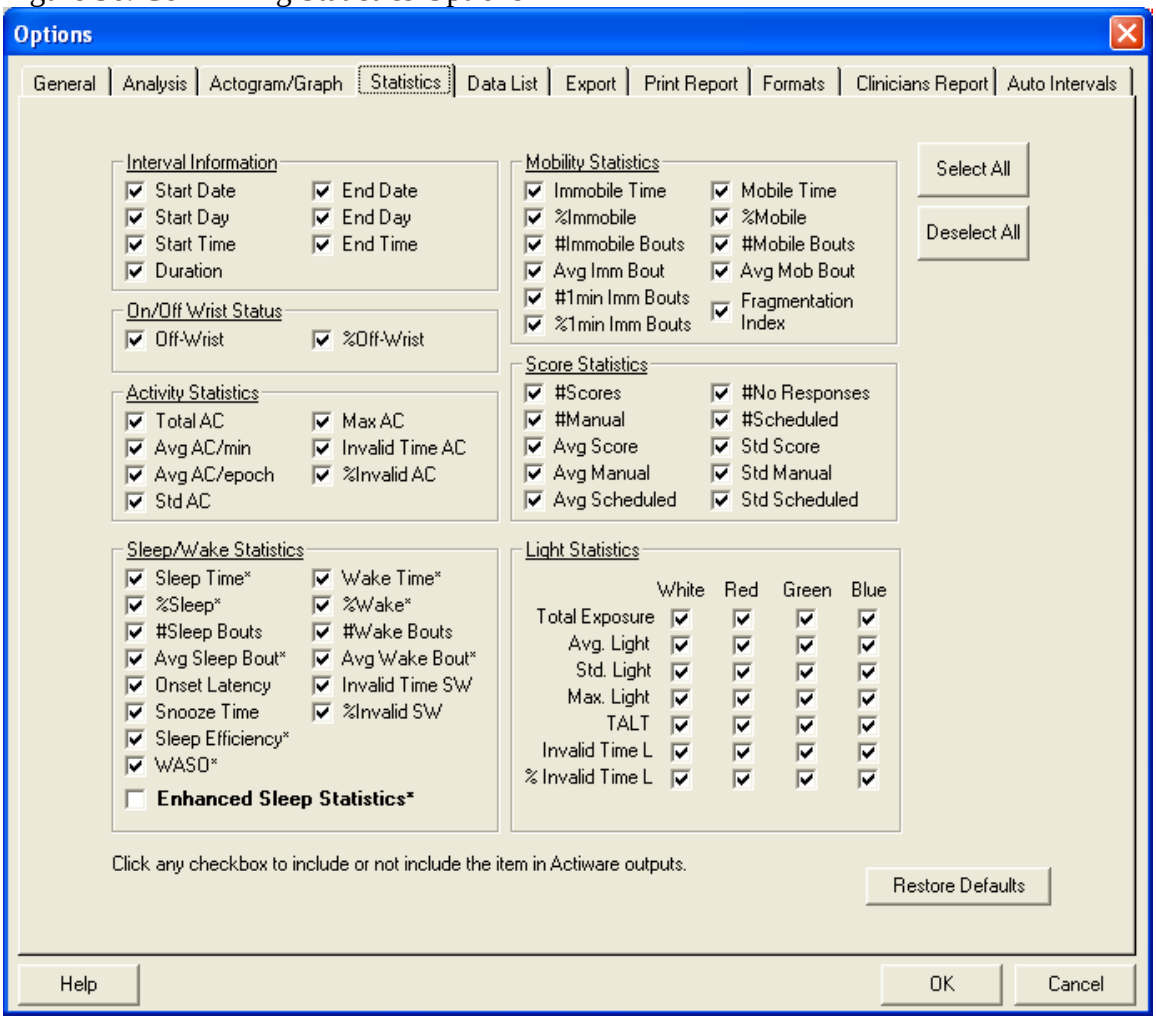
1. **Confirming Statistics:**
   a. For the newly saved actogram file labeled with the **subject ID + nonaps**, select **Tools > Options**.

Figure 55. Selecting Statistics Options View



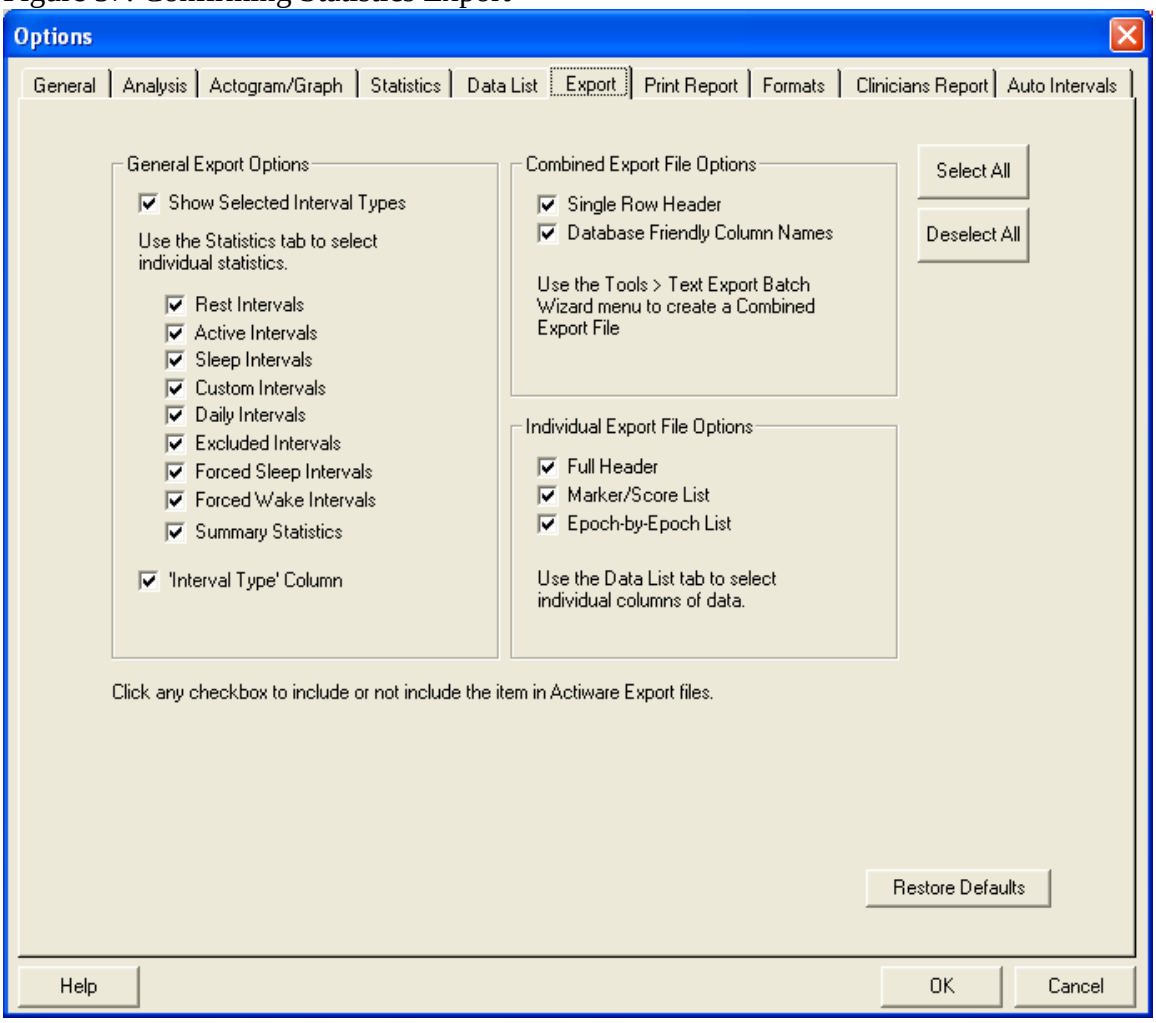
b. In the **Statistics** tab, confirm that all items are selected, except **Enhanced Sleep Statistics**.

Figure 56. Confirming Statistics Options



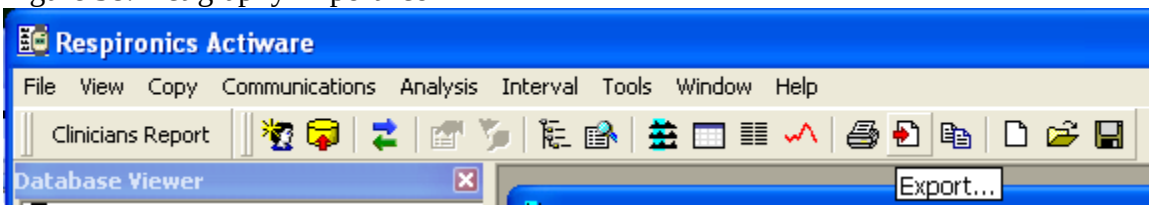
c. In the **Export** tab, confirm that all items are selected. Close the Options window.

Figure 57. Confirming Statistics Export



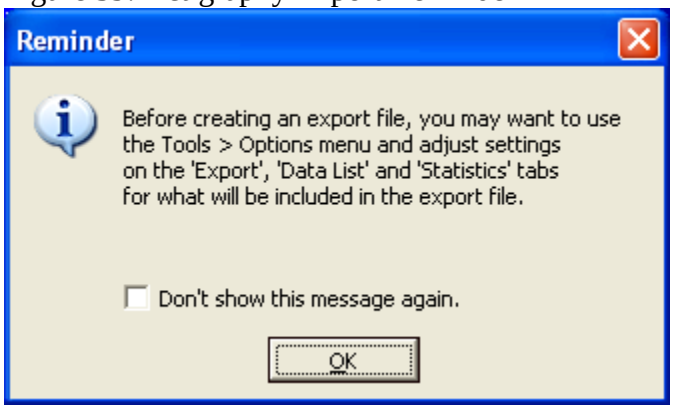
2. **Exporting Actogram Files:**
   a. In the main Actiware window, select the **Export** icon (a red horizontal arrow on top of a white page).

Figure 58. Actigraphy Export Icon



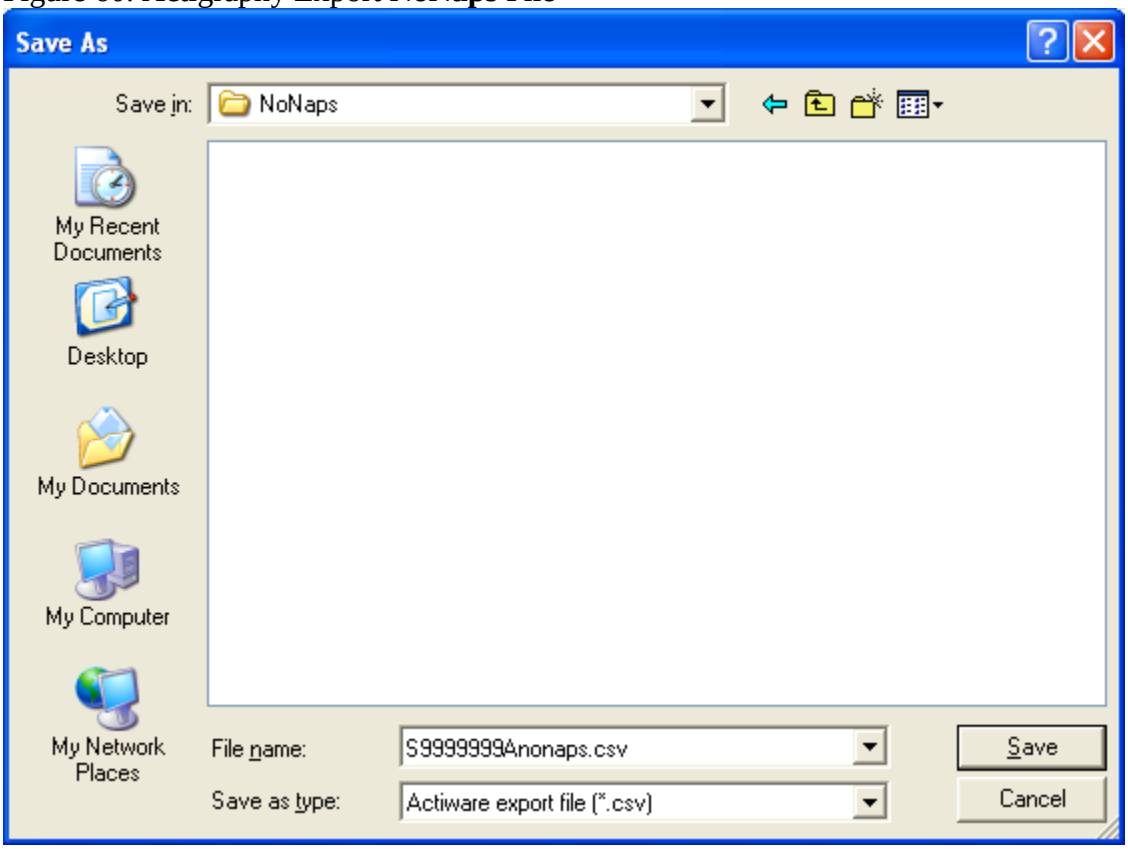
b. A reminder message will appear. Select **OK**.

Figure 59. Actigraphy Export Reminder



c. **Save** the actogram file in the **NoNaps** folder under the folder **Actigraphy_sasReports**. Label the **.csv** file with the **subject ID + contact occasion + nonaps**.

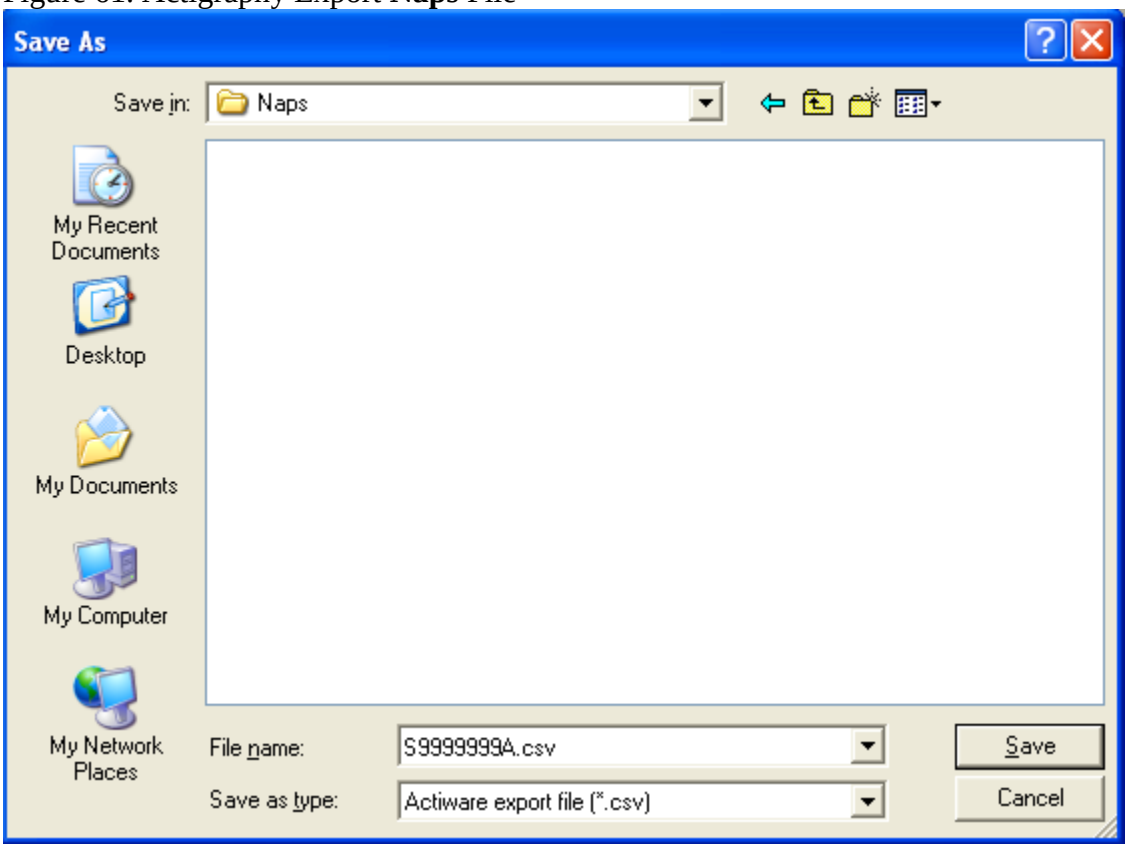
Figure 60. Actigraphy Export **NoNaps** File



d. **IMPORTANT:** Repeat steps G.1.a- 2.b for the original actogram file with naps included labeled with only the subject ID.

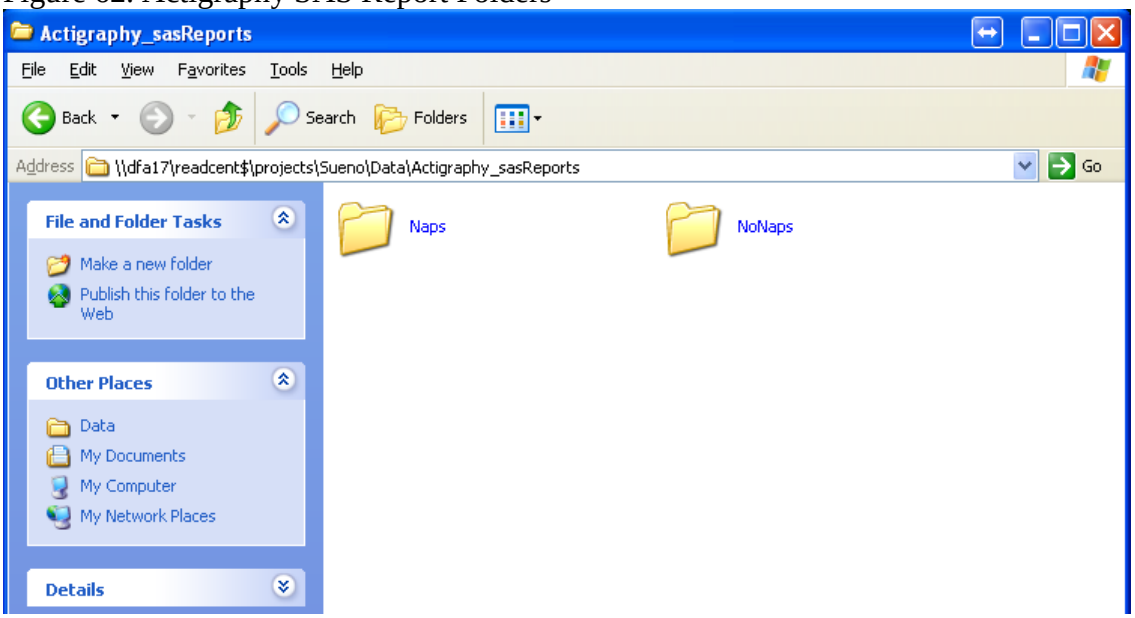
e. **SAVE** the original actogram file in the **Naps** folder under the folder **Actigraphy_sasReports**. Label the **.csv** file with the **subject ID + contact occasion**.

Figure 61. Actigraphy Export **Naps** File



Both the original and the new version of the actogram should be exported as a .csv file. These files should be saved in the **Actigraphy_sasReports** folder. The original version of the actogram should be saved in the **Naps** folder and the new version of the actogram should be saved in the **NoNaps** folder.

Figure 62. Actigraphy SAS Report Folders

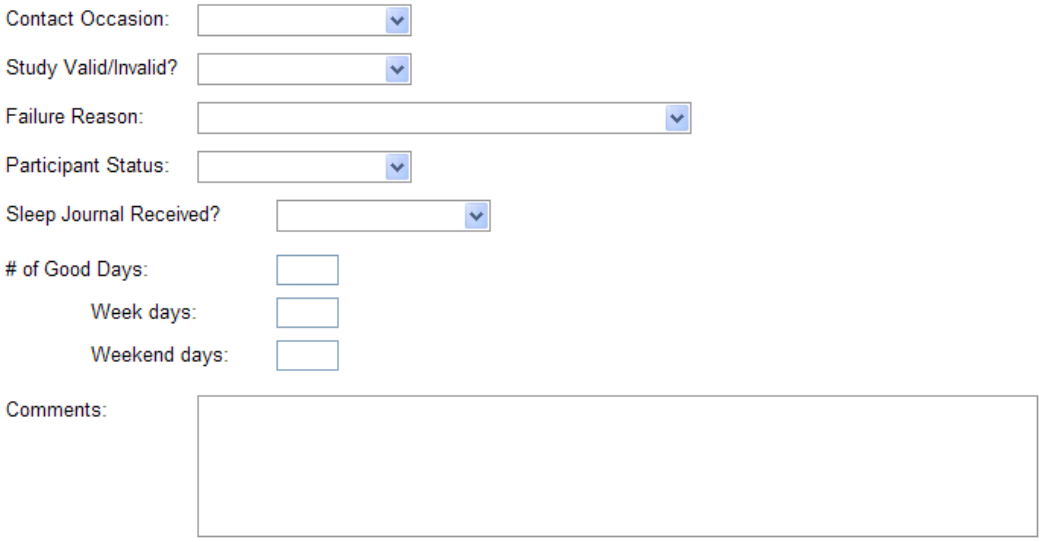


H. READING CENTER DATABASE ENTRY

Actigraphy data will be entered into this database so that there is a catalog of the received files. The first part of the receipt should have been completed prior to entering data into the Actigraphy Quality Form (see E.1-2). It is important to have completed the Actigraphy Quality Form *prior* to completing this receipt.

1. **Complete Actigraph Receipt Form:**
    a. Inside the Reading Center Database: **RC_bwh.mdb**, select the participant's file listed under **Select Record**.
    b. In the Actigraphy Receipt Form that had already been partially completed, enter the **Contact Occasion**. If it is unclear as to the contact occasion, enter "-1."

Figure 63. Entering the Actigraphy Receipt Form



    c. Enter whether the study is **invalid** or **valid**. An invalid study would be one where there were **fewer than 5 days of valid data**. Refer to the completed **Actigraphy Quality Form** for this information.
    d. **Failure Reason:** If **Valid** was entered, the Failure Reason field will auto fill as "-8" or "Not Applicable." If **Invalid** was entered, select the Failure Reason from the dropdown menu:
        i. **Contact Occasion 1 or -1:** Reference the **Study Failure Form** in order to obtain this information. If a Study Failure form is absent for the participant, refer to the **Actigraphy Quality Form**. Select the failure reason from the dropdown menu.
        ii. **Contact Occasion 2:** A Study Failure Form should NOT be present for this occasion. Reference the **Actigraphy Quality Form** in order to obtain this information.
        iii. Select **-8** or **Not Applicable** only if the failure reason cannot be determined.
    e. **Participant Status:** The purpose of this field is to determine whether a repeat trial will take place. If **Valid** was entered, the Participant Status field will auto fill

as "-8" or "Not Applicable." If **Invalid** was entered, select the Participant Status from the dropdown menu:

i. **Contact Occasion 1 or -1:** Reference the completed **Study Failure Form** in order to obtain this information. If the field site has not yet returned a completed version of the Study Failure Form with the Participant Status data entered, select "8" or "Pending" from the dropdown menu. When the completed Study Failure Form is returned to the Reading Center, change the Participant Status field referencing this form. If the site has clearly communicated that they are unwilling or unable to return a completed version of the Study Failure Form, enter "9" or "Missing".

ii. **Contact Occasion 2:** A Study Failure Form should NOT be present for this occasion. ***Always*** select **-8** or **Not Applicable** for the Participant Status when it is the second contact occasion and the study was invalid.

f. In the **Sleep Journal Received** field, enter whether the Daily Sleep Log was received. Select from the following dropdown options:
   i. Enter "-1" or "confusion/flag" if it is unclear whether there is a journal present for the participant that has the same contact occasion as the Actigraphy data.
   ii. Enter "-9" or "missing" if a sleep journal was never received from the field site.
   iii. Enter "0" or "no" if a blank sleep journal was received from the field site.
   iv. Enter "1" or "yes" if a sleep journal was received that had some amount of data entered by the participant.

g. For the **# of Good Days** field, enter the number of days that were considered to be valid based on the **Actigraphy Quality Form**. Under **Week days**, enter the number of days between and including Sunday and Thursday that were considered valid. Under **Weekend days**, enter the number of days that are Fridays or Saturdays that were considered valid. Refer to the **Actigraphy Quality Form** and the **Actigraphy** file for these values.

h. Enter **Comments** as needed.

2. **Save Completed Actigraphy Form:** click on the **Save** button in the upper right hand corner of the Actigraphy Receipt form. Click on the **Close** button in the upper right hand corner of the form, which results in automatically returning to the main window where the participant's record should be displayed under **Select Record**. Confirm that the record is present.

Sueño – Sleep Habits in HCHS

Overview of Actigraphy Processing

April 30, 2014

TABLE OF CONTENTS

1. OBJECTIVE

This document is designed to assist users of the Sueño dataset by providing an explanation of the analytic process used to create Sueño actigraphy variables.

This document is organized in the order in which data cleaning and optimization steps were taken and is best understood in conjunction with the Sueño Database Dictionary and Reading Center Manual of Procedures.

2. CONVERTING EPOCH LENGTH

The epoch length (time sampling interval) for data collection was procedurally set to 30-seconds, per study protocol. In cases where the epoch length was accidentally configured to 15-seconds, activity and light data were converted to 30 second epochs. Variable SAWA341 specifies the original epoch length in which data was recorded.

Activity data was converted to 30-second epochs by summing the activity counts in each pair of consecutive 15-second epochs. If data for one 15-second epoch was invalid but the data for the other 15-second epoch in the pair was valid, then the data in the available epoch was multiplied by two.

Light data was converted to 30-second epochs by averaging the light intensity in each pair of consecutive 15-second epochs. If data for one 15-second epoch was invalid but the data for the other 15-second epoch in the pair was valid, then the data in the available epoch was used as the value for the 30-second epoch.

3. DATA OPTIMIZATION

3.1 CALCULATING SLEEP/WAKE STATUS

Each epoch outside of a rest interval is scored as wake, regardless of the activity level. For epochs within a rest interval, Actiware uses a three part process to determine sleep/wake status.

First, Actiware computes a weighted average of the activity count in the epoch of interest, the four previous epochs, and the four subsequent epochs. If this weighted average is less than or equal to the pre-set threshold (40 counts/min for Sueño), the epoch is labeled as a low activity level; if it is greater than this threshold, the epoch is labeled as high activity.

Actiware labels each epoch with a high/low activity status only if a minimum of the five nearest epochs (the epoch of interest, two previous, and two subsequent) have valid counts. Thus, a missing value in one epoch will result in a missing activity level status for a series of 5 consecutive epochs. To minimize the amount of missing data, high/low activity level was recomputed calculating a weighted average based on the subset of nine epochs with non-missing data as long as a minimum of one out of the nine epochs had non-missing data.

Next, Actiware classifies each epoch as mobile or immobile based on the activity count in that epoch. If the count is less than the equivalent of 1 count per 15 seconds, the epoch is classified as immobile and if it is greater than or equal to this threshold, it is classified as mobile. Given the pre-set epoch length of 30 seconds, this translates in Sueño to immobile for an activity count < 2 and mobile for an activity count ≥ 2. Unlike activity level, no imputation was done for missing mobile/immobile scoring.

Finally, Actiware identifies the first low activity level epoch where 9 of the 10 prior epochs are immobile (based on the Sueño pre-set time to sleep onset setting of 5 minutes) as sleep onset. All subsequent epochs labeled as low activity level are then scored as sleep. All subsequent epochs labeled as high activity level as well as all epochs prior to sleep onset are scored as wake.

3.2 SETTING SLEEP OFFSET

The number of immobile minutes for sleep-end was pre-defined for Sueño to be 0. As such, the Actiware software defines sleep offset automatically to the out-of-bed time. For Sueño, sleep offset was redefined as the last epoch in the rest interval scored as sleep. All epochs following this one until the end of the rest interval were defined as snooze time and did not contribute to wake after sleep onset.

3.3 CONVERTING DAYLIGHT SAVINGS TIMES

Attempts were made to avoid data collection overlapping the start and end of daylight savings time (DST) whenever possible due to the abrupt impact of this clock change on sleep patterns. Actiware does not account for daylight savings time as the clock times are fixed at the time the watch is configured by staff. Steps were made to address clock changes resulting from DST. In particular, clock times were adjusted by an hour from those provided by Actiware to account for the actual clock time at the start and end of DST. Adjusted clock times were used to calculate timing variables only. In contrast, duration and sleep quality variables were not adjusted. For example, a participant who went to sleep at 10 PM and awoke at 6 AM on a night where the clock advanced an hour would correctly be noted as having an in-bed time of 10 PM, out-of-bed time of 6 AM, but the sleep duration would be 7 hours. Instances where data collection overlapped with a change in DST are labeled by the variable SAWA340.

3.4 ACTIWARE GENERATED VARIABLES

Variable definitions in the Sueño Database Dictionary containing the following statement indicate variables that were generated by Actiware and were not optimized;

“This variable is similar to SAWAXX; however, SAWAYY is derived from Actiware variable SAWAZZ before data optimization.”

Examples:

SAWA18 (Average Sleep Duration)
This is the average duration of time between sleep onset and sleep offset across all main rest intervals, in minutes. This variable is similar to SAWA152; however, SAWA18 is generated by Actiware software before data optimization.

SAWA45 (Average Sleep Time)
This is the average amount of time spent asleep across all main rest intervals with sleep, in hours. This variable is similar to the Sueño calculated variable SAWA59; however, SAWA46 is calculated based on data generated by Actiware software before data cleaning and imputation.

4. APPROACH TO EPOCHS WITH INVALID DATA

4.1 INVALID ACTIVITY DATA

All mean activity count variables excluded epochs with missing activity data from their calculation. Because days where extended amounts of missing data during a main rest interval were judged invalid and excluded from further analysis, every epoch within a valid main rest intervals has a valid high/low activity level. However, valid days may have included naps with extensive missing activity data and so missing high/low activity level data. These epochs were included in calculating nap durations which were calculated based simply on the time elapsed from the beginning to the end of the interval. However, epochs where activity level status could not be imputed were excluded from calculations of the amount of sleep (or wake) within an interval.

4.2 INVALID LIGHT DATA

Epochs with invalid light data were excluded in calculating any variables involving light exposure.

5. CATEGORIZING MAIN REST INTERVALS

5.1 DURATION

Days with no evidence that the participant had tried to sleep were marked with a 30-second main rest interval. These 30-second main rest intervals were included in the calculation of sleep time (SAWA54, set to 0 minutes), sleep duration (SAWA52, set to 0 minutes) and rest duration (SAWA50, set to 0 minutes) including weekday, weekend, workday, non-workday and reliable days. Main rest intervals of only 30-seconds were excluded in the calculation of all other duration as well as timing and sleep quality variables.

Days on which there was evidence the participant had tried to sleep but had been unsuccessful had a main rest interval marked for the entire period that it appeared they had been trying to sleep. Data from these intervals were included in calculating all main rest interval variables (duration and sleep timing), sleep duration variables (set to 0), sleep bouts (set to 0), sleep efficiency and sleep maintenance efficiency (set to 0) and sleep time (set to 0). Data from intervals with evidence the participant tried unsuccessfully to sleep was excluded in all other duration, sleep quality, and sleep timing variables.

5.2 WEEKDAY/WEEKEND

Main rest intervals were categorized as weekday if the out-of-bed time fell on a Monday-Friday.

Main rest intervals were categorized as weekend if the out-of-bed time fell on a Saturday or Sunday.

5.3 WORK/SCHOOL ATTENDANCE

A main rest interval is categorized as either a workday or a non-workday when the participant self reported in the daily sleep log that they did or did not attend work/school following the end of that main rest interval and before the start of the next main rest interval. Because work/school attendance was determined from the self reported daily sleep log, actigraphy data from a day for which the subsequent

diary entry was missing work/school attendance was excluded in computing workday/non-workday variables.

6. ASSIGNING NAPS TO MAIN REST INTERVALS

6.1 RELIABLE AND OVERALL

Because napping behavior was asked on the daily sleep log for the day prior to each main rest interval, naps were in general assigned to the subsequent main rest interval. Thus, in calculating nap variables "across all days" and "across all reliable days", naps were assigned to the main rest interval that took place after the nap ended. For example, if the main rest interval that took place after a nap was labeled as 'reliable', then all naps preceding that main rest interval until the previous main rest interval would also be labeled as reliable.

6.2 WEEKDAY/WEEKEND

Because napping behavior on a Friday was felt to better reflect weekday behaviors and those on a Sunday to reflect weekend behaviors, nap assignments were reversed in calculating weekday/weekend variables. That is to say, in calculating nap variables "across all weekdays" and "across all weekends", naps were assigned to the previous main rest interval. Therefore, naps were assigned to the main rest interval that took place before the nap started. For example, if the main rest interval that took place before a nap was initiated was labeled as a 'weekday', then all naps following that main rest interval, and before the next main rest interval, were categorized as 'weekday naps'.

6.3 WORKDAY/NON-WORKDAY

Similarly, in calculating nap variables "across all workdays" and "across all non-workdays", naps were assigned to the previous main rest interval. Therefore, naps were assigned to the main rest interval that took place before the nap started. For example, if the main rest interval that took place before a nap was initiated was labeled as a 'workday', then all naps following that main rest interval, and before the next main rest interval, were categorized as 'workday naps'.

7. CALCULATING STATISTICS FOR CLOCK TIMES

7.1 GENERAL PROCEDURES

For the purpose of calculating means of clock times, times were first expressed in date-time format. Dates were then replaced with each day's ordinal number, corresponding to its entry order in the QS database (see Reading Center MOP, section E). Clock times were expressed as the number of minutes away from midnight of the corresponding day. For example, an in bed time of 11:30 PM, is expressed as -30. If the next in bed time takes place at 10:00 AM on that same day, it is expressed as -840 (distance from the next midnight) and not as 600 (distance from closest midnight). Once all individual times have been converted, the mean is calculated and the time is then converted back to clock time by referencing to midnight. Standard deviations of clock times were similarly calculated.

8. PROCEDURES FOR DETERMINING SAWA338 AND SAWA339

8.1 DEFINING DAYS

In calculating variables SAWA338 (inter-day stability) and SAWA339 (intra-day variability), the goal was to identify a period of 7 consecutive days with minimal missing sleep/wake status data in which to perform the computations.

Days were defined as 24-hour periods of time starting at the pre-set start hour in Actiware. In most cases, this was set to noon with the exception of a few participants with highly unusual sleep patterns (see Reading Center MOP Section B).

8.2 IMPUTATION

Sleep/wake data was then further imputed beyond that described in Section 3.1 above for any missing patches lasting 1 hour or less by making the sleep/wake status of the entire missing patch equivalent to the status of the 15 minutes preceding the bout and 15 minutes following the bout assuming all 60 epochs were uniform in sleep/wake status (all sleep or all wake). No imputation was done if either 15-minute frame was not completely uniform (all wake or all sleep), if the preceding and subsequent 15 minute frames did not match, or if a single epoch in either frame had a missing sleep/wake status. In addition, no imputation was performed on missing patches of greater than 1 hour in duration.

8.3 OPTIMIZATION

Any day with more than 4 hours of missing data after imputation was excluded. In addition, days noted to have data failure due by the scorer due to a malfunctioning device were excluded.

Records with fewer than 7 consecutive days available for analysis were assigned a missing value for both SAWA 338 and SAWA 339. In addition, all 7 consecutive days were required to be before or after a DST change. For each record, with more than 7 consecutive days and no DST overlap meeting minimal criteria for data completeness, the 7-day interval with the least amount of missing data was selected for computation of SAWA338 and SAWA339.

8.4 IS AND IV CALCULATION

The inter-day stability (SAWA338) was calculated as the ratio between the variance of the average 24-hour sleep/wake pattern and the overall variance in sleep/wake status. This calculation uses 1-hour bins to compare wake/sleep ratios across all 24-hour days in the 7-day frame. This variable ranges from 0 to 1 with values closest to 1 indicating a stable sleep pattern over 24-hour days.

The intra-day variability (SAWA339) was calculated as the ratio of the mean squares of the difference between the proportion of sleep in all successive 1-hour bins and the overall variance across all epochs in the 7-day frame. This variable ranges from 0 to 1 with values closest to 1 indicating a more fragmented pattern within each day.

Sueño – Sleep Habits in HCHS

Appendices

Version 5.0
September 28, 2011

Sueño Manual of Procedures Appendices

<Letterhead>
SUEÑO – Sleep Ancillary to the Hispanic Community Health Study-Study of Latinos

<Date>
<Name>
<Address>

Dear <Name>,

Thank you for your participation in the Hispanic Community Health Study-Study of Latinos (HCHS-SOL). We are now inviting you to participate in a new research study from the HCHS-SOL called SUEÑO – Sleep Ancillary to HCHS-SOL. This study will try to better understand how Hispanic-Americans/Latinos sleep and how this might affect health. It will also help scientists better understand the final results from the Hispanic Community Health Study-Study of Latinos.

Participation in the SUEÑO study is fairly simple. You will be asked to come to the local Field Center at: [SUEÑO Field Center address]. There, you will have your height and weight measured and asked questions about your sleep and things that might affect your sleep. We will then give you a device like a watch to wear on your wrist that will measure when you sleep. You will be asked to wear this device at home for one week.

We will go over these procedures with you again before the study starts. You will receive $100.00 for completing the study.

You were selected from men and women who are participating in the HCHS-SOL who said they would be interested in hearing about future studies. Your name has been used only for the purpose of contacting you and will not be released to anyone. All the information you provide will be kept confidential in accordance with Federal laws. As usual only your Field Center, security-cleared staff at the University of North Carolina Coordinating Center and other staff who may conduct telephone-based interviews or data entry will have access to your personal information. Your personal identity will not be revealed in any publications or results. Your participation is voluntary and will not affect your participation in the HCHS-SOL.

Our clinic staff will telephone you within one week to discuss your interest in participating. We hope you will contribute your time to this important study.

Sincerely,
[Name of local PI]
[Field Center name]
SUEÑO – Sleep Ancillary to the Hispanic Community Health Study – Study of Latinos

<Letterhead>
SUEÑO – Sleep Ancillary to the Hispanic Community Health Study-Study of Latinos

<Date>
<Name>
<Address>

Estimada(o) <Name>,

Gracias por participar en el ESTUDIO SOBRE SALUD DE LA COMUNIDAD HISPANA/ESTUDIO DE LATINOS (conocido como **"**HCHS/SOL**",** por las siglas en inglés de **"**HISPANIC COMMUNITY HEALTH STUDY/STUDY OF LATINOS"). Lo invitamos a participar en un nuevo estudio de investigación llamado SUEÑO- Auxiliares del Sueño a HCHS-SOL. Este estudio tratará de entender mejor cómo los hispanoamericanos /latinos duermen y cómo esto puede afectar la salud. También ayudará a los científicos a comprender mejor los resultados finales del ESTUDIO SOBRE SALUD DE LA COMUNIDAD HISPANA/ESTUDIO DE LATINOS.

Participación en el estudio SUEÑO es bastante simple. Se le pedirá que venga al Centro local en: [SUEÑO Field Center address]. Ahí, se le tomara su estatura y peso y se la harán preguntas sobre su sueño y cosas que pueden afectar su sueño. Después le daremos un aparato parecido a un reloj para usar en su muñeca que medirá cuando duerme. Se le pedirá que use este aparato en su hogar durante una semana.

Repasaremos estos procedimientos con usted otra vez antes que el estudio comience. Recibirá $100.00 por su participación en este estudio.

Usted fue seleccionado entre hombres y mujeres que estaban participando en el estudio HCHS-SOL que expresaron interés en estudios en el futuro. Su nombre ha sido usado con el solo propósito de contactarse con usted y no le será dado a nadie. Toda la información que usted provea será mantenida confidencialmente en conformidad con las leyes Federales. Solamente el personal de su Centro de Investigación, el personal que ha sido verificado por seguridad en el Centro de Coordinación en la Universidad de Carolina del Norte, y el personal encargado de las entrevistas telefónicas o de ingresar datos en el sistema tendrán acceso a su información personal. No se revelará su identidad personal en ninguna publicación ni divulgación de los resultados. Su participación es voluntaria y no afectará su participación en el estudio de HCHS-SOL.

El personal de nuestra clínica lo/la llamará dentro de una semana para preguntarle si le interesa participar. Esperamos que contribuya con su tiempo a este importante estudio.

Sinceramente,
[Name of local PI]
[Field Center name]
SUEÑO – Sleep Ancillary to the Hispanic Community Health Study – Study of Latinos

Sueño – Sleep Habits in HCHS
Recruitment Call Script
9/17/2010

1) **Greeting -** Hello, this is [Caller's Full Name] from the Hispanic Community Health Study. Is Mr./Ms. [Subject's Last Name] available? *(if No, Continue to 1a; if Yes, continue to section 2).*
    a. Is there a better time or a better number to reach Mr./Ms. [Subject's Last Name]? *(Record time and number that subject should be called back; continue to 1b).*
    b. Thank you for your time today. I will try calling Mr./Ms. [Subject's Last Name] at that time/number. Good bye.

2) **Introduction** - Hello Mr./Ms. [Subjects' last Name]. This is [Caller's Full Name] from the Hispanic Community Health Study. I would like to tell you about a new study from the HCHS called Sueño. First, would you rather we speak in English or Spanish? (*Record preferred language on Screening Form. If English continue in English, if Spanish use Spanish script.*)

    Talking about the study should only take 15 minutes; is now a good time to talk? *(If No, continue to section 2a; if Yes, continue to section 2b).*
    a. I understand, is there another time I can call you that would be more convenient? *(Record time that subject should be called back)*. Thank you for your time today. I look forward to talking to you soon. Goodbye.
    b. Great. Did you receive the letter in the mail that we sent you about this new study? *(if No, continue to 2c; if Yes, continue to 2d).*
    c. I am sorry about that, however I can still tell you about the new study over the phone and send you the letter again. What I would like to do today is to 1- tell you about the Sueño study, 2- see if you are interested in being a part of the study and 3 –if you are interested, ask you a few questions to make sure you are eligible for the study (*continue to section 3*).
    d. Good. So today, I would like to 1- tell you a little more about this new study, Sueño, 2- see if you are interested in being a part of the study and 3 –if you are interested, ask you a few questions to make sure you are eligible for the study (*continue to section 3*).

3) **Description of Study** – The Sueño study is studying how Hispanic-Americans/Latinos sleep. In recent years, medical research has found that sleep may be important for health. The Sueño study will try to better understand how Hispanic-Americans/Latinos sleep and how this might affect health. This study will also help scientists better understand the final results from the Hispanic Community Health Study-Study of Latinos.

    Participation in the Sueño study is fairly simple. You will be asked to come to the local Field Center at: [Sueño Field Center address]. There, you will have your weight measured and asked questions about your sleep and things that might affect your sleep. This visit should only take about an hour to complete. We will then give you a device like a watch to wear on your wrist that will measure when you sleep. You will be asked to wear this device at home for one week.

    We will go over these procedures with you again before the study starts. You will receive $100.00 for completing the study.

4) **Subject Questions** – Do you have any questions so far? *(if No, continue to section 5; if Yes, try to answer questions).*

5) **Assess Interest in Participation** – Do you think you would be interested in participating in the Sueño study? *(if No, continue to section 5a; if Yes, continue to section 6).*

a. That's ok. Thank you for your time today. We appreciate you participation in HCHS. Have a great day. Goodbye.

6) **Assess Eligibility** – Great. We appreciate your interest in participating in the Sueño study. I will ask you a few questions now to make sure you are eligible for participating in the study.

a. Are you between the ages of 18 and 64? *(If No, go to section 7).*
b. Has a physician ever diagnosed you with narcolepsy? *(If Yes, go to section 7).*
c. Has a physician ever prescribed CPAP or BiPAP to treat you for sleep apnea? *(If Yes, go to section 7).*
d. For women only, are you currently pregnant? *(If Yes, go to section 7).*
e. *If answer to 6a is Yes and the answers to 6b-6d are No, then subject is eligible, continue to section 8.*

7) **Not Eligible** – Unfortunately, you are not currently eligible to participate in the Sueño study. *(If subject is pregnant (Yes on question 6d), continue to section 7a; if ineligible for another reason continue to section 7d*).

a. While you are pregnant, you are not eligible to participate. However, you would be eligible 3 month after you give birth. Would it be ok if we contacted you again 3 months after your due date? (*if No, continue to section 7c; if Yes continue to section 7b*).
b. Thank you. When is your due date? *(record due date).* Great. We will call you again 3 months after then. Thank you for your time today. I look forward to talking to you soon. Goodbye.
c. That's ok. Thank you for your time today. Goodbye.
d. Thank you for your time today. We appreciate you participation in HCHS. Have a great day. Goodbye.

8) **Eligible** – Great, you are eligible for the Sueño study. Would you like to schedule your Field Center Visit today? (*if No, continue to 8a; if Yes continue to 8b*)

a. That's ok. When is the best time to call you again to schedule this visit? (*record time; continue to section 9*).
b. Good. When would be a convenient time for the visit? (if you know times that are available at your field site you can list them for subject) (*continue to section 10*)

9) **End Call (field center visit not scheduled)** - Again thank you for your time today and for your participation in HCHS. I will call you back to schedule the field center visit. Have a great day. Goodbye.

10) **End Call (field center visit scheduled)** – Again thank you for your time today and for your participation in HCHS. We will send an appointment reminder in the mail and call you again before your field center visit to confirm your appointment. I look forward to talking to you soon. Have a great day. Goodbye.

1. **Greeting**: Hola, le habla [caller's full name] del Estudio de Salud de la Comunidad Hispana. ¿Está el/la Sr/a [Subject's Last name] disponible? (*if No, Continue to 1a; if Yes, continue to section 2).*
   a. ¿Cuál sería un mejor momento para ubicar a el/la Sr/a [Subject's Last name]? (*Record time and number that subject should be called back; continue to 1b).*
   b. Gracias por su tiempo. Llamaré a el/la Sr/a [Subject's Last name] a ese número/hora. Adiós.
2. **Introduction**: Hola Sr/a [Subject's Last name]. Le habla [caller's full name] del Estudio de Salud de la Comunidad Hispana. Me gustaría hablarle sobre un nuevo estudio de HCHS llamado Sueño. Primero, ¿prefiere que le hablemos en inglés o español? (*Record preferred language on Screening Form. If English, continue in English, if Spanish use Spanish script).*

   Hablar sobre el estudio toma sólo uno 15 minutos; ¿es éste un buen momento para hablar? (*If No, continue to section 2a; if Yes, continue to section 2b).*
   a. Entiendo, ¿en qué momento puedo yo llamarlo/a que le sea más conveniente? (*Record time that subject should be called back).* Gracias por su tiempo en el día de hoy. Espero hablar con Ud. pronto. Adiós.
   b. Bien. ¿Recibió la carta por correo que le mandamos sobre este nuevo estudio? *(If No, continue to 2c; if Yes, continue to 2d*).
   c. Siento que no la haya recibido, sin embargo puedo aún hablarle sobre el nuevo estudio en el teléfono and mandarle la carta nuevamente. Lo que me gustaría hacer hoy es 1-hablar del estudio Sueño, 2-ver si está interesado/a en formar parte del estudio y 3-si está interesado/a, hacerle unas pocas preguntas para asegurarme que reúna los requisitos necesarios para el estudio (*continue to section 3).*
   d. Perfecto. Lo que me gustaría hacer hoy es 1-hablar del estudio Sueño, 2-ver si está interesado/a en formar parte del estudio y 3-si está interesado/a, hacerle unas pocas preguntas para asegurarme que reúna los requisitos necesarios para el estudio (*continue to section 3).*

3. **Description of Study—**El estudio Sueño está estudiando como los hispanoamericanos/latinos duermen. En los últimos años la investigación médica ha encontrado que el sueño puede ser importante para la salud. El estudio Sueño tratará de entender mejor cómo los hispanoamericanos/latinos duermen y cómo esto puede afectar la salud. Este estudio también ayudará a los científicos a entender mejor los resultados finales del Estudio de Salud de la Comunidad Hispana—Estudio de Latinos.

   La participación en el estudio Sueño es bastante simple. Se le pedirá que venga al centro local en: [Sueño Field Center address]. Allí, se le medirá su peso y se le harán preguntas sobre su sueño y cosas que afecten su sueño. Completar esta visita sólo lleva aproximadamente una hora de su tiempo. Le daremos un aparato como un reloj que se lleva en su muñeca que medirá cuando Ud duerme. Se le pedirá que use este aparato en casa durante una semana.

   Repasaremos estas instrucciones con Ud. antes de empezar el estudio. Recibirá $100 por completar el estudio.

4. **Subject Questions:** ¿Tiene alguna pregunta hasta ahora? (*If No, continue to section 5; If Yes, try to answer questions).*

5. **Assess Interest in Participation**: Cree que está interesado/a en participar en el estudio Sueño? (*If No, continue to section 5ª; if Yes, continue to section 6).*

    a. Está bien. Gracias por su tiempo en el día de hoy. Apreciamos su participación en HCHS. Tenga un buen día. Adiós.

6. **Assess Eligibility:** Bien. Apreciamos su interés en participar en el estudio Sueño. Le voy a hacer algunas preguntas ahora para estar seguro/a que reúne los requisitos necesarios para participar en el estudio.
    a. ¿Tiene entre 18 y 64 años? (*If No, go to section 7).*
    b. ¿Ha sido en algún momento diagnosticado/a con narcolepsia por un médico? *(If Yes, go to section 7).*
    c. ¿Ha sido recetado/a CPAP o BIPAP por un médico para tratarlo/a por apnea del sueño?
    d. *For women only*, ¿está actualmente embarazada? *(If Yes, go to section 7)*
    e. *If answer to 6a is Yes and the answers to 6b-6d are No, then subject is eligible, continue to section 8.*

7. **Not Eligible**- Desafortunadamente, usted actualmente no cumple con los requisitos para participar en el estudio Sueño. (If subject is pregnant (Yes on question 6d), continue to section 7a; if ineligible for another reason continue to section 7d).
    a**.** Mientras esté embarazada usted no cumple con los requisitos necesarios para participar. Sin embargo, usted los cumpliría 3 meses después de dar a luz. ¿Estaría bien si la contactamos nuevamente 3 meses luego de haber dado a luz? (*if No, continue to section 7c; if Yes continue to section 7b)*
    b. Gracias. ¿En qué fecha da a luz? (record due date). Muy Bien. La llamaremos de nuevo 3 meses más tarde. Gracias por su tiempo en el día de hoy. Espero hablar con usted pronto. Adiós.
    c. Eso está bien. Gracias por su tiempo en el día de hoy. Adiós.
    d. Gracias por su tiempo en el día de hoy. Apreciamos su participación en HCHS. Que tenga un buen día. Adiós.

8. **Eligible**- Muy bien, usted es elegible para el estudio Sueño. ¿Le gustaría coordinar una cita para su Centro hoy? (*if No, continue to 8a; if Yes continue to 8b*)
    a. Está bien. ¿Cuándo sería el mejor momento para llamarlo/a nuevamente y coordinar esta cita? (record time; continue to section 9).
    b. Bien. ¿Cuándo sería un tiempo conveniente para su visita? (if you know times that are available at your field site you can list them for subject) (*continue to section 10*)

9. **End Call (field center visit not scheduled)-** Nuevamente gracias por su tiempo en el día de hoy y por su participación en HCHS. Lo/a llamaré de nuevo para coordinar la visita al centro. Que tenga un buen día. Adiós.

10. **End Call (field center visit scheduled)-** Nuevamente gracias por su tiempo en el día de hoy y por su participación en HCHS. Mandaremos un recordatorio de la cita en el correo y lo/a llamaremos de nuevo antes de su visita al centro para conformar su cita. Que tenga un buen día. Adiós.

Screening Form
HCHS/SOL Sleep Ancillary Study

ID NUMBER:									FORM CODE: VERSION: A 09/08/10	Contact Occasion	0	1	SEQ #	0	1

ADMINISTRATIVE INFORMATION

0a. Completion Date (mm/dd/yyyy): ☐☐/☐☐/☐☐☐☐ 0b. Staff ID: ☐☐☐

Instructions: This individual eligibility screening form must be completed before the participant can be scheduled for their ancillary study interview. Enter one form per person screened for the ancillary study.

NOTE TO STAFF: Use appropriate Sueño recruitment script when completing this form.

A. Eligibility Screening Status for Individuals in Sueño Ancillary Study

1. Does the participant prefer Spanish or English?
   - Neither language 0 ☐ → **INELIGIBLE**
   - Spanish 1 ☐
   - English 2 ☐

2. Is the participant between the age of 18 and 64?
   - No 0 ☐ → **INELIGIBLE**
   - Yes 1 ☐

3. Has participant been diagnosed by physician with narcolepsy?
   - No 0 ☐
   - Yes 1 ☐ → **INELIGIBLE**

4. Is participant using CPAP or BiPAP for treatment of sleep apnea?
   - No 0 ☐
   - Yes 1 ☐ → **INELIGIBLE**

5. Is participant currently pregnant?
   - No 0 ☐
   - Yes 1 ☐ → **GO TO QUESTION 5a**

5a. If yes, would participant be willing to participate after delivery?
   - No 0 ☐ → **INELIGIBLE**
   - Yes 1 ☐ → **DEFERRED, note follow up call date**

5b. If yes, when is estimated due date? (mm/dd/yyyy): ☐☐/☐☐/☐☐☐☐

6. Individual Participation Status:
   - Refuses to participate 1 ☐
   - Unable to contact, status unknown 2 ☐
   - Ineligible 3 ☐ → **INELIGIBLE, closing script**
   - Agrees to participate 4 ☐ → **ELIGIBLE, schedule visit**
   - Deferred 5 ☐

6a. Appointment Date (mm/dd/yyyy): ☐☐/☐☐/☐☐☐☐

6b. Appointment Time: ☐☐:☐☐ _ _ (am/pm)

B. Demographic Information Pre-filled by HCHS/SOL Data Management System

ID NUMBER:								FORM CODE: VERSION: A 09/08/10	Contact Occasion			SEQ #		

7. Gender: Male 1☐ Female 2☐

8. Age: ☐☐ years

9. Hispanic/Latino background from PIE/PIS

Dominican or Dominican Descent	0 ☐
Central American or Central American descent	1 ☐
Cuban or Cuban descent	2 ☐
Mexican or Mexican descent	3 ☐
Puerto - Rican or Puerto Rican descent	4 ☐
South American or South American descent	5 ☐
More than one heritage	6 ☐
Other	7 ☐

If other, please specify: _____

10. Self identification of racial group from PIE/PIS

American Indian or Alaskan Native	1 ☐
Asian	2 ☐
Native Hawaiian or Other Pacific Islander	3 ☐
Black or African – American	4 ☐
White	5 ☐
More than one race	6 ☐
Unknown or Not reported	7 ☐

Sueño – Sleep Habits in HCHS/SOL

Screening Form (ANE) Question by Question Instructions

General Instructions
The screening form (ANE) is completed at the time of screening call of identified HCHS/SOL participants that may be eligible for Sueño. The form will document individual eligibility and enrollment into the ancillary study. It is important to complete a form for each participant who is screened for the ancillary study in order to estimate refusal rates. Unbiased estimates of refusal rates will enable the investigators to manage recruitment more efficiently and to be able to characterize enrollment.

Once part A of each form is complete, it should be keyed immediately into the Sueño study data management system within 48-72 hours after collection. Note that weekly recruitment and scheduling reports that are being shared with the study investigators and project office based on data from these forms. Part B of the form is automatically filled by the HCHS/SOL DMS using information from the main study baseline files.

Question by Question Instructions

PART A

Q1 This question asks the respondent his/her language of preference. If the respondent does not feel comfortable communicating in either Spanish or English, the person is ineligible. Read the closing script and end call with respondent. Continue to Q6 to complete individual participation status.
If a person responds, "It does not matter", probe further to determine his/her language of preference. Mark either Spanish or English. Continue to Q2.

Q2 The question asks if the respondent is within the age limits of the study. If they have not yet had their 18th birthday or have had their 65th birthday, then they are ineligible. Read the closing script, end call with respondent and continue to Q6 to complete individual participation status. If respondent is between 18 and 64 years of age (inclusive), continue to Q3.

Q3 The question asks about diagnosis of narcolepsy. If they were diagnosed by a physician with narcolepsy they are ineligible. Read the closing script, end call with respondent and continue to Q6 to complete individual participation status. If respondent has never been diagnosed with narcolepsy by a physician even if they believe they may have the disease, continue to Q4.

Q4 The question asks about usage of CPAP or BiPAP for the treatment of sleep apnea. If they have used CPAP or BiPAP in their home for sleep apnea they are ineligible. Read the closing script, end call with respondent and continue to Q6 to complete individual participation status. If respondent has never used CPAP or BiPAP or only used it while in the hospital, continue to Q5.

Q5 This question only needs to be asked of female respondents; it asks if the respondent is currently pregnant. For male respondents automatically mark "no" and continue to Q6. If the respondent is currently pregnant, it does not necessarily exclude them. The respondent can be deferred until 3 months after their delivery date. If the respondent is pregnant, continue to Q5a. If the respondent is not pregnant, continue to Q6

Q5a The question assesses whether the respondent would be willing to participate after delivery. If they are not interested in deferring until after delivery, then they are ineligible; read the closing script, end the call and continue to Q6. Please indicate on Q6 that the respondent refuses to participate (not ineligible). If the respondent is interested in deferring, continue to Q5b.

Q5b The question asks the respondent their due date. Record date. This information will be used to determine when the respondent should be re-contacted and screened again for eligibility. Continue to Q6.

Q6 This question is for administrative purposes only. It is a status code for the individual level eligibility.

Refuses to participate – respondent is not interested in ancillary study participation/not interested in deferring if pregnant. Participants who miss multiple appointments should have their status changed to this status.

Unable to contact, eligibility not confirmed – NO contact has been made after the required number of attempts to contact this individual, and his/her individual eligibility status is unknown. The required number of attempts is determined based on local Field Center procedures.

Ineligible – respondent may be ineligible due to one of the following criteria for participation:

(1) Respondent is not between 18 and 64 years of age,
(2) Respondent has diagnosis of narcolepsy
(3) Respondent has used CPAP or BiPAP for the treatment of sleep apnea

Agrees to participate – Respondent agrees to participate. Go to 6a to schedule interview. Remember to change the appointment date/time if the subject reschedules.

Q6a Set appointment date and record with two digit month, two digit day, and four digit year.

Q6b Set appointment time and record with two digit hour and two digit minute. Record "AM/PM" in the spaces provided.

PART B

Q7-Q10 The demographic characteristics for the participants are automatically filled by the HCHS/SOL data management system. Leave blank; there is no need to enter this information for the ancillary study.

Sueño Screening Contact Worksheet

HCHS/SOL PARTICIPANT ID Number: ☐☐☐☐☐☐☐☐

Date of initial screening contact ☐☐/☐☐/☐☐☐☐
MM / DD / YYYY

Day of Week Date (MM/DD/YY)	Time	Notes	Result Code	Interviewer Code
S M T W T F S / /	A P			
S M T W T F S / /	A P			
S M T W T F S / /	A P			
S M T W T F S / /	A P			
S M T W T F S / /	A P			
S M T W T F S / /	A P			
S M T W T F S / /	A P			
S M T W T F S / /	A P			
S M T W T F S / /	A P			
S M T W T F S / /	A P			
S M T W T F S / /	A P			
S M T W T F S / /	A P			
S M T W T F S / /	A P			
S M T W T F S / /	A P			
S M T W T F S / /	A P			

***Enter the *final* result of screening attempts on the Ancillary Study Screening form (ANE)**

(**1**) Refuses to participate in ancillary study
(**2**) Unable to contact, status unknown
(**3**) Ineligible for ancillary study
(**4**) Agrees to participate in ancillary study
(**5**) Deferred

HCHS/SOL Medication Use Questionnaire

ID NUMBER:									FORM CODE: MDE VERSION: A 8/30/07	Contact Occasion		SEQ #	

Acrostic: _____

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) 0b. Staff ID: ☐☐☐

Instructions: This form should be completed during the participant's visit. Affix the participant ID label above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. If a number is entered incorrectly, mark through the incorrect entry with an "=". Code the correct entry clearly above the incorrect entry.

A. Reception

As you know, HCHS/SOL is recording all prescription and over-the-counter medications used by participants in the past four weeks, including cold and allergy medications, vitamins, herbal remedies, and other supplements. These medications include solid and non-solid formulations that you may swallow, inhale, apply to the skin or hair, inject, implant, or place in the ears, eyes, nose, mouth, or any other part of the body.

1. Did you bring all the medications that you used in the past four weeks, or their containers?

Yes, all of them 1 ☐ → **GO TO SECTION B, QUESTION 5**
No, some of them 2 ☐ → **GO TO SECTION A, QUESTION 3**
No, none of them 3 ☐

2. Is this because you forgot, because you have not taken any medications at all in the last four weeks, or because you could not bring your medications?

Took no medication 1 ☐ → **GO TO SECTION C, QUESTION 34**
Forgot or was unable to bring medication 2 ☐

That's alright. Since the information on medications is so important, we would still like to ask you about it during the interview.

3. May we follow up on this after the visit so that we can get the information from the other medication labels? *(Explain follow-up options)*

No or not applicable.. 0 ☐ → **Scan/transcribe what you can in Section B and attempt to convert refusals; indicate this on tracking form**
Yes..... 1 ☐

4. Describe method of follow-up to be used:_____

ID NUMBER:									VERSION: A 8/30/07	Occasion			SEQ #		

B. Medication Record

Copy the MEDICATION UPC / NDC from each medication label. For each medication, begin with the left-most space in fields a-c and the rightmost space in field d. Using upper case letters, carefully copy the MEDICATION NAME. Using periods to indicate decimal points, copy the formulation STRENGTH (weight for solids and concentration for non-solids). Using upper case letters and standard abbreviations, copy the UNITS used to measure strength. For combination medications, use a forward slash (/) to separate active ingredients, corresponding strengths, and units.

#	(a) Medication UPC / NDC		Medication name (b)
5.			
	(c) Strength	(d) Units	
6.			
	(c) Strength	(d) Units	
7.			
	(c) Strength	(d) Units	
8.			
	(c) Strength	(d) Units	
9.			
	(c) Strength	(d) Units	
10.			
	(c) Strength	(d) Units	
11.			
	(c) Strength	(d) Units	
12.			
	(c) Strength	(d) Units	
13.			
	(c) Strength	(d) Units	
14.			
	(c) Strength	(d) Units	

ID NUMBER:		VERSION: A 8/30/07	Occasion		SEQ #	

#	(a) Medication UPC		Medication name (b)
15.			
	(c) Strength	(d) Units	
16.			
	(c) Strength	(d) Units	
17.			
	(c) Strength	(d) Units	
18.			
	(c) Strength	(d) Units	
19.			
	(c) Strength	(d) Units	
20.			
	(c) Strength	(d) Units	
21.			
	(c) Strength	(d) Units	
22.			
	(c) Strength	(d) Units	
23.			
	(c) Strength	(d) Units	
24.			
	(c) Strength	(d) Units	
25.			
	(c) Strength	(d) Units	

ID NUMBER:									VERSION: A 8/30/07	Occasion			SEQ #		

#	(a) Medication UPC		Medication name (b)
26.			
	(c) Strength	(d) Units	
27.			
	(c) Strength	(d) Units	
28.			
	(c) Strength	(d) Units	
29.			
	(c) Strength	(d) Units	

30. Total number of medications in bag..... ☐☐

31. Number of medications in bag unable to successfully scan or transcribe ☐☐

32. HCHS/SOL ID staff number of person scanning / transcribing medications

a. Scanner / transcriber (items 5-29): ..... ☐☐☐

b. Date of scanning / transcription: ..... ☐☐/☐☐/☐☐☐☐
Month Day Year

ID NUMBER: | VERSION: A 8/30/07 | Occasion | SEQ #

C. Medication Use Interview

Now I would like to ask about a few specific medications.

33. Were any of the medications you took during the last four weeks for: *(If "Yes", verify that the medication NAME is on the medication record.)*

	No	Yes	Unknown
a. Asthma	0 ☐	1 ☐	9 ☐
b. Chronic bronchitis or emphysema	0 ☐	1 ☐	9 ☐
c. High blood sugar or diabetes	0 ☐	1 ☐	9 ☐
d. High blood pressure or hypertension	0 ☐	1 ☐	9 ☐
e. High blood cholesterol	0 ☐	1 ☐	9 ☐
f. Chest pain or angina	0 ☐	1 ☐	9 ☐
g. Abnormal heart rhythm	0 ☐	1 ☐	9 ☐
h. Heart failure	0 ☐	1 ☐	9 ☐
i. Blood thinning	0 ☐	1 ☐	9 ☐
j. Stroke	0 ☐	1 ☐	9 ☐
k. Mini-stroke or TIA	0 ☐	1 ☐	9 ☐
l. Leg pain while walking or claudication	0 ☐	1 ☐	9 ☐

34. During the last four weeks, did you take any aspirin or aspirin-containing products including Alka-Seltzer, cold and allergy medication or headache powder? This **excludes** acetaminophen (for example, Tylenol), ibuprofen (for example, Advil, Motrin or Nuprin), and naproxen (for example, Aleve).

Show participant List #1: Commonly Used Aspirin or Aspirin-Containing Products

No 0 ☐ → **GO TO QUESTION 37**
Yes 1 ☐
Unknown 9 ☐ → **GO TO QUESTION 37**

35. How many days during the last four weeks did you take aspirin or aspirin-containing medication?

☐☐ Number of days

If number of days equals "00" → **GO TO QUESTION 37**

36. For what purpose are you taking aspirin? (*Interviewer: Do NOT read choices.)*

Participant mentioned avoiding heart attack or stroke 1 ☐
Participant did not mention avoiding heart attack or stroke 2 ☐

ID NUMBER:									FORM CODE: MDE VERSION: A 8/30/07	Contact Occasion			SEQ #		

37. During the past four weeks, did you take any [other] medication for arthritis, fever, or muscle aches and pains, or cramps? *(Read bracketed "other" unless no medications were reported.)*

No 0 ☐
Yes 1 ☐
Unknown 9 ☐

38. **Excluding** aspirin, acetaminophen (for example, Tylenol), and corticosteroids (for example prednisone), are you NOW taking other anti-inflammatory or arthritis medications on a regular basis? Common examples are shown on this list.

Show participant List #2: Commonly Used Non-Steroidal Anti-Inflammatory Drugs, NSAIDS

No 0 ☐ → **END QUESTIONNAIRE**
Yes 1 ☐
Unknown 9 ☐ → **END QUESTIONNAIRE**

39. Unless already recorded in Items B5-B29, record the following information for the medication identified by Item 38.

Already recorded 1 ☐

(a) Medication UPC		Medication name (b)
☐☐☐☐☐☐☐☐☐☐☐☐		
(c) Strength	(d) Units	

40. How many pills per week are you taking, on average?

☐☐ Number of pills per week

41. Staff ID number of person who interviewed the participant: ..... ☐☐☐

Medication Use Questionnaire_Spanish
HCHS/SOL Sleep Ancillary Study

ID NUMBER:									FORM CODE: MDS VERSION: A 08/18/10	Contact Occasion		SEQ #	

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) 0b. Staff ID: ☐☐☐

Instructions: This form should be completed during the participant's visit. Affix the participant ID label above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. If a number is entered incorrectly, mark through the incorrect entry with an "=". Code the correct entry clearly above the incorrect entry.

A. Reception

Como usted sabe, HCHS/SOL (por sus siglas en inglés) está llevando un registro de todos los medicamentos que los participantes han usado en las últimas cuatro semanas (ya sea de venta libre o aquellos que se obtienen con receta médica), incluyendo medicamentos para la gripe o alergias, vitaminas, remedios a base de hierbas y otros suplementos. Estos medicamentos incluyen fórmulas sólidas y no sólidas que usted haya ingerido, inhalado, que se haya aplicado en la piel o en el cabello, que se haya inyectado, implantado o colocado en los oídos, ojos, nariz, boca o cualquier otra parte del cuerpo.

1. ¿Trajo usted todos los medicamentos que ha usado en las últimas cuatro semanas o trajo sus envases?

Sí, todos 1 ☐ → **GO TO SECTION B, QUESTION 5**
No, algunos de ellos 2 ☐ → **GO TO SECTION A, QUESTION 3**
No, ninguno de ellos 3 ☐

2. ¿Se debe esto a que se le olvidó o porque no ha estado tomando ningún medicamento en las últimas cuatro semanas, o porque no pudo traer sus medicamentos?

No tomó ningún medicamento 1 ☐ → **GO TO SECTION C, QUESTION 34**
Se le olvidó o no pudo traer los medicamentos 2 ☐

Está bien. En vista de que la información sobre los medicamentos es muy importante, todavía nos gustaría preguntarle sobre ellos durante la entrevista.

3. ¿Podemos hacer un seguimiento de esto después de la visita, para que así podamos obtener la información sobre las etiquetas de los otros medicamentos? *(Explain follow-up options)*

No or not applicable.. 0 ☐ → **Scan/transcribe what you can in Section B and attempt to convert refusals; indicate this on tracking form**
Yes..... 1 ☐

4. Describe method of follow-up to be used:_____

ID NUMBER:									VERSION: A 08/18/10 Occasion			SEQ #		

B. Medication Record

Copy the MEDICATION UPC / NDC from each medication label. For each medication, begin with the left-most space in fields a-c and the rightmost space in field d. Using upper case letters, carefully copy the MEDICATION NAME. Using periods to indicate decimal points, copy the formulation STRENGTH (weight for solids and concentration for non-solids). Using upper case letters and standard abbreviations, copy the UNITS used to measure strength. For combination medications, use a forward slash (/) to separate active ingredients, corresponding strengths, and units.

#	(a) Medication UPC / NDC		Medication name (b)
5.			
	(c) Strength	(d) Units	
6.			
	(c) Strength	(d) Units	
7.			
	(c) Strength	(d) Units	
8.			
	(c) Strength	(d) Units	
9.			
	(c) Strength	(d) Units	
10.			
	(c) Strength	(d) Units	
11.			
	(c) Strength	(d) Units	
12.			
	(c) Strength	(d) Units	
13.			
	(c) Strength	(d) Units	
14.			
	(c) Strength	(d) Units	

ID NUMBER:		VERSION: A 08/18/10	Occasion		SEQ #	

#	(a) Medication UPC		Medication name (b)
15.			
	(c) Strength	(d) Units	
16.			
	(c) Strength	(d) Units	
17.			
	(c) Strength	(d) Units	
18.			
	(c) Strength	(d) Units	
19.			
	(c) Strength	(d) Units	
20.			
	(c) Strength	(d) Units	
21.			
	(c) Strength	(d) Units	
22.			
	(c) Strength	(d) Units	
23.			
	(c) Strength	(d) Units	
24.			
	(c) Strength	(d) Units	
25.			
	(c) Strength	(d) Units	

ID NUMBER:									VERSION: A 08/18/10	Occasion			SEQ #		

#	(a) Medication UPC		Medication name (b)
26.			
	(c) Strength	(d) Units	
27.			
	(c) Strength	(d) Units	
28.			
	(c) Strength	(d) Units	
29.			
	(c) Strength	(d) Units	

30. Total number of medications in bag..... ☐☐

31. Number of medications in bag unable to successfully scan or transcribe ☐☐

32. HCHS/SOL ID staff number of person scanning / transcribing medications and interviewing the participant:

a. Scanner / transcriber (items 5-29): ..... ☐☐☐

b. Date of scanning / transcription: ..... ☐☐/☐☐/☐☐☐☐
Month Day Year

ID NUMBER:									VERSION: A 08/18/10 Occasion			SEQ #		

C. Medication Use Interview
Ahora me gustaría preguntarle sobre algunos medicamentos específicos.

33. De los medicamentos que usted ha tomado durante las últimas cuatro semanas, ¿fueron algunos para: *(If "Yes", verify that the medication NAME is on the medication record.)*

	No	Sí	Desonocido
a. Asma	0 ☐	1 ☐	9 ☐
b. Bronquitis crónica o enfisema	0 ☐	1 ☐	9 ☐
c. Azúcar alta en la sangre o diabetes	0 ☐	1 ☐	9 ☐
d. Alta presión sanguínea o hipertensión	0 ☐	1 ☐	9 ☐
e. Alto colesterol en la sangre	0 ☐	1 ☐	9 ☐
f. Dolor en el pecho o angina	0 ☐	1 ☐	9 ☐
g. Ritmo cardíaco anormal	0 ☐	1 ☐	9 ☐
h. Falla cardíaca	0 ☐	1 ☐	9 ☐
i. Para hacer su sangre más líquida	0 ☐	1 ☐	9 ☐
j. Embolia cerebral o derrame cerebral	0 ☐	1 ☐	9 ☐
k. Mini-embolia o TIA (por sus siglas en inglés)	0 ☐	1 ☐	9 ☐
l. Dolor en la pierna al caminar o claudicación	0 ☐	1 ☐	9 ☐

34. Durante las últimas cuatro semanas, ¿ha tomado usted algún tipo de aspirina o productos que contengan aspirina, incluyendo Alka-Seltzer, medicamento para la gripe o alergia, o medicamento en polvo para el dolor de cabeza? Esto **no** incluye el acetaminofeno (por ejemplo, Tylenol), ibuprofeno (por ejemplo, Advil, Motrin o Nuprin) y naproxeno (por ejemplo, Aleve).

Show participant List #1: Commonly Used Aspirin or Aspirin-Containing Products

No 0 ☐ → **GO TO QUESTION 37**
Sí 1 ☐
Desconocido 9 ☐ → **GO TO QUESTION 37**

35. Durante las últimas cuatro semanas, ¿cuántos días tomó usted aspirina o un medicamento que contenga aspirina?

☐☐ Número de días

If number of days equals "00" → **GO TO QUESTION 37**

ID NUMBER:									FORM CODE: MDS VERSION: A 08/18/10	Contact Occasion			SEQ #		

36. ¿Con qué propósito está tomando usted aspirina? (*Interviewer: Do NOT read choices to participant.)*
    Participant mentioned "*para evitar ataque al corazón o embolia"* 1 ☐
    Participant did not mention "*para evitar ataque al corazón o embolia"* 2 ☐

37. Durante las últimas cuatro semanas, ¿ha tomado usted algunos [otros] medicamentos que fueron para la artritis, la fiebre, los dolores musculares o los calambres? *(Read bracketed "other" unless no medications were reported.)*

    No 0 ☐
    Sí 1 ☐
    Desconocido 9 ☐

38. **Sin** incluir la aspirina, el acetaminofeno (por ejemplo, Tylenol) y corticosteroides (por ejemplo, la prednisona), ¿está usted tomando AHORA algún otro antiinflamatorio o medicamento para la artritis en forma regular? Ejemplos comunes se muestran en esta lista.

Show participant List #2: Commonly Used Non-Steroidal Anti-Inflammatory Drugs, NSAIDS

    No 0 ☐ → **END QUESTIONNAIRE**
    Sí 1 ☐
    Desconocido 9 ☐ → **END QUESTIONNAIRE**

39. Unless already recorded in Items B5-B29, record the following information for the medication identified by Item 38.

    Already recorded 1 ☐

(a) Medication UPC		(b) Medication name
☐☐☐☐☐☐☐☐☐☐☐☐		
(c) Strength	(d) Units	

40. ¿Cuántas pastillas por semana toma usted como promedio?

    ☐☐ Número de pastillas a la semana

41. Staff ID number of person who interviewed the participant: ..... ☐☐☐

Sueño – Sleep Habits in HCHS/SOL

Medication Usage (MDE/MDS) Question by Question Instructions

General Instructions

The purpose of the Medication Survey is to assess medication usage in the four weeks preceding the examination date. Information on both prescription and over-the-counter medications is ascertained via scanning of bar code symbols, transcription of labels, and interview. To obtain this information, the participant is asked prior to the clinic visit to bring to the field center all medications, over-the counter preparations, vitamins, minerals, and dietary supplements taken in the four-week period preceding the visit, or their containers. Notification of this request is mailed to the participant with the written instructions for the exam visit, and is re-stated during the appointment reminder call. Interviewers require certification in interviewing techniques and familiarity with the data entry procedures for electronic and paper versions of the form. Paper data entry and subsequent keying will only be used in the event of equipment malfunction or DMS inaccessibility. Scanners / transcribers of medication information also require certification.

Question by Question Instructions

Administrative Information

Item 0a: Enter the date the participant was seen in the clinic. Use leading zeroes where necessary to fill all boxes. For example, September 3, 2007 would be entered as:

0	9	/	0	3	/	2	0	0	7

Item 0b: The staff person completing this form must enter their three-digit Staff ID number in the boxes provided.

A. Reception

Item 1: Read the question as written.

1. Did you bring all the medications that you used in the past four weeks, or their containers?

Yes, all .....1 → **Go to Section B Item 5**
No, Some of them .....2 → **Go to Section A, Item 3**
No, None of them 3

If the response is "Yes, all", go to Section B (MEDICATION RECORD) and begin the scanning / transcription. As the participant delivers the medications, indicate where (and by whom) they will be returned before he / she leaves. Mention that medication names will be scanned / copied from the labels, and that if required, medications will be taken out of their container only in the presence of, and with approval of the participant. Finally, indicate that a trained interviewer will later ask a few questions about some specific medications. Do not transcribe medications until the participant has signed the informed consent.

If the response is "Some of them", go to Item 3 to make arrangements for those medications which were not brought and scan / transcribe those medications which were brought in Section B (MEDICATION RECORD).

If the response is "No", proceed to the next item.

Item 2: Read the question as written.

2. Is this because you forgot, because you have not taken any medications at all in the last four weeks, or because you could not bring your medications?

Took no medications.....0 → **Go to Section C, Item 34**
Forgot or was unable to bring medications.....1

If the response is "Took no medications" in the past four weeks, Section A ends here. Leave Section B (MEDICATION RECORD) blank and skip to INTERVIEW, Section C (field or screen forward). Item 33 is left blank, and the interviewer continues administering items 34-40.

If the response is "Forgot or was unable to bring medications", reassure the respondent and proceed to the next item.

Items 3-4: Read item 3 as written. Ideally, follow-up involves the participant returning to the field center with the medications for Scanning / Transcription. Reasonable alternatives to the ideal include recording the medications at the participant's home (especially those sites that will be retrieving the actigraphs from the participant's homes) or telephone interview.

3. May we follow up on this after the visit so that we can get the information from the other medication labels? (Explain follow-up options)

No or not applicable.....0 →
Yes 1

Scan / transcribe what you can in Section B. Attempt to convert refusals and indicate this on tracking form

If the participant agrees to follow-up, make arrangements for obtaining the information Describe the method of follow-up in item 4. If the participant brought some medications, complete as much of Section B (MEDICATION RECORD) as possible before going on to Item 33. If participant follow-up occurs and additional or a complete list of medications are given, make sure to update this form starting with Question 1 in Section A.

In case of deliberate omission to bring medications to the field center, attempt participant conversion. Leave Section B (MEDICATION RECORD) blank if no medications were brought in. Even if the participant declines to bring in (or provide medication names by telephone), attempt to complete as much of Section C (INTERVIEW) as possible. If the participant has not brought his / her medications, but remembers the medication name, strength and units of all medications taken during the previous four weeks with confidence, the interviewer should record this information, but arrange a follow-up to confirm its accuracy.

B. MEDICATION RECORD

Introduction: Section B (MEDICATION RECORD) is designed to document information about each medication used by participants. Bar Code Scanning / Transcription includes recording the Universal Product Code (UPC) / National Drug Code (NDC) in section (a), the name in section (b), the strength in section (c), and the units in section (d) for each medication used within the four weeks prior to the interview.

Medication UPC / NDC, Medication Name, Strength, and Units (Items 5-29a-d)

Overview: Separate the medications into those with and without a UPC-labeled container. Attempt to scan the UPC-labeled containers. Set aside containers that are scanned *successfully* (automatically linked to information in sections [b-d] that matches information on their labels). For medications in UPC-labeled containers that cannot be scanned *successfully* (as defined above), transcribe the UPCs. When UPCs cannot be transcribed *successfully*, transcribe NDCs, if available, or medication names. When NDCs and medication names cannot be transcribed *successfully*, manually transcribe as much information as possible in sections (a-d).

Scanning: A UPC bar code symbol is a pattern of black bars and white spaces, below (or above) which are twelve numbers. In example [1], the first six numbers—614141—comprise the globally unique company prefix assigned by the Uniform Code Council. The next five—54321—comprise the item reference. The last—2—is a computer-generated check digit used to verify accuracy. The symbol encodes all twelve numbers (collectively referred to as the Global Trade Item Number [GTIN]). In this context, we informally refer to the GTIN as a Universal Product Code (UPC). A ten- or eleven-digit National Drug Code (NDC), which by federal law is assigned to all pharmaceuticals sold in the U.S., is often represented within the UPC and recorded elsewhere on medication packaging. Several variations in UPC / NDC spacing, and hyphenation are illustrated in examples [2-3]. Scan the bar code symbol with the wand to capture the UPC / NDC. Rescan it as needed. *EXTREMELY IMPORTANT: JUDGE SUCCESS OF THE SCAN BY VERIFYING THAT THE INFORMATION THAT AUTOMATICALLY POPULATES SECTIONS (B-D) MATCHES INFORMATION ON THE MEDICATION LABEL.*

[1] [2]

.....[3]

UPC / NDC: 306030048167 311017110010
Name: Azo-Septic .....Dr. Scholl's Clear Away Plantar

Strength: 95 40
Units: MG %

Transcription: Transcribe all medications without a UPC-labeled container *and* those with a UPC-labeled container that cannot be scanned *successfully* (as defined above). Specifically, in section (a), transcribe the unsuccessfully scanned UPC, if possible. If the UPC cannot be transcribed *successfully*, transcribe the NDC in section (a). The NDC is often recorded elsewhere on the medication packaging. If the NDC cannot be transcribed *successfully* transcribe in section (b) the complete medication name as written on the container. Medication labels may contain standard abbreviations (Table 1). In section (c), transcribe the numeric strength (weight for solids and concentration for non-solids). In section (d), transcribe the units that measure strength using a standard abbreviation (Table 2). Formatting and transcription standards are detailed below.

Table 1. Standard abbreviations of medication names

Medication Name	Abbreviation	Medication Name	Abbreviation	Medication Name	Abbreviation
A Acetaminophen	APAP	Aluminum	AL	Amitriptyline	AMITRIP
Antibiotic	ANTIBIO	Antihistamine	ANTIHIST	Arthritic	ARTHR
Aspirin	ASA	Aspirin, phenacetin & caffeine	APC	Ammononium	AMMON
B Balanced Salt Solution	BSS	Buffered	BUF		
C Caffeine	CAFF	Calcium	CA	Capsules	CAP
Carbonate	CARBON	Chewable	CHEW	Chlordiazepoxide	CHLORDIAZ
Chloride	CL	Chlorpheniramine	CHLORPHEN	Codeine	COD
Compound	CPD or CMP or CMPD	Concentrate	CON		
D Decongestant	DECONG	Dextromethorphan	DM	Dioctylsodium sulfosuccinate	DSS
E Expectorant	EXP	Extra	EX		
F Ferrous	FE	Fluoride	FL	Formula	FORM
G Gluconate	GLUCON	Glyceryl Guacolate	GG	Guaifenesin	GG
H Hydrochloride	HCL	Hydrochlorthiazide	HCTZ	Hydrocortisone	HC
Hydroxide	HYDROX				
I Inhalation	INHAL	Injection	INJ	Intravenous	IV
J Junior	JR				
L Laxative	LAX	Liquid	LIQ	Long acting	LA
Lotion	LOT				
M Magnesium	MG	Maximum	MAX	Minerals	M
Multivitamins	MULTIVIT				
N Nitroglycerin	NTGN				
O Ointment	OINT	Ophthalmic	OPTH		
P Penicillin	PCN	Pediatric	PED	Perphenazine	PERPHEN

Phenobarbitol	PB	Phenylephrine	PE	Phenylpropanolamine	PPA
Potassium	K	Potassium Chloride	KCL	Potassium Iodide	KI
Powder	PWD	Pyrilamine	PYRIL		
R Reliever	REL				
S Simethicone	SIMETH	Sodium	SOD	Solution	SOLN
Strength	STR	Suppository	SUPP	Suspension	SUSP
Sustained action	SA	Sustained release	SR	Syrup	SYR
T Tablets	TAB	Theophyllin	THEOPH	Therapeutic	T
Time disintegration	TD				
V Vaccine	VAC	Vitamin	VIT		
W With	W				

Table 2. Standard abbreviations of metric units

Units	Standard Abbreviation	Units	Standard Abbreviation
Anti-Clotting Factor Xa International Units/Milliliter	A-XA IU/ML	Milligram/Drop	MG/DROP
Billion Cells of Lactobacilli	B CELL	Milligram/Gram	MG/GM
Bioequivalent Allergy Units/Milliliter	BAU/ML	Milligram/Inhalation‡	MG/INH
Actuation*	ACT	Milligram/Hour	MG/HR
Enzyme-Linked Immunosorbent Assay Units/Milliliter	ELU/ML	Milligram/Milligram	MG/MG
Gram†	GM	Milligram/Milliliter	MG/ML
Gram/Dose	GM/DOSE	Milligram/Spray	MG/SPRAY
Gram/Gram	GM/GM	Milligram/Teaspoon§	MG/TSP
Gram/Milliliter	GM/ML	Milliliter	ML
Kallikrien Inactivator Units/Milliliter	KIU/ML	Milliliter/Milliliter	ML/ML
Flocculation Units	LFU	Millimole	MMOLE
Megabecquerels/Milliliter	MBQ/ML	Millimole/Milliliter	MMOLE/ML
Microgram†	MCG	Million International Units	MIU
Microgram/Actuation	MCG/ACT	Million International Units/Milliliter	MIU/ML
Microgram/Hour	MCG/HR	Million Units	MU
Microgram/Inhalation‡	MCG/INH	Million Units/Gram	MU/GM
Microgram/Milliliter	MCG/ML	Million Units/Milliliter	MU/ML
Microgram/Spray	MCG/SPRAY	Minim	MINIM
Microgram/Square Centimeter	MCG/SQCM	Minim/Milliliter	MINIM/ML
Millicuries/Milliliter	MCI/ML	Percent	%
Milliequivalent	MEQ	Plaque Forming Units/Milliliter	PFU/ML
Milliequivalent/Gram	MEQ/GM	Protein Nitrogen Units/Milliliter¶	PNU/ML
Milliequivalent/Liter	MEQ/L	Unit	UNIT
Milliequivalent/Milligram	MEQ/MG	Unit/Actuation	UNIT/ACT
Milliequivalent/Milliliter	MEQ/ML	Unit/Gram	UNIT/GM

Milligram†	MG	Unit/Milligram	UNIT/MG
Milligram/Actuation	MG/ACT	Unit/Milliliter	UNIT/ML

*Actuation = activation of a dispensing de vice. †1 GM = 1000 MG; 1 MG = 1000 MCG. ‡Of aerosolized powder. §Of e.g. powdered or granulated oral medications. ¶Of allergenic extracts.

Standard Format: Beginning with item 5, transcribe the numeric UPC / NDC (a) working from the right-most box. Transcribe all parts of each medication name as written on the container (b), numeric strength (c), and standard units (d). If using the paper form, carefully transcribe medication name and units in UPPER CASE CHARACTERS (CAPITAL LETTERS). When necessary, use a period (.) to indicate the location of a decimal point in strength and a forward slash (/) to separate active ingredients of generic products, their respective strengths and units. In every case, transcribe in standard format even when the same information or a portion of the information appears in the previous item. Do not use ditto marks (") to indicate a repeat of the previous item.

Medication UPC / NDC (Items 5-29a): Transcribe the UPC / NDC when it cannot be scanned *successfully* (as defined above). Be sure to transcribe the first and last numbers of the UPC which may be found in the lower (middle or upper) left and right regions of the UPC bar code symbol (e.g. 6 and 2 in example [1], above).

Medication Name (Items 5-29b): Transcribe the medication name using a forward slash (/) to separate active ingredients of generic medications. *EXTREMELY IMPORTANT: DO NOT TRANSCRIBE E.G. MANUFACTURER NAME, FLAVOR, WHETHER MEDICATIONS ARE SUGAR-FREE, OR LOW-SODIUM.* Since a few companies have trademarked their formulation (dosage form), the complete medication name may include it. Although we do not transcribe the number of pills dispensed, the prescribed dose, actual dose, or frequency of medications taken, medication names also may include numbers or characters that can be mistaken for number dispensed, dose or frequency. If in doubt, it is preferable to include questionable information in the medication name to facilitate identification, coding and classification. Therefore, transcribe all formulations, numbers and characters that may be part of the medication name. Examples are provided in Table 3. Standard abbreviations of medication names were provided in Table 1 (above).

Table 3. Examples of medication names that include special formulations, numbers or characters

Medication Name	
DILANTIN KAPSEALS*	ORTHO-NOVUM 10/11-28
ASA ENSEALS†	STUARTNATAL 1 + 1
ANACIN-3	NPH ILETIN I
ACEROLA-C	SK-AMPICILLIN
TRIAMINIC-12	CALTRATE 600 PLUS VITAMIN D
OVRAL-28	HCTZ/TRIAMTERENE‡

*Kapseals = capsules. †Enseals = enteric-coated capsules. ‡The "/" separates HCTZ (hydrochlorothiazide) and triamterene, two active ingredients.

Strength (Items 5-29c): The strength of most solid medications is given in number of milligrams. Transcribe the numeric strength (weight for solids and concentration for non-solids) using a period (.) to indicate the location of a decimal point and a forward slash (/) to separate the strength of active ingredients of generic products (e.g. medication name = HCTZ/TRIAMTERENE, strength = 25/37.5).

Units (Items 5-29d): Transcribe the metric units that measure strength using one of the standard abbreviations in Table 2 (continuing the above example, units = MG/MG). Prior metric conversion of non-standard units (e.g. for liquids: 1 fluid ounce = 30 ML; 1 tablespoon = 15 ML; 1 teaspoon = 5 ML; and for solids: 1 grain = 65 MG; 1 ounce = 31 GM) may be necessary in unusual cases. Note that for insulin, strength is often given in number of units per milliliter (e.g. 100U/ML, 100/ML and U100). All three of these non-standard abbreviations are equivalent to the preferred format (strength = 100; units = UNIT/ML).

Combination Medications: Combination medications contain multiple active ingredients (two or more medications in a single formulation). For example, consider a brand name combination of HCTZ 25 MG and TRIAMTERENE 37.5 MG called DYAZIDE. In the U.S., it is sold only in this fixed combination. Because fixed combination medications do not generally list a strength (c) or units (d), these fields may be left blank when transcribing them (i.e. medication name = DYAZIDE; strength = _[blank]_ ; units = __[blank]__). Other combination medications are sold in more than one fixed combination. For example, consider a brand name combination of HCTZ and PROPRANOLOL called INDERIDE (LA). In the U.S., it is sold in many different combinations (HCTZ 25 or 50 MG and PROPRANOLOL 40, 80, 120 or 160 MG). Because variable combination medications generally list the strength and units, complete these fields when transcribing them (i.e. medication name = INDERIDE; strength =25/40 or 25/80; units = MG/MG; or medication name = INDERIDE LA; strength = 50/80, 50/120 or 50/160; units = MG/MG).

Examples: Feosol Iron Supplement Therapy 45 mg

#	(a) Medication UPC / NDC													Medication name (b)
5.	**3**	**4**	**9**	**6**	**9**	**2**	**9**	**4**	**1**	**6**	**0**	**5**		FEOSOL IRON SUPPLEMENT THERAPY
	(c) Strength						(d) Units							
	45						MG							

Lipitor 10 mg

#	(a) Medication UPC / NDC													Medication name (b)
6.	**3**	**0**	**0**	**7**	**1**	**0**	**1**	**5**	**5**	**2**	**3**	**7**		LIPITOR
	(c) Strength						(d) Units							
	10						MG							

Regular Strength Tylenol 325 mg

#	(a) Medication UPC / NDC													Medication name (b)
7.	**5**	**0**	**5**	**8**	**0**	**4**	**9**	**6**	**6**	**0**				REGULAR STRENGTH TYLENOL
	(c) Strength						(d) Units							
	325						MG							

Neosynephrine Regular Strength ½ percent

#	(a) Medication UPC / NDC													Medication name (b)
8.	**3**	**0**	**0**	**2**	**4**	**1**	**3**	**5**	**3**	**0**	**1**	**0**		NEOSYNEPHRINE REGULAR STRENGTH
	(c) Strength						(d) Units							
	0.5						%							

Metamucil 3.4 g per dose

#	(a) Medication UPC / NDC													Medication name (b)
9.	**0**	**3**	**7**	**0**	**0**	**0**	**7**	**4**	**0**	**7**	**8**	**0**		METAMUCIL
	(c) Strength						(d) Units							
	3.4						G/DOSE							

Robitussin 100 mg per teaspoon

#	(a) Medication UPC / NDC													Medication name (b)
10.	**3**	**0**	**0**	**3**	**1**	**8**	**6**	**2**	**4**	**1**	**2**	**8**		ROBITUSSIN
	(c) Strength						(d) Units							
	100/5						MG/ML							

Magnesium Citrate Solution 1.745 g per ounce

#	(a) Medication UPC / NDC													Medication name (b)
11.	**8**	**4**	**0**	**9**	**8**	**6**	**0**	**1**	**0**	**2**	**5**	**5**		MAGNESIUM CITRATE SOLUTION
	(c) Strength						(d) Units							
	1.745/30						G/ML							

Prioritizing Transcription: Polypharmacy tends to increase with age, but even if a participant is using more than 25 medications, only 25 can be transcribed in items (5-29). Therefore, prioritize transcription if there are more than 25 medications. If it is clearly necessary to defer prioritization, transcribe the UPC (a), name (b), strength (c), and units (d) of additional medications on the back of the last page of the form. Deferral may allow more effective prioritization based on the number and type of medications available for transcription. In any case, use the following algorithm to guide prioritization: [1] prescription medications; then [2] aspirin, aspirin-containing medications and non-steroidal anti-inflammatory drugs (e.g. Alka-Seltzer, headache powders, cold or arthritis medications, et cetera); followed by [3] other over-the-counter preparations; and finally [4] vitamins and food supplements.

The Medication Dictionary: For reference, paper versions of the Medication Dictionary will be distributed to each Field Center. The dictionary lists medication names (trade / brand and generic ingredient) in alphabetical order. Medication names that begin with a number, ditto ("), or a hyphen (-) are listed first. If a medication name is separated by a hyphen (-), the portion of the name preceding the hyphen is listed in alphabetical order. Strength and units are not included in the dictionary, so only use the numbers appearing in it to differentiate between medications.

Preparing to Use the Medication Dictionary: Before using the medication dictionary to look up a

medication, first check the spelling of its transcribed name against its container's label. Verify that numbers referring to quantity dispensed, dose, or frequency were not inappropriately transcribed as part of the medication name because they should not be used in the matching process. Be aware that while some pharmacists use standardized abbreviations (Table 1, above) others do not. Also be aware that some medications use suffixes to distinguish between different combinations containing the same primary ingredient (Table 4).

Table 4. Examples of medication suffixes used to distinguish combinations

Medication Name	1° Ingredient	2° Ingredients	
DARVON	propoxyphene hydrochloride		
DARVON N	propoxyphene napsylate		
DARVON W ASA	propoxyphene hydrochloride	aspirin	
DARVON CMPD	propoxyphene hydrochloride	aspirin	caffeine

Using the Medication Dictionary: Use the dictionary as needed to look up medications (that when scanned or transcribed) do not automatically populate sections [a-d] with an appropriate match or list of potential matches from which to choose. For medication names containing more than one word, look for a match of the complete medication name in the dictionary. If the complete name matches, enter the corresponding UPC. If a complete match cannot be found, but the dictionary contains a single entry for the ingredient(s) in the medication (usually the first word of the medication name), and there are no other entries containing this word, select the corresponding UPC. This often occurs when [1] the brand *and* generic medication name are transcribed, but only one is in the dictionary; [2] the formulation of the medication is transcribed, but is not in the dictionary; [3] the manufacturer name is transcribed, but is not in the dictionary; or [4] words referring to other ingredients are transcribed, but are not in the dictionary or are in the dictionary in a different order (Table 5). ***EXTREMELY IMPORTANT**: IF A MEDICATION NAME IS NOT IN THE DICTIONARY, DO NOT GUESS AT A MATCH. SIMPLY SET THE STATUS CODE TO Q (QUESTIONABLE) SO THAT THE COLLABORATIVE STUDIES COORDINATING CENTER CAN INVESTIGATE.*

Table 5. Examples of medication names that may not automatically populate sections [a-d]

Medication Name Transcribed As	Reason For Failure	Re-Transcribe As
CORDARONE/AMIODARONE	CORDARONE is the brand name for AMIODARONE	AMIODARONE
DIMETAPP ELIXIR	ELIXER is the formulation	DIMETAPP
ECKERD ALLERGY RELIEF TABS	ECKERD is the manufacturer	ALLERGY RELIEF
TYLENOL NO. 3	NO. 3 refers to another active ingredient (codeine)	APAP W CODEINE

Items 30-31: Once all medications that can be successfully scanned or transcribed have been processed, count the total number of different medications (including those that cannot be successfully scanned or transcribed). Item 30 mentions the total number of medications in the bag. The parent study sent bags for the participants to put their medications in when they reported for their visit. However, Sueño is not providing bags to the participants so the "bag" part of the question can be ignored. Enter the total number of medications that were brought into the visit in Item 30. Set aside loose pills, containers that are unmarked, unclearly labeled, or hold more than one medication (e.g. medisets), if necessary in consultation with another trained staff person, for later examination by a trained interviewer. Add the number of medications that you are unable to successfully scan or

transcribe. Enter this number in Item 31. For example, if there were 7 medications brought in by the participant, and you were able to successfully scan or transcribe 5 of them, Items 30 and 31 would be completed as follows:

30. Total number of medications in bag ..... | 0 | 7 |

31. Number of medications unable to successfully scan or transcribe… | 0 | 2 |

Items 32a,b: The staff person scanning / transcribing the medications must enter their three-digit HCHS/SOL Staff ID number in item 32a and the date of medication scanning / transcription in item 32b. If necessary, make a note on the Medication Survey Form, and inform the participant that a trained interviewer will ask for help identifying loose pills and medications in containers that are unmarked, unclearly labeled, or hold more than one medication. *EXTREMELY IMPORTANT: AT NO TIME SHOULD MEDICATIONS BE LEFT UNATTENDED IN THE RECEPTION AREA OR MEDICATION CONTAINERS BE OPENED IN THE ABSENCE OF THE PARTICIPANT.*

C. MEDICATION USE INTERVIEW

Identifying Unknown Medications: Determine from Item 31 on the form at the end Section B whether there are any medications that were not successfully scanned or transcribed including loose pills, medications in containers that are unmarked, unclearly labeled, or hold more than one medication. With the participant's help, read the imprint(s) on each unknown pill, then search [1] the *Facts and Comparisons Drug Identifier* on your computer, or if necessary, [2] the *Ident-A-Drug,Reference* on the web (**www.identadrug.com**; username=_____; password=_____) to identify each pill from its imprint(s), shape, and / or color. If possible, record the UPC / NDC (a) or medication name (b) and if not transcribed *successfully* (as defined above), its strength (c) and units (d). If the medication cannot be identified, record UNKNOWN and the imprint(s) under medication name (b) and draw two horizontal lines (=) through the boxes for the UPC / NDC (a). If additional medications can be identified and recorded, adjust the total for item 31 accordingly. Thereafter, probe the participant about any other medications that may have been taken in the previous four weeks. For additional medications recalled by the participant, record with as much detail as possible the medication name (b), and if not automatically linked to information in sections [c-d] that matches information provided by the participant, strength (c), and units (d). If there is any doubt, arrange for follow-up to obtain more accurate information from the participant.

During the remainder of the Medication Survey interview or during a subsequent interview, the participant may recall other medications taken during the past four weeks. Transcribe the medication UPC (a), name (b), strength (c) and units (d) of each just as if they had been brought in. However, do not adjust the total for item 31. This documents that information on some medications was provided from the participant's memory.

Items 33a-l: Following the transition statement provided, ask if medications were taken in the past four weeks for the twelve listed reasons. Synonyms that may be used in response to participant questions are listed parenthetically and below (Table 6).

Table 6. Synonyms that may be used in response to participant questions about items 33a-k

Question text	Synonyms
a. Asthma	
b. Chronic bronchitis or emphysema	Chronic obstructive pulmonary disease or COPD
c. High blood sugar	Diabetes
d. High blood pressure	Hypertension
e.High blood cholesterol	Hypercholesterolemia
f. Chest pain	Angina
g. Abnormal heart rhythm	Arrhythmia
h. Heart failure	Congestive heart failure or CHF
i. Blood thinning	Anticoagulation
j. Stroke	Cerebrovascular accident or CVA
k. Mini-stroke	Transient ischemic attack or TIA
l. Leg pain while walking	Claudication or peripheral arterial disease or PAD

For example, if the participant had taken medication for asthma and claudication and no other listed conditions, code item 33 as follows:

	Yes	No	Unknown
a. Asthma	(Y)	N	U
b. Chronic bronchitis or emphysema (chronic obstructive pulmonary disease [COPD])	Y	(N)	U
c. High blood sugar (diabetes)	Y	(N)	U
d. High blood pressure (hypertension)	Y	(N)	U
e. High blood cholesterol (hypercholesterolemia)	Y	N	(U)
f. Chest pain (angina)	Y	N	(U)
g. Abnormal heart rhythm (arrhythmia)	Y	(N)	U
h. Heart failure (congestive heart failure [CHF])	Y	(N)	U
i. Blood thinning (anticoagulation)	Y	(N)	U
j. Stroke (cerebrovascular accident [CVA])	Y	(N)	U
k. Mini-stroke (transient ischemic accident [TIA])	Y	(N)	U
l. Leg pain while walking (claudication or peripheral arterial disease [PAD])	(Y)	N	U

If any of the conditions are answered affirmatively, be sure that the medication is recorded in Section B by asking “Did we include that medicine in the list I just transcribed?”. DO NOT ask the participant to identify which medication was used to treat any of the conditions. For example, if the participant reported taking a medication to lower blood pressure during the last two weeks (Item 33a), and no recognized antihypertensive medications were recorded in Section B, DO NOT probe to determine if the names of all medications taken during the last two weeks were recorded. If the participant indicates that the names of all his / her medications have been transcribed, DO NOT probe further to determine which medication was used to treat the high blood pressure. Regardless of whether the participant reported taking any medications during the past four weeks or whether they brought any medication to the field center, proceed with the next item.

Item 34: If skipping in from Item 2, preface this question with an explanation e.g. *“I know you said you took no medications, but we include the next few questions as a memory jogger.”* Then ask the question as worded and show participant List #1: Commonly Used Aspirin or Aspirin-Containing Medications. Although its primary purpose is to identify participants who are taking aspirin, item 34 is broadly constructed to include aspirin and other medications which may contain aspirin but are not necessarily labeled as aspirin, such as "Alka-Seltzer, cold medicine or headache powder". Therefore, this question may identify persons taking medications that do not include “aspirin”, per se. With a positive response, continue with item 35 and verify that the relevant information on the medication(s) was recorded in Items 5-29. If the response is NO or UNKNOWN, skip to item 37.

Item 35: Item 35 is narrower in scope and refers specifically to aspirin or aspirin-containing medications that have been taken within the four weeks preceding the clinic visit. Record the number of days in this four week period (maximum of 28 days) that aspirin or aspirin-containing medications were taken. If no aspirin or aspirin-containing medications were taken, enter "00” and skip to Item 37.

Item 36: Ask item 36 as written, but DO NOT READ THE CHOICES. If the participant mentions avoiding heart attack or stroke as part of his / her response, record "1". Participants could be following the advice of their provider of medical care in doing this, or they could be acting on their own, based on information obtained through the media, friends or other sources. If the participant mentions "blood

thinning" or avoiding blood clots as the reason for taking aspirin, record "1". If neither a heart attack nor stroke is mentioned, record "2", even if the aspirin were prescribed by a physician.

Item 37: Read item 37 to all participants following the instructions provided at the end of the question, i.e., read the bracketed "other" if the response to Item 34 was "Yes". The use of analgesic and anti-inflammatory medications that do not contain aspirin is verified because these medications (like aspirin) may affect some of the hemostasis tests. With a "Yes" response, confirm whether the reported medications are transcribed in Section B.

Item 38-40: Read item 38 to all participants and show them List #2: Commonly Used Non-Steroidal Anti-Inflammatory Drugs (NSAIDS), the most common, non-aspirin-containing treatments for arthritis. Item 38 excludes acetaminophen (e.g. Tylenol) and aspirin (as separate entities) as well as steroids. This item focuses on current, regular use (NOW) of NSAIDS, regardless of the reason for their use. If asked by the participant, "regular" is defined as at least once a week for several months. If the response is "No" or "Unknown", go to closing. If the response is "Yes", continue by completing Item 39 (unless already recorded in Section B) and Item 40 (in response to the question, "How many pills per week are you taking on average?")

Item 41: The staff person who interviewed the participant must their three-digit HCHS/SOL Staff ID number in item 41.

List #1: Commonly Used Aspirin-Containing Medications (3 page list, page 1)

1/2HALFPRIN
ACETAMINOPHEN / MAGNESIUM SALICYLATE / CAFFEINE
ACETAMINOPHEN / SALICYLAMIDE
ACETAMINOPHEN / SALICYLAMIDE / CAFFEINE
ACETAMINOPHEN / SALICYLAMIDE / PHENYLTOLOXAMINE
ACETYL SALICYLIC ACID
ADDED STRENGTH HEADACHE R
ADDED STRENGTH PAIN RELIE
ADPRIN B
ADULT STRENGTH ANALGESIC
ADULT STRENGTH PAIN RELIE
AF-MIGRAINE
ALBERTSON'S EFFERVESCENT
ALBERTSON'S ENTERIC COATE
ALBERTSON'S HEADACHE FORM
ALKA-SELTZER
AMIGESIC
ANABAR
ANACIN
ANALGESIC
ACETAMINOPHEN / SALICYLAMIDE / PHENYLTOLOXAMINE / CAFFEINE
ARTHRITIS PAIN FORMULA
ARTHRITIS STRENGTH BC
ARTHROPAN
ASA
ASCRIPTIN
ASP
ASPERGUM
ASPIR-81
ASPIRCAF
ASPIRIN / ANTACID
ASPIRIN / CAFFEINE
ASPIRIN / ACETAMINOPHEN / CAFFEINE
ASPIRIN / ALUMINUM HYDROXIDE / MAGNESIUM HYDROXIDE / CALCIUM CARBONATE
ASPIRIN / ALUMINUM HYDROXIDE / MAGNESIUM HYDROXIDE
ASPIRIN / ACETAMINOPHEN / CAFFEINE / CALCIUM GLUCONATE
ASPIRIN / ACETAMINOPHEN / SALICYLAMIDE / CAFFEINE
ASPIRIN / CAFFEINE
ASPIRIN / CAFFEINE / BUTALBITAL
ASPIRIN / CA CARBONATE
ASPIRIN / CINNAMEDRINE / CAFFEINE
ASPIRIN / SALICYLAMIDE / CAFFEINE
ASPIR-LOW
ASPIR-MOX
ASPIRTAB
ASPIR-TRIN
ASPRIDROX
BACK PAIN-OFF
BACKACHE MAXIMUM STRENGTH
BACKACHE RELIEF EXTRA STR
BAYER LOW STRENGTH
BAYER PLUS EXTRA STRENGTH
BC
BL MIGRAINE FORMULA
BUFFASAL
BUFFERIN
BUFPIRIN
BUTALBITAL / ASA / CAFFEINE
BUTALBITAL / ASPIRIN / CAFFEINE
BUTALBITAL COMPOUND

ASPIRIN	CETAZONE-T
ASPIRIN GUM	CHOLINE / MAGNESIUM SALICYLATES
ASPIRIN / DIPHENHYDRAMINE EFFERVESCENT	CHOLINE MAGNESIUM TRISALICYLATE

List #1: Commonly Used Aspirin-Containing Medications (3 page list, page 2)

CHOLINE SALICYLATE	GENACOTE	OSCO ADDED STRENGTH PAIN
CMT	GOODY'S	OSCO ANALGESIC ADULT STRE
COPE	HALFPRIN	OSCO EFFERVESCENT ANTACID
CVS BACKACHE RELIEF	HCA PAIN RELIEVER	OSCO LOW STRENGTH ENTERIC
CVS EFFERVESCENT ANTACID	HEADACHE FORMULA ADDED ST	P-A-C
CVS HEADACHE RELIEF	HEADACHE RELIEF	PAIN RELIEF
CVS MIGRAINE RELIEF	HEADRIN EX STRENGTH PAIN	PAIN RELIEF EXTRA STRENGT
DEWITT'S PILLS	HM ADULT ANALGESIC	PAIN RELIEF EXTRA STRENGT
DIFLUNISAL	LEVACET	PAIN RELIEVER ADDED STREN
DISALCID	LOBAC	PAIN RELIEVER PLUS
DOAN'S	MAGAN	PAINAID
DOLOBID	MAGNAPRIN	PAIN-OFF
DOLOREX	MAGNESIUM SALICYLATE	PANRITIS FORTE
DURABAC	MAGNESIUM SALICYLATE / ACETAMINOPHEN	PHENYLTOLOXAMINE / MAGNESIUM SALICYLATE
DURAXIN	MAGNESIUM SALICYLATE / DIPHENHYDRAMINE	PIROSAL
EASPRIN	MAG-PHEN	QC PAIN RELIEVER PLUS
ECASA	MAGSAL	RA ANTACID PAIN RELIEF
ECK MIGRAINE RELIEF	MEDI-SELTZER	RA MIGRAINE RELIEF
ECOTRIN	MEPROBAMATE / ASPIRIN	RID-A-PAIN COMPOUND
ECPIRIN	MIDOL MAXIMUM STRENGTH	SALETO
ED-FLEX	MIGRAINE FORMULA	SALICYLAMIDE / CAFFEINE
EFFERVESCENT ANTACID / PAIN	MIGRAINE RELIEF	SALFLEX
EFFERVESCENT PAIN RELIEF	MINITABS	SALSALATE
EFFERVESCENT PAIN RELIEVE	MOBIDIN	SAV-ON ADDED STRENGTH PAI
EQUAGESIC	MOBIGESIC	SAV-ON ANALGESIC ADULT ST
EXCEDRIN	MOMENTUM MUSCULAR BACKACH	SAV-ON BACKACHE RELIEF EX

EX-PAIN	MONO-GESIC	SAV-ON EFFERVESCENT ANTAC
EXTRA STRENGTH BAYER	MP ENCOPRIN	SB BACKACHE EXTRA STRENGT
EXTRAPRIN	MP REGRIPRIN	SB EFFRSCENT ANTACID/PAIN
FARBITAL	MST 600	SB LOW DOSE ASA EC
FIORINAL	MYOGESIC	SB MENSTRUAL
FORTABS	NEUTRALIN	SB PAIN RELIEF F/ACT
FRENADOL	NINOPRIN	SB PAIN RELIEF X-STR
GENACED	NOVASAL	SG EFFERVESCENT ANTACID/P

List #1: Commonly Used Aspirin-Containing Medications (3 page list, page 3)

SG PAIN RELIEVER ADDED ST	SUPAC	UNI-TREN
SM HEADACHE ADDED STRENGT	SUPER STRENGTH PAIN RELIE	VANQUISH
SM HEADACHE PAIN RELIEVER	SUREPRIN	V-R EFFERVESCENT PAIN REL
SOBA ANALGESIC	TETRA-MAG	ZEE-ZELTZER
SOBA PAIN RELIEVER HEADAC	THERAPY BAYER	ZORPRIN
SODIUM SALICYLATE	THIOCYL	
ST JOSEPH ADULT	TRICOSAL	
STANBACK	TRILISATE	

List #2: Commonly Used Non-Steroidal Anti-Inflammatory Drugs (NSAIDS)

ACTRON	KETOPROFEN
ADDAPRIN	KETOROLAC
ADVANCED PAIN RELIEF	LANSOPRAZOLE / NAPROXEN
ADVIL	LODINE
ALEVE	MECLOFENAMATE
ALL DAY RELIEF	MEDI-PROFEN
ANAPROX	MEDIPROXEN
ANSAID	MEFENAMIC ACID
ARTHROTEC	MELOXICAM
BEXTRA	MENADOL
CATAFLAM	MIDOL
CELEBREX	MOBIC
CELECOXIB	MOTRIN
CLINORIL	NABUMETONE
CVS INFANTS' CONCENTRATED	NALFON
DAYPRO	NAPRELAN
DICLOFENAC	NAPROSYN
DICLOFENAC / MISOPROSTOL	NAPROXEN
DYSPEL	NUPRIN
ELIXSURE	ORUDIS
ETODOLAC	ORUVAIL
FELDENE	OXAPROZIN
FENOPROFEN	PHENYLBUTAZONE
FLURBIPROFEN	PIROXICAM
GENPRIL	PONSTEL
HALTRAN	PREVACID / NAPRAPAC
IBU	PROFEN
IBU-DROPS	PROVIL
IBUPROFEN	Q-PROFEN
IBUTAB	RELAFEN
INDOCIN	ROFECOXIB
INDOMETHACIN	RUFEN
I-PRIN	SULINDAC
TAB-PROFEN	VALDECOXIB
TOLECTIN	VIOXX
TOLMETIN	VOLTAREN
TORADOL	

Anthropometry Form
HCHS/SOL Sleep Ancillary Study

ID NUMBER:									FORM CODE: VERSION: 09/17/10	Contact Occasion		SEQ #	

Acrostic

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) 0b. Staff ID: ☐☐☐

Instructions: Complete the measurements below and record any notes.

1. Do you have an electronic implantable device (pacemaker, defibrillator, etc.)?
   - No 0 ☐
   - Yes 1 ☐ **DO NOT PERFORM BIA, WEIGH IN WEIGHT ONLY MODE, SKIP Q5-Q9.**

2. Assessment of ability to stand (choose one):
   - Can stand erectly on both feet. 1 ☐
   - Can stand on both feet, but posture not erect. 2 ☐
   - Cannot stand on both feet. 3 ☐ END QUESTIONNAIRE

3. Standing height (round to nearest cm): ☐☐☐ cm

4. Weight: ☐☐☐.☐ kg

5. Fat (%): ☐☐.☐ %

6. Impedance: ☐☐☐ Ohms

7. Fat mass: ☐☐☐.☐ kg

8. Lean body mass (FFM): ☐☐☐.☐ kg

9. Total body water (TBW): ☐☐☐.☐ kg

10. Notes: _____

_____

Sueño – Sleep Habits in HCHS/SOL

Anthropometry (APE) Question by Question Instructions

General Instructions:
Anthropometry consists of assessing the participant's height, weight and body composition measurements. These measurements are used to assess the relationship between obesity and sleep problems. The APE form records presence of an electronic implantable device (EID), ability to stand, height, weight and bio-impedance output values from the Tanita scale. As the technician progresses through the examination procedures, they will record (or directly enter) the measurements into the APE form. They will then record any reason why the any measurements were not obtained or any notes that may be applicable (if the subject has a prosthetic, etc). Take care that the specific anthropometric guidelines outline in the Sueño MOP are followed each time measurements are recorded on the APE form.

Question by Question Instructions:

Q1 Ask participant if they have an electronic implantable device (EID) (examples of EID's are pacemakers or defibrillators). If participants ask what an EID is you can explain that it is a device that uses electricity to help your body function properly, such as a pacemaker. Other less common EIDs are spinal cord stimulators and deep brain stimulators. Assessing the presence of an EID is important because it is dangerous to perform BIA (Q5-Q9) on people that have these devices. If a person does have an EID then they must be weighed in the Weight Only mode. Please see Sueño MOP for instructions on this procedure.

Q2 This questions whether the participant can stand for the anthropometry measurements. If you directly observe that the participant walked without assistance to the area where the anthropometry equipment is located, then this question does not need to be verbalized. Instead, the technician can make their assessment from the participant's mobility. If the participant did not walk without assistance, then the interviewer should ask participant if they are able to stand without assistance. If they cannot stand, record this on Q2 and end the anthropometry section of the study visit. If they can, assess if they stand erect on both feet when they stand for the height measurement. If the participant cannot stand erect, record this and make note of the circumstances in the notes section (Q10).

Q3-Q9 Measure the participant's height, weight and body composition measurements using the methods outlined in the Sueño MOP. Keep in mind that if the person has an EID, they should be weighed in the Weight Only mode and the measurements listed in Q5-Q9 will not be obtained.

Q10 Record any notes that may be relevant. If it was indicated in Q2 that the person could not stand erect, describe circumstances. If the person has a cast that could not be easily removed and weight and BIA measurements were not obtained make note of this. If the person have a prosthetic limb please make note of this.

OMB#:
0925-0584
Exp. 2/28/2011

Medical History Questionnaire
HCHS/SOL Sleep Ancillary Study

ID NUMBER:									FORM CODE: MQE VERSION: A 08/10/10	Contact Occasion		SEQ #	

Acrostic

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

0b. Staff ID: ☐☐☐

Instructions: Enter the answer given by the participant for each response. The special value, "Q", is allowed for cases where the response 'Don't know/refused' is not listed as an option. If age onset is unknown enter the special missing value, "==", in the item.

Do you have any of the following conditions?

1. Has a doctor ever said that you have high blood pressure or hypertension?

No 0 ☐
Yes 1 ☐ → FOR WOMEN: GO TO QUESTION 1a

1a. Was this during pregnancy only?

No 0 ☐
Yes 1 ☐

2. Has a doctor ever said that you have angina?

No 0 ☐
Yes 1 ☐

3. Has a doctor ever said that you had a heart attack?

No 0 ☐
Yes 1 ☐

4. Has a doctor ever said that you had heart failure?

No 0 ☐
Yes 1 ☐

5. Has a doctor ever said that you had some other kind of heart problem?

No 0 ☐
Yes 1 ☐
If yes, please specify:_____

6. Have you ever had a balloon angioplasty, a stent, or bypass surgery to the arteries in your heart to improve the blood flow to your heart?

No 0 ☐
Yes 1 ☐

ID NUMBER:									FORM CODE: MQE VERSION: A 08/10/10	Contact Occasion			SEQ #			

7. Has a doctor ever said that you had a stroke?

No 0 ☐
Yes 1 ☐

8. Has a doctor ever said that you had a mini-stroke or TIA (transient ischemic attack)?

No 0 ☐
Yes 1 ☐

9. Have you had a balloon angioplasty or surgery to the arteries of your neck to prevent or correct a stroke?

No 0 ☐
Yes 1 ☐

10. Has a doctor ever said that you have an aortic aneurysm, an AAA, or ballooning of your aorta?

No 0 ☐
Yes 1 ☐

11. Has a doctor ever said that you have peripheral arterial disease (problems with circulation, blocked arteries to the legs)?

No 0 ☐→ GO TO QUESTION 13
Yes 1 ☐

12. Have you had an operation, a balloon angioplasty, a stent, or an amputation for this condition?

No 0 ☐
Yes 1 ☐

13. Has a doctor ever said that you have diabetes (high sugar in blood or urine)?

No 0 ☐→ GO TO QUESTION 14
Yes 1 ☐

13a. At what age were you first told this?

☐☐ Age in years

13b.FOR WOMEN: Was this during pregnancy only?

No 0 ☐
Yes 1 ☐

13c. Are you being treated with insulin?

No 0 ☐→ GO TO QUESTION 14
Yes 1 ☐

13d. Was insulin the first medicine used for diabetes?

No 0 ☐
Yes 1 ☐

ID NUMBER:									FORM CODE: MQE VERSION: A 08/10/10	Contact Occasion			SEQ #			

14. Have you ever been told by a doctor that you had a sleep disorder?

No 0 ☐ → END QUESTIONNAIRE
Yes 1 ☐
Don't Know 9 ☐ → END QUESTIONNAIRE

15. Which sleep disorder(s)?

	NO	YES	
a. Insomnia	0 ☐	1 ☐	
b. Restless legs	0 ☐	1 ☐	
c. Narcolepsy	0 ☐	1 ☐	
d. Apnea	0 ☐	1 ☐	→ IF RESPONSE TO Q15d IS "YES", ASK Q15d.1.
e. Other	0 ☐	1 ☐	

If other, please specify:_____

➔ **15d.1. Have you been prescribed a CPAP or BIPAP machine, or a device to wear in your mouth to treat your sleep apnea?**

No 0 ☐
Yes 1 ☐

Medical History Questionnaire_Spanish
HCHS/SOL Sleep Ancillary Study

ID NUMBER:									FORM CODE: MQS VERSION: A 09/01/10	Contact Occasion		SEQ #	

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

0b. Staff ID: ☐☐☐

Instructions: Enter the answer given by the participant for each response. The special value, "Q", is allowed for cases where the response 'Don't know/refused' is not listed as an option. If age onset is unknown enter the special missing value, "==", in the item.

¿Tuvo usted algunas de las siguientes enfermedades?

1. ¿Alguna vez le ha dicho un doctor que usted tiene presión sanguínea alta o hipertensión?
   No 0 ☐
   Sí 1 ☐ → FOR WOMEN: GO TO QUESTION 1a

   1a. ¿Sucedió esto durante el embarazo solamente?
   No 0 ☐
   Sí 1 ☐

2. ¿Alguna vez le ha dicho un doctor que usted tiene angina de pecho?
   No 0 ☐
   Sí 1 ☐

3. ¿Alguna vez le ha dicho un doctor que usted tuvo un ataque al corazón?
   No 0 ☐
   Sí 1 ☐

4. ¿Alguna vez le ha dicho un doctor que usted tuvo insuficiencia cardiaca o falla cardiaca?
   No 0 ☐
   Sí 1 ☐

5. ¿Alguna vez le ha dicho un doctor que usted tuvo algún otro problema del corazón?
   No 0 ☐
   Sí 1 ☐
   Si "sí", por favor especifique: _____

6. ¿Le han hecho procedimientos como angioplastia con balón, (para dilatarle los vasos del corazón), o le han puesto un "stent", o le han hecho cirugía de bypass del corazón?
   No 0 ☐
   Sí 1 ☐

ID NUMBER:									FORM CODE: MQS VERSION: A 09/01/10	Contact Occasion			SEQ #			

7. ¿Alguna vez algún doctor le ha dicho que usted tuvo un derrame cerebral, apoplejía, o ataque cerebral?

No 0 ☐
Sí 1 ☐

8. ¿Alguna vez le ha dicho un doctor que usted tuvo un derrame (ataque) cerebral pequeño o transitorio conocido como TIA en inglés?

No 0 ☐
Sí 1 ☐

9. ¿Le han hecho una angioplastia con balón (dilatación) o cirugía de las arterias del cuello para prevenir o corregir una apoplejía o derrame (ataque) cerebral?

No 0 ☐
Sí 1 ☐

10. ¿Alguna vez le ha dicho un doctor que usted tiene o tuvo un aneurisma en la aorta, un aneurisma aórtico abdominal (AAA, por sus siglas en ingles) o dilatación de su aorta?

No 0 ☐
Sí 1 ☐

11. ¿Alguna vez le ha dicho un doctor que usted tiene enfermedad arterial periférica (problemas con la circulación, arterias bloqueadas en sus piernas)?

No 0 ☐ → GO TO QUESTION 13
Sí 1 ☐

12. ¿Ha tenido usted un “bypass”, una angioplastia con balón, le han puesto un “stent”, o le han amputado una extremidad (pierna o pie) debido a esta condición?

No 0 ☐
Sí 1 ☐

13. ¿Alguna vez le ha dicho un doctor que usted tiene diabetes (azúcar alta en la sangre o en la orina)?

No 0 ☐ → GO TO QUESTION 14
Sí 1 ☐

13a. ¿A qué edad le dijeron esto por primera vez?

☐☐ Edad en años

13b.PARA MUJERES: ¿Fue esto durante el embarazo solamente?

No 0 ☐
Sí 1 ☐

13c. ¿Está usando insulina?

No 0 ☐ → GO TO QUESTION 14
Sí 1 ☐

13d. ¿Fue insulina la primera medicina que usó para la diabetes?

No 0 ☐
Sí 1 ☐

ID NUMBER:									FORM CODE: MQS VERSION: A 09/01/10	Contact Occasion			SEQ #			

14. ¿Alguna vez le ha dicho un doctor que usted tiene un problema para dormir o problemas del sueño?

No 0 ☐ → END QUESTIONNAIRE
Sí 1 ☐
No sabe 9 ☐ → END QUESTIONNAIRE

15. ¿Qué problemas del sueño le dijo que tiene?

	No	Sí	
a. Insomnio	0☐	1☐	
b. Síndrome de piernas inquietas	0☐	1☐	
c. Narcolepsia	0☐	1☐	
d. Apnea	0☐	1☐	→ IF RESPONSE TO Q15d IS "YES", ASK Q15d.1.
e. Otro	0☐	1☐	

Si otro, por favor especifique: _____

15d.1. ¿Alguna vez le han recetado usar una máquina (CPAP o BiPAP, por sus siglas en ingles) o algún dispositivo (aparato) para el tratamiento de la apnea del sueño?

No 0 ☐
Sí 1 ☐

Sueño – Sleep Habits in HCHS/SOL

Medical History (MQE/MQS) Question by Question Instructions

General Instructions

This section of the interview asks questions about personal medical history. The overall layout of this form starts with a determination of doctor-diagnosed medical conditions. Age of onset is determined for select conditions.

Question by Question Instructions

Q1 Question assesses participant history of doctor-diagnosed high blood pressure or hypertension. Occasionally, participants will indicate that their doctor told them they have "pre-hypertension". This should be coded as "no". Women who answer, "yes" to this question are administered a follow-up question, "Was this during pregnancy only" (Q1a). This question is asked because hypertension seen only during pregnancy is considered a different condition compared to women diagnosed with hypertension when not pregnant.

Q2 Questions assess personal history of angina. Angina pectoris or angina is caused by insufficient blood flow reaching part of the heart usually due to a narrowing of a coronary artery. Chest pain is a hallmark symptom of persons with angina. However, not all persons who experience chest pain have this condition. Therefore, it is important to check the yes box on this set of questions only if they can state that a doctor told them they had angina.

Q3 Questions assess personal history of heart attack. A heart attack is where a portion of the heart muscle has died from inadequate blood flow. The clinical name for heart attack is myocardial infarction.

Q4 Questions assess personal history of doctor diagnosed heart failure. Another clinical name for this condition is congestive heart failure or congestive cardiac failure. This diagnosis covers a variety of conditions in which the heart is unable to pump a sufficient amount of blood through the body. Heart failure should not be confused with heart attack or myocardial infarction.

Q5 Question designed to capture other types of heart problems not asked about in Q1-4. If the participant indicates yes, you are provided space to record the name of the condition.

Q6 Question assesses personal history of undergoing several cardiac procedures called a balloon angioplasty (or stent) and/or bypass surgery. Both procedures are designed to restore blood flow through coronary arteries which provide critical oxygen to the heart. A balloon angioplasty involves running a catheter from an artery in the thigh to the blocked coronary artery located on the outside wall of the heart. A small balloon attached to the catheter is then inflated to open up the passageway. Sometimes a "stent" is left to help maintain the opening.
A coronary artery bypass is sometimes referred to by its acronym "CABG" (pronounced 'cabbage'). This procedure uses healthy arteries harvested from other parts of the body which are

then used to ‘bypass’ damaged arteries supplying blood to the heart. The terms double and triple bypass mean that 2 and 3 arteries supplying blood to the heart have been surgically bypassed. You should check the ‘yes’ box on Q9 if the participant has had either an angioplasty or a bypass or both.

Q7 Question assesses personal history of doctor diagnosed stroke. An alternate clinical name for this condition is cerebrovascular accident (CVA). There are two major forms of stroke: 1) a thrombosis or embolism is when an artery which supplies oxygen to the brain is blocked, and 2) a hemorrhage is when one of these brain arteries bursts or leaks. Both forms of stroke can cause permanent damage to the brain. Stroke should not be confused with transient ischemic stroke, which is described below.

Q8 Question assesses personal history of doctor-diagnosed mini-stroke or transient ischemic attack (TIA). These mini-strokes can cause stroke-like symptoms caused by temporary blockages in the arteries supplying blood to the brain (confusion, numbness, weakness on one side of the body, etc). The short duration of symptoms is the main difference between TIA and stroke, which is assessed in Q7. Short duration is defined as less than 24 hours.

Q9 Question assesses personal history of balloon angioplasty or other surgery on the arteries of the neck to prevent a stroke. Balloon angioplasty (with or without a stent) can be used to clear blocked or partially blocked arteries in the neck which supply blood to the brain. A carotid endarterectomy can also be performed, in which the arteries in the neck are surgically opened and cleaned.

Q10 Question assesses personal history of abdominal aortic aneurysm (AAA) or ballooning of the aorta. The aorta is the largest artery in the body and is attached to the heart. All blood which has been replenished with oxygen by the heart passes through the aorta as it travels to other parts of the body. The ballooning of the aorta is caused by a weakness in the wall of this artery. Rupture of an AAA or weakened aneurysm can cause death.

Q11 Question assesses personal history of peripheral arterial disease (PAD) or blocked arteries of the legs. This condition is sometimes referred to as peripheral vascular disease (PVD). This condition is caused by partial blockages of the large arteries which supply blood to the lower extremities. It can cause pain when walking and in its more severe forms, pain while at rest, loss of sensation in the legs, and the need to amputate one or both legs due to gangrene (decay of tissue). If the participant indicates in Q11 that they had have PAD/PVD then you administer Q12, which inquires about treatment for this condition.

Q12 Question inquiries about the treatment for peripheral arterial disease. This question is only to be asked if participant responds “Yes” to Q11.

Q13 Questions assess personal history and age at onset of diabetes. Diabetes mellitus is a group of diseases in which the body cannot produce or effectively use insulin, a hormone which is used by the body to process sugars and other foods as energy for the body. This inability to process sugars and other energy sources can lead to chronically high levels of glucose circulating through the body. Some participants may indicate that a doctor has told them that they have “pre-

diabetes". These individuals do not meet the strict definition of diabetes and should be coded "no" on Q13.

Participants answering yes to Q13 are then administered Q13a-13d. These questions will be used to further classify those with diabetes (e.g., insulin-dependent diabetes). Q13a asks participant to estimate his/her age at diagnosis of diabetes. A code of "= =" is used when the participant states that the age of onset is "unknown".

Q13b should only be administered to women since it asks about diabetes during pregnancy (called gestational diabetes).

Q13c asks if they are being treated with insulin (which can be injected or administered by a pump). Those responding yes to this question are asked in Q13d if insulin was the first type of medicine used to treat their diabetes.

Q14 Question assesses personal history of doctor-diagnosed sleep disorders. If the participant is unsure of what you mean by sleep disorders, you can give examples such as insomnia and restless legs syndrome. Those responding "no or don't know" to this question or are not administered Q15 and 15d.1 and the questionnaire is finished. Those who respond "yes" to this question are then asked which sleep disorder they have.

Q15 Read each listed sleep disorder to the participant and check the box if they have the condition. Check all conditions that apply. Insomnia is the inability to sleep and/or the ability to remain asleep. Restless leg syndrome is characterized by the urge to move limbs in order to reduce uncomfortable sensations. Excessive daytime sleepiness is the primary symptom of narcolepsy. Sleep apnea is present when there are long pauses in breathing during sleep (e.g., 10 or more seconds between breaths) which cause lowered circulating oxygen levels in the bloodstream. Q15e is used to record any doctor-diagnosed sleep disorder not listed above. Check the box and write in the name of the disorder.

Interviewer can also use the following text in Spanish to explain sleep disorders:
a. Insomnio - es la incapacidad para dormir y / o la capacidad de permanecer dormido
b. Síndrome de piernas inquietas – cuando siente un deseo profundo de mover las piernas mientras está durmiendo o reposando
c. Narcolepsia – cuando se queda dormido(a) de repente, especialmente durante el día
d. Apnea – que deja de respirar mientras duerme

Q15d.1 This question is only asked if the participant responds "Yes" to Q15d, apnea. Assess whether the participant has been prescribed a CPAP or BIPAP machine to treat their sleep apnea. A continuous positive airway pressure (CPAP) device uses a small compressor to pump a controlled stream of air through a mask worn while sleeping. A bilevel positive airway pressure (BIPAP) device works in a similar fashion except that it provides differing air pressure level during breathing in as compared to when breathing out.

Sleep Attitudes
HCHS/SOL Sleep Ancillary Study

ID NUMBER: | | | | | | | | |

FORM CODE: SSE
VERSION: A 06/22/10

Contact Occasion | | |

SEQ # | | |

ADMINISTRATIVE INFORMATION

0a. Completion Date: | | | / | | | / | | | | | (Month / Day / Year)

0b. Staff ID: | | | |

Instructions: Enter the answer given by the participant for each response. The special value, "Q", is allowed for cases where the response 'Don't know/refused' is not listed as an option.

Sleep Attitudes

How much do you agree with each of the following statements?

	Completely agree	Mostly agree	Mostly disagree	Completely disagree
1. Snoring during sleep is normal.	1 ☐	2 ☐	3 ☐	4 ☐
2. If you did not sleep enough one night, you can make it up the next night.	1 ☐	2 ☐	3 ☐	4 ☐
3. Regular exercise is good for sleep.	1 ☐	2 ☐	3 ☐	4 ☐
4. A hot bath before bed helps with sleep.	1 ☐	2 ☐	3 ☐	4 ☐
5. A light snack before bed helps with sleep.	1 ☐	2 ☐	3 ☐	4 ☐
6. Leaving some time to unwind before bed helps with sleep.	1 ☐	2 ☐	3 ☐	4 ☐
7. Watching TV or listening to the radio while in bed is recommended for sleeping.	1 ☐	2 ☐	3 ☐	4 ☐
8. It is normal to fall asleep in class or church if the speaker is boring and long winded.	1 ☐	2 ☐	3 ☐	4 ☐
9. It is normal to feel very sleepy in the mid-afternoon.	1 ☐	2 ☐	3 ☐	4 ☐
10. If you do not get enough sleep, it can affect performance at work.	1 ☐	2 ☐	3 ☐	4 ☐
11. If you do not get enough sleep, it can result in higher risk of accidents.	1 ☐	2 ☐	3 ☐	4 ☐
12. If you do not get enough sleep, it can lead to health problems.	1 ☐	2 ☐	3 ☐	4 ☐

ID NUMBER:									FORM CODE: SSE VERSION: A 06/22/10	Contact Occasion			SEQ #			

	Completely agree	Mostly agree	Mostly disagree	Completely disagree
13. If you do not get enough sleep, it can make it difficult to get along with others.	1 ☐	2 ☐	3 ☐	4 ☐
14. A regular sleep schedule is important for getting good sleep.	1 ☐	2 ☐	3 ☐	4 ☐
15. Sleeping during the night is better than sleeping during the day.	1 ☐	2 ☐	3 ☐	4 ☐
16. Getting enough sleep each night is important for overall health.	1 ☐	2 ☐	3 ☐	4 ☐
17. Eight hours of sleep per night are needed to be fully rested.	1 ☐	2 ☐	3 ☐	4 ☐
18. Daytime naps or siestas are good for your health.	1 ☐	2 ☐	3 ☐	4 ☐
19. As you get older, you do not need as much sleep to feel rested.	1 ☐	2 ☐	3 ☐	4 ☐
20. Sleeping is a pleasurable activity.	1 ☐	2 ☐	3 ☐	4 ☐

Sleep Attitudes_Spanish
HCHS/SOL Sleep Ancillary Study

ID NUMBER:									FORM CODE: SSS VERSION: A 08/30/10	Contact Occasion		SEQ #	

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

0b. Staff ID: ☐☐☐

Instructions: Enter the answer given by the participant for each response. The special value, "Q", is allowed for cases where the response 'Don't know/refused' is not listed as an option.

Sleep Attitudes

¿Qué tan de acuerdo está usted con las siguientes frases?

	Completamente de acuerdo	Mayormente de acuerdo	Mayormente no estoy de acuerdo	Completamente no estoy de acuerdo
1. El roncar cuando dormimos es normal.	1 ☐	2 ☐	3 ☐	4 ☐
2. Si usted no durmió lo suficiente una noche lo puede recuperar la próxima noche.	1 ☐	2 ☐	3 ☐	4 ☐
3. El ejercicio en forma regular es bueno para el sueño.	1 ☐	2 ☐	3 ☐	4 ☐
4. Un baño caliente antes de ir a la cama ayuda a dormir.	1 ☐	2 ☐	3 ☐	4 ☐
5. Un bocadillo antes de ir a la cama ayuda a dormir.	1 ☐	2 ☐	3 ☐	4 ☐
6. Tomar tiempo para relajarse antes de ir a cama ayuda a dormir.	1 ☐	2 ☐	3 ☐	4 ☐
7. Ver televisión o escuchar la radio cuando está en la cama es recomendable para dormir.	1 ☐	2 ☐	3 ☐	4 ☐
8. Es normal que le dé sueño cuando está en la clase o en la iglesia si el orador es aburrido y el tema es largo.	1 ☐	2 ☐	3 ☐	4 ☐
9. Es normal que le dé sueño después del medio día.	1 ☐	2 ☐	3 ☐	4 ☐
10. Si usted no duerme lo suficiente le puede afectar el desempeño de su trabajo.	1 ☐	2 ☐	3 ☐	4 ☐

ID NUMBER:									FORM CODE: SSS VERSION: A 08/30/10	Contact Occasion			SEQ #			

	Completamente de acuerdo	Mayormente de acuerdo	Mayormente no estoy de acuerdo	Completamente no estoy de acuerdo
11. Si usted no duerme lo suficiente puede resultar en un riesgo más alto de accidentes.	1 ☐	2 ☐	3 ☐	4 ☐
12. Si usted no duerme lo suficiente puede resultar en problemas de salud.	1 ☐	2 ☐	3 ☐	4 ☐
13. Si usted no duerme lo suficiente puede hacer que no se lleve bien con los demás.	1 ☐	2 ☐	3 ☐	4 ☐
14. El tener un horario fijo para dormir es importante para la buena salud.	1 ☐	2 ☐	3 ☐	4 ☐
15. El dormir durante la noche es mejor que dormir durante el día.	1 ☐	2 ☐	3 ☐	4 ☐
16. El dormir lo suficiente todas las noches es importante para la salud.	1 ☐	2 ☐	3 ☐	4 ☐
17. Se necesitan ocho horas de dormir cada noche para estar bien descansado.	1 ☐	2 ☐	3 ☐	4 ☐
18. El dormitar durante el día o tomarse una siesta es bueno para la salud.	1 ☐	2 ☐	3 ☐	4 ☐
19. A medida que envejecemos, no necesitamos dormir tanto tiempo para sentirnos descansados.	1 ☐	2 ☐	3 ☐	4 ☐
20. El dormir es un acto placentero.	1 ☐	2 ☐	3 ☐	4 ☐

Sueño – Sleep Habits in HCHS/SOL

Sleep Attitudes (SSE/SSS) Question by Question Instructions

General Instructions:

The Sleep Attitudes Questionnaire is a 20-item measure created to assess participant perception of the importance of sleep and ideas about sleep hygiene. Views about various aspects of sleep (sleep hygiene, implications of poor sleep, outcomes, etc.) are addressed. Point out to participants that all 20 items on this instrument will have the same four response categories, which are: completely agree, mostly agree, mostly disagree, and completely disagree. Note that all the questions must be read to the participant and that the answer choices should still be repeated after each question.

Q1-Q20: Read the script exactly as it appears. You may re-read the answer options if the participant requests. When asking these questions, be careful to not comment on respondent's answers and to record answers in a non-judgmental manner. If you are asked about the meaning of specific questions, you should encourage participants to interpret questions in the way that makes the most sense to them. It is critical that you do not provide definitions or interpretations of these questions.

Work Schedule Questionnaire

ID NUMBER: | | | | | | | | |
Acrostic

FORM CODE: WSE
VERSION: A 09/13/10

Contact Occasion | | SEQ # | |

ADMINISTRATIVE INFORMATION

0a. Completion Date: | | / | | / | | | | | (Month / Day / Year)

0b. Staff ID: | | |

Instructions: Enter the answer given by the participant for each response. The special value, "Q", is allowed for cases where the response 'Don't know/refused' is not listed as an option.

A. Current Employment Status

1. Are you currently employed?
   - No 0 ☐ → GO TO QUESTION 2
   - Yes 1 ☐ → GO TO QUESTION 3

2. Are you either of the following:

	No	Yes
a. Homemaker (i.e. care for family home)	0 ☐	1 ☐ → END QUESTIONNAIRE
b. Student	0 ☐	1 ☐ → END QUESTIONNAIRE
c. Retired/Disabled	0 ☐	1 ☐ → END QUESTIONNAIRE
d. Unemployed/Seeking Work	0 ☐	1 ☐ → END QUESTIONNAIRE

3. In a typical week, how many hours do you work per week? *Please include time worked in all jobs you may have.*

| | | | Hours

4. How many jobs do you have?
   - One 1 ☐
   - Two 2 ☐
   - Three 3 ☐
   - More than three 4 ☐

5. How many months in a year did you work in the past year?

| | Months

6. In a typical week, how many days do you go to work per week?

| Number of days per week

7. On a typical day, do you have a regular work schedule?
   - No 0 ☐ → GO TO QUESTION 10
   - Yes 1 ☐

ID NUMBER:									FORM CODE: WSE VERSION: A 09/13/10	Contact Occasion			SEQ #			

8. When do you usually begin work? ☐☐:☐☐ __ __
am/pm

9. When do you usually end work? ☐☐:☐☐ __ __
am/pm

10. How many days per month do you work extra hours beyond your usual schedule?
☐☐ Days per month

11. Which of the following best describes your usual work schedule? (*Mark only one*)

Day shift	1	☐
Afternoon shift	2	☐
Night Shift	3	☐
Split Shift	4	☐
Irregular shift/on call	5	☐
Rotating shift	6	☐

12. At your current job(s), do you ever work the late night shift (after midnight)?
No 0 ☐ → GO TO QUESTION 14
Yes 1 ☐

13. Do you work the late night shift (after midnight)…?

Usually (at least 3 days per week)	1	☐
Sometimes (at least 1 day per week)	2	☐
Rarely (less than 1 day per week)	3	☐
On a rotating schedule	4	☐ (*Please specify*): _____

14. At your current job(s), do you ever work the early morning shift (start work before 6am)?
No 0 ☐→ GO TO QUESTION 16
Yes 1 ☐

15. Do you work the early morning shift (start work before 6am)…?

Usually (at least 3 days per week)	1	☐
Sometimes (at least 1 day per week)	2	☐
Rarely (less than 1 day per week)	3	☐
On a rotating schedule	4	☐ (*Please specify*): _____

16. On average, how long does it take for you to travel from home to work each day?
☐ Hours ☐☐ Minutes

17. On average, how long does it take for you to travel from work to home each day?
☐ Hours ☐☐ Minutes

Work Schedule Questionnaire_Spanish
HCHS/SOL Sleep Ancillary Study

ID NUMBER: ☐☐☐☐☐☐☐☐ FORM CODE: WSS VERSION: A 09/13/10 Contact Occasion ☐☐ SEQ # ☐☐

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) 0b. Staff ID: ☐☐☐

Instructions: Enter the answer given by the participant for each response. The special value, "Q", is allowed for cases where the response 'Don't know/refused' is not listed as an option.

A. Current Employment Status

1. ¿Trabaja actualmente?
   - No 0 ☐ → GO TO QUESTION 2
   - Sí 1 ☐ → GO TO QUESTION 3

2. ¿Es usted…?

	No	Sí	
a. Ama de casa (por ejemplo, cuida el hogar de la familia)	0 ☐	1 ☐ →	END QUESTIONNAIRE
b. Estudiante	0 ☐	1 ☐ →	END QUESTIONNAIRE
c. Retirado/Incapacitado	0 ☐	1 ☐ →	END QUESTIONNAIRE
d. Desempleado/Buscando Empleo	0 ☐	1 ☐ →	END QUESTIONNAIRE

3. En una semana típica, ¿Cuántas horas trabaja en su(s) empleo(s)?
   ☐☐☐ Horas

4. ¿Cuántos trabajos tiene?
   - Uno 1 ☐
   - Dos 2 ☐
   - Tres 3 ☐
   - Más de tres 4 ☐

5. ¿Cuántos meses del año trabajó usted durante el último año?
   ☐☐ Meses

6. En una semana típica, ¿cuántos días a la semana va usted a trabajar?
   ☐ Número de días a la semana

7. En un día típico, ¿tiene usted un horario de trabajar regular?
   - No 0 ☐ → GO TO QUESTION 10
   - Sí 1 ☐

8. ¿A qué hora comienza usted a trabajar normalmente? ☐☐:☐☐ __ __ am/pm

9. ¿A qué hora termina usted de trabajar normalmente? ☐☐:☐☐ __ __ am/pm

10. ¿Cuántos días al mes trabaja usted horas adicionales además de su horario normal de trabajo?

☐☐ Días al mes

11. ¿Cuál de los siguientes turnos describe mejor su horario <u>normal</u> de trabajo? (*Mark only one*)

Turno de la mañana	1 ☐
Turno de la tarde	2 ☐
Turno de la noche	3 ☐
Turno dividido en dos	4 ☐
Turno irregular/ estar disponible cuando se le necesite	5 ☐
Turnos rotativos	6 ☐

12. En su trabajo actual, ¿alguna vez trabaja tarde durante el turno de la noche (después de la medianoche)?

No 0 ☐ → GO TO QUESTION 14
Sí 1 ☐

13. ¿Trabaja usted en el turno de la noche (después de la medianoche)…?

Usualmente (al menos 3 días a la semana)	1 ☐
A veces (al menos 1 día a la semana)	2 ☐
Raramente (menos de 1 día a la semana)	3 ☐
Rotativamente	4 ☐ (*Por favor, especifique*): _____

14. ¿Trabaja usted en el turno de la mañana (antes de las 6 AM)?

No 0 ☐→ GO TO QUESTION 16
Sí 1 ☐

15. ¿Trabaja usted en el turno de la mañana (antes de las 6AM)…?

Usualmente (al menos 3 días a la semana)	1 ☐
A veces (al menos 1 día a la semana)	2 ☐
Raramente (menos de 1 día a la semana)	3 ☐
Rotativamente	4 ☐ (*Por favor, especifique*): _____

16. En un día típico, ¿cuánto tiempo le toma viajar de la casa al trabajo?

☐ Horas ☐☐ Minutos

17. En un día típico, ¿cuánto tiempo le toma viajar del trabajo a la casa?

☐ Horas ☐☐ Minutos

Sueño – Sleep Habits in HCHS/SOL

Work Schedule (WSE/WSS) Question by Question Instructions

General Instructions:
The questions on occupation are designed to learn about the participants' current work schedule and commute. Keep in mind that participants may have more than one job.

Question by Question Instructions:

Q1 This initial question will guide the administration of the questionnaire by classifying participants as currently working or not. Any person who is earning some income in return for the services or work they provide is considered employed. Participants who have retired from one job but are continuing to work at another job or who re-entered the labor force after retirement should answer 'yes' to this question. Students and homemakers should answer 'no' to this question. If a subjects answers 'no' on Q1, continue to Q2. If a subject answers 'yes' to Q1, skip to Q3.

Q2 Participants may need some clarification regarding what a homemaker is and how to define a student. If the participant requests clarification, the following definitions may be used:
a. HOMEMAKER Any person whose primary responsibility is caring for the children in their family and taking care of the home environment (*Alma de la casa*). This could also be a person whose primary responsibility is taking care of an ill person or elderly person at home. A person who is unemployed and looking for work is not considered a homemaker.
b. STUDENT Any person attending a community college, technical school, or university either part-time or full-time.
c. RETIRED/DISABLED Any person that has left the workforce due to retirement or because they are not able to work due to a disability. These people may be getting assistance from the government, but they are not currently working.
d. UNEMPLOYED/SEEKING WORK Any person not currently employed. These people may be receiving unemployment benefits or government assistance, but are not currently employed.
Despite the answer to Q2, if the person is unemployed the questionnaire should be ended after Q2.

Q3 A typical week can be understood as an average, common, or standard week. The participant should consider ALL of their jobs when determining their total hours worked per week. IMPORTANT: the Spanish translation of this question was changed to "En una semana típica,¿Cuántas horas trabaja en su(s) empleo(s)?" Please consider this when viewing earlier versions of this form.

Q4 This question asks how many jobs a participant currently has. Include both part-time and full-time jobs.

Q5 This is a standard question used to determine if a participant faces seasonal unemployment, which occurs often in the US.

Q6 A typical week can be understood as an average, common, or standard week. Participants should provide an average or estimate of the number of days worked. This will allow researchers to understand if participants' work, part-time, full time, or more than that. As with question 5, the interviewer will need to prompt the participant to consider ALL the participant's jobs when answering this question.

Q7 This question is intended to help researchers understand a number of issues related to sleep and health. A regular work schedule has predictable times and hours with little variation.

The question is used to begin a skip pattern that helps to identify those that do shift work and/or perform overtime work.

Q8 Participants should be directed to note the EARLIEST time that they start work ON A TYPICAL DAY.

Q9 Participants should be directed to note the LATEST time that they end work ON A TYPICAL DAY.

Q10 The goal of this question is to determine if the participant works overtime all the time or only occasionally.

Q11 This question should refer to the participant's PRIMARY job identified in Q3. Many people work in shifts. The precise definitions of each shift may vary by an employer. However, if the participant needs clarification on the meaning or hours typically associated with each of these shifts, the following definitions can be provided with the understanding that the times may vary by 1-2 hours:

DAY SHIFT: The day shift will typically be between 6am-2pm or 9am-5pm.

AFTERNOON SHIFT: The afternoon shift will typically be 2pm-10pm or 3pm-11pm

NIGHT SHIFT: The night shift will typically be 10pm-6am or 11pm-7am

SPLIT SHIFT: A person with a split shift works twice over a day with 2 or more hours between work periods. For example, they might regularly work both four hours in the day and four hours in night shift on some days.

IRREGULAR SHIFT OR ON-CALL: A person with an irregular shift is one who works when called and never knows his/her shift for certain.

ROTATING SHIFT: A rotating shift means that you work one type of shift sometimes and another at other times. However, this is systematic. You know which shift you will work on each day.

Q12 It is important to learn if the person has EVER worked after midnight in any of their current jobs. They might work a different shift now but in the past, they did work at night. Or if they work the night shift now then this answer will automatically be coded 'yes.'

Q13 Because working at night is felt to be particularly difficult, we are interested in continuing to probe this topic. This question asks if the night work noted in Q12 is on a regular basis or if it only occurs occasionally or on a rotating basis.

Q14 It is important to learn if the person has EVER worked in the early morning (before 6am) in any of their current jobs. They might work a different shift now but in the past, they worked in the early morning.

Q15 We are interested in continuing to probe this topic. This question asks if the early morning work noted in Q14 is on a regular basis or if it only occurs occasionally or on a rotating basis

Q16 Commute time may be an important factor that limits sleep duration. In this question, the amount of time that it takes someone to get from home to their first job of the day (whether they take public transportation, carpool, drive themselves, walk, etc.) is assessed. If a person regularly runs errands during their commute (such as dropping children off at a child care provider), please include this time in the response.

Q17 Since commute times to and from work may be different, a second question is asked to determine the time it takes for the participant to travel home after their last job.

Sleep Questionnaire
HCHS/SOL Sleep Ancillary Study

ID NUMBER:									FORM CODE: SPE VERSION: A 08/16/10	Contact Occasion		SEQ #	

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) 0b. Staff ID: ☐☐☐

Instructions: Enter the answer given by the participant for each response. The special value, "Q", is allowed for cases where the response 'Don't know/refused' is not listed as an option.

The following <u>two</u> questions refer to the times you get in and out of bed in order to sleep (not including naps).

1. What time do you usually go to bed?

   a. On weekdays? ☐☐:☐☐ __ __ am/pm

   b. On weekends? ☐☐:☐☐ __ __ am/pm

2. What time do you usually wake up?

   a. On weekdays? ☐☐:☐☐ __ __ am/pm

   b. On weekends? ☐☐:☐☐ __ __ am/pm

3. During a usual week, how many times do you nap for 5 minutes or more?

   None 0 ☐
   1 or 2 times 1 ☐
   3 or 4 times 2 ☐
   5 or more times 3 ☐

The next questions ask about your sleep habits. Please choose *one* of the answers for each of the following questions. Pick the answer that best describes how often you experienced the situation in the *past 4 weeks.*

	No, not in the past 4 weeks	Yes, less than once a week	Yes, 1 or 2 times a week	Yes, 3 or 4 times a week	Yes, 5 or more times a week
4. Did you have trouble falling asleep?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
5. Did you wake up several times at night?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
6. Did you wake up earlier than you planned to?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
7. Did you have trouble getting back to sleep after you woke up too early?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
8. Did you take sleeping pills to help you sleep?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
9. Did you have sleep difficulties that made you very irritable?	1 ☐	2☐	3 ☐	4 ☐	5 ☐
10. Did you feel overly sleepy during the day?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

11. Overall, was your typical night's sleep during the past 4 weeks:

Very sound or restful	0 ☐
Sound or restful	1 ☐
Average quality	2 ☐
Restless	3 ☐
Very restless	4 ☐

12. What is the chance that you would doze off or fall asleep (not just "feel tired") in each of the following situations? If you are never or rarely in the situation, please give your best guess for what would happen. (*Choose one box for each item)*

	No Chance	Slight Chance	Moderate Chance	High Chance
a. Sitting and reading	1 ☐	2 ☐	3 ☐	4 ☐
b. Watching TV	1 ☐	2 ☐	3 ☐	4 ☐
c. Sitting inactive in a public place (such as a theater or a meeting)	1 ☐	2 ☐	3 ☐	4 ☐
d. Riding as a passenger in a car for an hour without a break	1 ☐	2 ☐	3 ☐	4 ☐
e. Lying down to rest in the afternoon when circumstances permit	1 ☐	2 ☐	3 ☐	4 ☐
f. Sitting and talking to someone	1 ☐	2 ☐	3 ☐	4 ☐
g. Sitting quietly after a lunch without alcohol	1 ☐	2 ☐	3 ☐	4 ☐
h. In a car, while stopped for a few minutes in traffic	1 ☐	2 ☐	3 ☐	4 ☐
i. At the dinner table	1 ☐	2 ☐	3 ☐	4 ☐
j. While driving	1 ☐	2 ☐	3 ☐	4 ☐

13. How often do you snore now? *(Mark only one)*

Never	1 ☐
Rarely (1-2 nights a week)	2 ☐
Sometimes (3-5 nights a week)	3 ☐
Always or almost always (6-7 nights a week)	4 ☐
Don't know	9 ☐

14. How often do you have times when you stop breathing during your sleep?

Never	1 ☐
Rarely (1-2 nights a week)	2 ☐
Sometimes (3-5 nights a week)	3 ☐
Always or almost always (6-7 nights a week)	4 ☐
Don't know	9 ☐

15. Do you ever experience a desire to move your legs because of discomfort or disagreeable sensations in your legs?

No	0 ☐	→ **END QUESTIONNAIRE**
Yes	1 ☐	
Don't know	9 ☐	→ **END QUESTIONNAIRE**

16. Do you sometimes feel the need to move to relieve the discomfort, for example by walking, or to relieve the discomfort by rubbing your legs?

No	0 ☐
Yes	1 ☐
Don't know	9 ☐

17. Are these symptoms worse when you are at rest, with at least temporary relief by activity?

No	0 ☐
Yes	1 ☐
Don't know	9 ☐

18. Are these symptoms worse later in the day or at night?

No	0 ☐
Yes	1 ☐
Don't know	9 ☐

Sleep Questionnaire_Spanish
HCHS/SOL Sleep Ancillary Study

ID NUMBER:									FORM CODE: SPS VERSION: A 09/01/10	Contact Occasion		SEQ #	

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) 0b. Staff ID: ☐☐☐

Instructions: Enter the answer given by the participant for each response. The special value, "Q", is allowed for cases where the response 'Don't know/refused' is not listed as an option.

Las siguientes <u>dos</u> preguntas se refieren a la hora que va a la cama a dormir y la hora que se levanta de la cama al despertarse (no incluye las siestas).

1. ¿A qué hora se va a dormir generalmente?

   a. Durante los días de semana ☐☐:☐☐ __ __ am/pm

   b. Durante los fines de semana ☐☐:☐☐ __ __ am/pm

2. ¿A qué hora se despierta generalmente?

   a. Durante los días de semana ☐☐:☐☐ __ __ am/pm

   b. Durante los fines de semana ☐☐:☐☐ __ __ am/pm

3. Durante una semana normal, ¿cuántas veces toma usted una siesta de 5 minutos o más?

Ninguna	0 ☐
1 o 2 veces	1 ☐
3 o 4 veces	2 ☐
5 veces o más	3 ☐

ID NUMBER:									VERSION: A 09/01/10	Occasion			SEQ #		

Las siguientes preguntas tratan de sus hábitos de dormir. Por favor, escoja una respuesta para cada pregunta. Escoja la respuesta que mejor describe con qué frecuencia se ha encontrado en cada situación durante las últimas *4 semanas.*

	No, no en las últimas 4 semanas	Sí, menos de una vez por semana	Sí. 1ó 2 veces por semana	Si, 3 ó 4 veces por semana	Si, 5 ó más veces por semana
4. ¿Tuvo problemas para quedarse dormido(a)?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
5. ¿Se despertó varias veces durante la noche?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
6. ¿Se despertó más temprano de lo que había planeado?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
7. ¿Tuvo problemas para quedarse dormido(a) nuevamente después de que se despertó más temprano de lo acostumbrado?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
8. ¿Toma pastillas para ayudarse a dormir?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
9. ¿Tuvo problemas para dormir que lo(a) hacían sentirse irritable?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
10. ¿Se sintió con mucho sueño durante el día?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

11. En general, ¿cómo ha dormido durante las noches normales en las últimas 4 semanas?

Muy profundo o muy descansado(a)	0 ☐
Profundo o descansado(a)	1 ☐
Más o menos bien	2 ☐
Intranquilo(a)	3 ☐
Muy intranquilo(a)	4 ☐

ID NUMBER: | VERSION: A 09/01/10 | Occasion | SEQ #

12. ¿Qué probabilidad hay de que usted se adormezca o se quede dormido(a) (no sólo "sentirse cansado(a)") en cada una de las siguientes situaciones? Si usted nunca se encuentra en tal situación o se encuentra en esa situación rara vez, por favor, dénos la respuesta que a su parecer, se parece mejor a lo que sucedería. Seleccione una opción para cada frase.

	Ninguna probabilidad	Poca probabilidad	Probabilidad moderada	Mucha probabilidad
a. Sentado(a) y leyendo	1 ☐	2 ☐	3 ☐	4 ☐
b. Viendo televisión	1 ☐	2 ☐	3 ☐	4 ☐
c. Sentado(a) y estando inactivo(a) en un lugar público (tal como en un teatro o en una reunión)	1 ☐	2 ☐	3 ☐	4 ☐
d. Ir como pasajero(a) en un automóvil durante una hora sin tomar un descanso	1 ☐	2 ☐	3 ☐	4 ☐
e. Recostarse a descansar en la tarde cuando las circunstancias lo permiten	1 ☐	2 ☐	3 ☐	4 ☐
f. Sentado(a) y hablando con alguien	1 ☐	2 ☐	3 ☐	4 ☐
g. Sentado(a) tranquilamente después de almorzar, sin haber tomado alcohol	1 ☐	2 ☐	3 ☐	4 ☐
h. En un automóvil, cuando se detiene por unos pocos minutos en el tráfico	1 ☐	2 ☐	3 ☐	4 ☐
i. En la mesa a la hora de cenar	1 ☐	2 ☐	3 ☐	4 ☐
j. Mientras maneja	1 ☐	2 ☐	3 ☐	4 ☐

13. ¿Con qué frecuencia ronca actualmente? *(Mark only one)*

Nunca	1 ☐
Rara vez (1a 2 noches por semana)	2 ☐
Algunas veces (3 a 5 noches por semana)	3 ☐
Siempre o casi siempre (6 a 7 noches por semana)	4 ☐
No sabe	9 ☐

14. ¿Con qué frecuencia tiene usted momentos cuando deja de respirar mientras duerme?

Nunca	1 ☐
Rara vez (1 a 2 noches por semana)	2 ☐
Algunas veces (3 a 5 noches por semana)	3 ☐
Siempre o casi siempre (6 a 7 noches por semana)	4 ☐
No sabe	9 ☐

ID NUMBER:									FORM CODE: SPS VERSION: A 09/01/10	Contact Occasion			SEQ #		

15. ¿Alguna vez ha sentido el deseo de mover sus piernas debido a la incomodidad o por sensaciones desagradables en sus piernas?

No	0 ☐	→ **END QUESTIONNAIRE**
Sí	1 ☐	
No sabe	9 ☐	→ **END QUESTIONNAIRE**

16. ¿Siente alguna vez la necesidad de moverse para aliviar la incomodidad, como por ejemplo caminar, o de aliviar la incomodidad frotando sus piernas?

No	0 ☐
Sí	1 ☐
No sabe	9 ☐

17. ¿Son estos síntomas peores cuando está descansando, pero con algún alivio temporal al realizar alguna actividad?

No	0 ☐
Sí	1 ☐
No sabe	9 ☐

18. ¿Son estos síntomas peores mas tarde en el día o durante la noche?

No	0 ☐
Sí	1 ☐
No sabe	9 ☐

Sueño – Sleep Habits in HCHS/SOL

Sleep Form (SPE/SPS) Question by Question Instructions

General Instructions:
This section of the interview asks about sleep patterns and symptoms of sleep disturbances.

Question by Question Instructions:

Q1-2. Ask the participant what (clock) times they usually go to bed in order to sleep. The participant should provide the times relative to their usual longest period in bed (i.e., not including naps). To clarify, ask participant to report bed and wake times that are most usual for them on their average weekday and weekend. If participant works or goes to school for most of the year, ask them to report the times they would go to bed and wake when following this schedule. If they are a shift worker, they should provide the most frequent times they go to sleep for a period that includes their longest sleep period (e.g., if working the night shift, this may be 7 AM to 2 PM). The clock times should reflect times from "lights off" to arising from bed. For example, if they read in bed, or watch TV in bed before sleep, they should report the times they turn off the light and close their eyes in an attempt to sleep. If they lay in bed awake in the morning, they should report the times they actually get out of bed. Part A refers to their schedule on weekdays and Part B for weekends. Sleep schedules may vary during vacation times compared to work or school times. If so, they should report usual weekend and weekday times for the times of the year when working or going to school versus other days, unless they only work or go to school for a minority of the year. Check to make sure that the times for awakening occur after the times reported for falling asleep. Use a 12 hour clock time frame, and also check that AM and PM are checked appropriately. Provide information to the nearest minute.

Q3. A nap is defined as any period of sleep lasting at least 5 minutes aside from the major sleep period. Ask how often they nap for 5 or more minutes during a usual week. Include all naps whether they are voluntary (planned) or involuntary (unplanned). It does not matter if they nap in their usual sleep quarters or elsewhere, or fall asleep in a chair or bed.

Q4-10. Ask the participant to estimate how often they have experienced each of the identified symptoms over the prior 4 weeks. Interviewer should place emphasis on 4 weeks. If symptoms have varied over this period, the participant should estimate how often the symptom has occurred on average over this time.

Q4 refers to difficulty getting to sleep after turning off the lights for their longest sleep period.

Q5 refers to waking up 2 or more times during their longest sleeping period. These can be very short or long periods, and should be counted regardless of whether or not they got out of bed.

Q6 typically refers to early morning awakenings – waking up earlier than they intended or needed to, or earlier than the alarm clock was set with regards to the major sleep period.

Q7 refers to problems getting back to sleep if waking up too early. If they answered 'no' to Q6, they should answer 'no' to Q7.

Q8 refers to any use of sleeping pills to help them sleep over the last 4 weeks. These may be prescription (e.g., Ambien) or non-prescription medications, such as anti-histamines, including herbal remedies that come in pill form.
Q9 refers to their assessment of whether sleep problems made them feel grumpy – this could be based on self impression or what others have told them.
Q10 refers to their self perception of feeling overly sleepy during the day. They do not need to report actual instances of falling asleep. Some people have trouble distinguishing tiredness or fatigue from sleepiness. Here, sleepiness refers to trouble staying awake and alert—not just tired.

Q11. Ask the participant to rate the quality of his usual night's sleep. Average quality refers to something midway between very sound to very restless—not perceived to be particularly restful or restless. It does not refer to what they think is the quality of the "average" person's sleep.

Q12. 12a-h. These questions make up the Epworth Sleepiness Scale, the most common assessment of daytime sleepiness. Ask the participant to rate his chance of dozing off (not just feeling tired) in each of the situations.
12a-j. If the person has never or only rarely engages in any given activity (e.g., driving), he should guess how likely he would fall asleep if he actually did that activity. 12c refers to activities where the participant may be sitting quietly in a public place, such as a movie theatre or a meeting hall or church, but does not refer to loud active places like a sports stadium. 12e. refers to situations where the participant can lay down and rest, whether it was a planned nap or not. 12h. refers to likelihood of dozing while driving a car and stopped for a few minutes in traffic or at a traffic light. 12i. refers to sitting at the dinner table for a meal. 12j. refers to any likelihood of dozing while driving a car.

Q13-14. Ask the participant to estimate his frequency of snoring (Q 13) (or stop breathing, Q 14) over a typical week (number of nights per week.) If the participant's usual sleep time is in the day (i.e, shift workers), he should estimate his sleeping frequency during his longest period of sleeping in the day. He can report these symptoms based on his own perceptions or based on what others have told him. He does not have to judge how loudly his snoring was to answer this question. If he only knows how often he snored or stopped breathing in the past (because there were people who witnessed his sleep in the past but not the present) he should answer the question based on the most recent information he is aware of. 'Stop breathing' may include breathing pauses followed by snorting sounds.

Q15. Ask the participant whether he ever experiences a need to move his legs because of uncomfortable feelings in his calves. This should not include feelings that his feet "fell asleep" or were "numb" but refer to more of an irritating, creeping, crawling sensation. If answering no, then do not ask Q16-17.

Q16. If answered yes to Q15, then ask (Q16) if this disagreeable feeling results in a need to move his legs with walking, or rub his legs, to relieve this sensation?

Q17. If answered yes to Q15, then ask the participant if these leg symptoms are usually worse when resting and feel at least temporarily better by moving the legs. If they report they are worse at rest but not better with movement, answer 'no' to Q 17.

Q18 Ask if these leg symptoms are worse later in the day or at night compared to earlier in the day. If participant asks for clarification, later in the day can be defined as 6 pm – midnight.

Neighborhood Stress
HCHS/SOL Sleep Ancillary Study

ID NUMBER:									FORM CODE: NSE VERSION: A 08/10/10	Contact Occasion		SEQ #	

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

0b. Staff ID: ☐☐☐

Instructions: Enter the answer given by the participant for each response. The special value, "Q", is allowed for cases where the response 'Don't know/refused' is not listed as an option.

Neighborhood Stress

Things about people's neighborhoods may be important to their health. Now we would like to ask you some questions about what it is like to live in your neighborhood. By neighborhood we mean the area around where you live and around your house. It may include places you shop, religious or public institutions, or a local business district. It is the general area around your house where you might perform routine tasks, such as shopping, going to the park, or visiting with neighbors. Please take the time to answer carefully, but do not spend too much time on any one question. Remember that there are no right or wrong answers.

1. How many blocks are in the area that you think of as your neighborhood? ☐☐

2. How long have you lived in this neighborhood? (years OR months)
☐☐ Years : or ☐☐ Months

For each of the following statements, please tell me whether you agree by choosing the best option.

	Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly Disagree
3. This is a close-knit neighborhood	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
4. People around here are willing to help their neighbors	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
5. People in this neighborhood generally don't get along with each other	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
6. People in this neighborhood can be trusted	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
7. People in this neighborhood do not share the same values	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

ID NUMBER:									FORM CODE: NSE VERSION: A 08/10/10	Contact Occasion			SEQ #			

8. How safe from crime do you consider your neighborhood to be? Please rate on a scale from 1 to 5.

Very safe	1 ☐
	2 ☐
Safe	3 ☐
	4 ☐
Not at all safe	5 ☐

Think about your neighborhood as a whole, then please choose the response for each of the following to show how much of a problem each one is in your neighborhood.

	Very serious Problem	Somewhat serious problem	Minor problem	Not really a problem
9. Excessive noise	1 ☐	2 ☐	3 ☐	4 ☐
10. Heavy traffic or speeding cars	1 ☐	2 ☐	3 ☐	4 ☐
11. Lack of access to adequate food shopping	1 ☐	2 ☐	3 ☐	4 ☐
12. Lack of parks or playgrounds	1 ☐	2 ☐	3 ☐	4 ☐
13. Trash and litter	1 ☐	2 ☐	3 ☐	4 ☐
14. No sidewalks or poorly maintained sidewalks	1 ☐	2 ☐	3 ☐	4 ☐
15. Violence	1 ☐	2 ☐	3 ☐	4 ☐

Neighborhood Stress_Spanish
HCHS/SOL Sleep Ancillary Study

ID NUMBER: ☐☐☐☐☐☐☐☐ FORM CODE: NSS VERSION: A 08/18/10 Contact Occasion ☐☐ SEQ # ☐☐

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) 0b. Staff ID: ☐☐☐

Instructions: Enter the answer given by the participant for each response. The special value, "Q", is allowed for cases where the response 'Don't know/refused' is not listed as an option.

Neighborhood Stress

Los vecindarios (o barrios) donde vive la gente pueden ser importantes para la salud. Por ello nos gustaría hacerle unas preguntas sobre la vida en su vecindario. Por vecindario nos referimos a los alrededores de su casa, incluyendo por ejemplo los lugares donde hace las compras, instituciones públicas y religiosas, o un distrito de negocios local. Incluye los lugares donde hace cosas de la vida diaria, por ejemplo: donde compra, va al parque o visita a los vecinos. Tome el tiempo necesario para responder con exactitud, pero no pase demasiado tiempo en ninguna de las preguntas. Ninguna repuesta es más correcta que las demás.

1. ¿Cuántos bloques o manzanas tiene el área que usted considera su vecindario? ☐☐

2. ¿Cuánto tiempo ha vivido en este vecindario? (años y/o meses) ☐☐ Años : y/o ☐☐ Meses

Para cada una de las siguientes afirmaciones, díganos si está de acuerdo o no seleccionando la opción más apropiada.

	Totalmente de acuerdo	De acuerdo	Ni de acuerdo ni en desacuerdo	En desacuerdo	Totalmente en desacuerdo
3. En este vecindario la gente está muy unida	1☐	2☐	3☐	4☐	5☐
4. Las personas aquí están dispuestas a ayudar a los vecinos	1☐	2☐	3☐	4☐	5☐
5. Las personas de este vecindario en general no se llevan bien entre sí	1☐	2☐	3☐	4☐	5☐
6. Se puede confiar en las personas de este vecindario	1☐	2☐	3☐	4☐	5☐
7. Las personas en este vecindario no comparten los mismos valores	1☐	2☐	3☐	4☐	5☐

ID NUMBER:									FORM CODE: NSS VERSION: A 04/01/10	Contact Occasion			SEQ #			

8. En relación con la delincuencia, ¿es seguro su vecindario? Por favor evalúelo basado en una escala de 1 a 5:

Muy seguro	1 ☐
	2 ☐
Seguro	3 ☐
	4 ☐
Muy inseguro	5 ☐

Piense en su vecindario, luego indique la opción correspondiente si cada una de las situaciones que aparecen a continuación es un problema en su vecindario

	Problema muy grave	Problema grave	Problema menor	No es realmente un problema
9. Ruido excesivo	1 ☐	2 ☐	3 ☐	4 ☐
10. Mucho tráfico o automóviles que van muy rápido	1 ☐	2 ☐	3 ☐	4 ☐
11. No hay donde comprar buena comida	1 ☐	2 ☐	3 ☐	4 ☐
12. Falta de parques o lugares para jugar o hacer deportes	1 ☐	2 ☐	3 ☐	4 ☐
13. Basura y desperdicios	1 ☐	2 ☐	3 ☐	4 ☐
14. Falta de aceras o aceras en mal estado	1 ☐	2 ☐	3 ☐	4 ☐
15. Violencia	1 ☐	2 ☐	3 ☐	4 ☐

Sueño – Sleep Habits in HCHS/SOL

Neighborhood Stress (NSE/NSS) Question by Question Instructions

The neighborhood stress scale is a measure of stress associated with the conditions in one's external living environment. These items assess such factors as neighborhood support, safety, cleanliness, noise level, and accessibility to resources. Note that this measure has items with very different response options and multiple parts.

Read the script exactly as it appears. Carefully and slowly read the description of what 'neighborhood' refers to in the instructions. If they ask any questions about how they should define neighborhood, you should prompt participants to define neighborhood in whatever way is most meaningful to them. Proceed by asking each question and then reading each response category. You may re-read the answer options if the participant requests. When asking these questions, you should be careful to not comment on respondent's answers and to record answers in a non-judgmental manner.

Q1 Question asks about how many blocks the participant considers to be his or her neighborhood. Participant should define their neighborhood in whatever manner is most meaningful to him/her.
SPANISH: Se debe definir 'barrio' en cualquier manera que prefiere.

Q2 Participants are asked how long they have lived in their neighborhood in years and months. If the participant only states the answer in years, ask them if they can tell you months as well. For example, if the participant states that they lived in their neighborhood for five years, ask: *And how many months?*
SPANISH: ¿Cuántos meses?

Q3-Q7 Point out to participants that the next five statements will have the same five response categories, which are: strongly agree, agree, neither agree nor disagree, disagree, and strongly disagree. Then proceed to read each statement and each response option.

Q8 Ask participants to rate safety "on a scale of 1 to 5, with 1 being very safe, 3 safe, and 5 not at all safe". If asked clarify response item 2 as between safe and very safe and item 4 as between safe and not at all safe.

Q9-Q15 Point out to participants that the next seven statements will have the same four response categories, which are: very serious problem, somewhat serious problem, minor problem, and not really a problem. Then proceed to read each statement and each response option.

Sleep Questionnaire II
HCHS/SOL Sleep Ancillary Study

ID NUMBER:									FORM CODE: SQE VERSION: A 08/10/10	Contact Occasion		SEQ #	
Acrostic													

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

0b. Staff ID: ☐☐☐

Instructions: Enter the answer given by the participant for each response. The special value, "Q", is allowed for cases where the response 'Don't know/refused' is not listed as an option.

*Check the response for each item that best describes you during **the past two weeks**.*

1. Considering only your own "feeling best" rhythm, at what time would you get up if you were entirely free to plan your day?

5:00 – 6:30 am	1 ☐
6:30 – 7:45 am	2 ☐
7:45 – 9:45 am	3 ☐
9:45 – 11:00 am	4 ☐
11:00 am – 12:00 (noon)	5 ☐

2. During the first half hour after having woken in the morning, how tired do you feel?

Very tired	1 ☐
Fairly tired	2 ☐
Fairly refreshed	3 ☐
Very refreshed	4 ☐

3. At what time in the evening do you feel tired and, as a result, in need of sleep?

8:00 – 9:00 pm	1 ☐
9:00 – 10:15 pm	2 ☐
10:15 pm – 12:45 am	3 ☐
12:45 – 2:00 am	4 ☐
2:00 – 3:00 am	5 ☐

4. At what time of the day do you think that you reach your "feeling best" peak?

5:00 – 8:00 am	1 ☐
8:00– 10:00 am	2 ☐
10:00– 4:45 pm	3 ☐
5:00 – 9:45 pm	4 ☐
10:00– 4:45 am	5 ☐

5. One hears about "morning" and "evening" types of people. Which ONE of these types do you consider yourself to be?

Definitely a "morning" type.	1 ☐
Rather more a "morning" than an "evening" type	2 ☐
Rather more an "evening" than a "morning" type	3 ☐
Definitely an "evening" type	4 ☐

ID NUMBER:									FORM CODE: SQE VERSION: A 08/10/10	Contact Occasion			SEQ #			

*Check the response for each item that best describes you during **the past two weeks**.*

6. Please rate the current **SEVERITY** of your difficulty falling asleep.

None	0 ☐
Mild	1 ☐
Moderate	2 ☐
Severe	3 ☐
Very Severe	4 ☐

7. Please rate the current **SEVERITY** of your difficulty staying asleep.

None	0 ☐
Mild	1 ☐
Moderate	2 ☐
Severe	3 ☐
Very Severe	4 ☐

8. Please rate the current **SEVERITY** of your problem of waking up too early.

None	0 ☐
Mild	1 ☐
Moderate	2 ☐
Severe	3 ☐
Very Severe	4 ☐

9. How **SATISFIED**/dissatisfied are you with your current sleep pattern?

Very Satisfied	0 ☐
Satisfied	1 ☐
Neither Satisfied or Dissatisfied	2 ☐
Dissatisfied	3 ☐
Very Dissatisfied	4 ☐

10. In the past 2 weeks, have you had a problem with your sleep?

No 0 ☐ → GO TO QUESTION 14

Yes 1 ☐

11. To what extent do you consider your sleep problem to **INTERFERE** with your daily functioning (e.g. daytime fatigue, ability to function at work/ daily chores, concentration, memory, mood, etc.)?

Not at all interfering	0 ☐
A little	1 ☐
Somewhat	2 ☐
Much	3 ☐
Very much interfering	4 ☐

12. How **NOTICEABLE** to others do you think your sleeping problem is in terms of impairing the quality of your life?

Not at all noticeable	0 ☐
Barely	1 ☐
Somewhat	2 ☐
Much	3 ☐
Very much noticeable	4 ☐

ID NUMBER:									FORM CODE: SQE VERSION: A 08/10/10	Contact Occasion			SEQ #			

13. How **WORRIED**/distressed are you about your current sleep problem?
    - Not at all 0 ☐
    - A little 1 ☐
    - Somewhat 2 ☐
    - Much 3 ☐
    - Very much 4 ☐

14. Do you have a TV in your bedroom?
    - No 0 ☐ → GO TO QUESTION 16
    - Yes 1 ☐

*For this section, please check the response for each item that best describes you during **the past four weeks**.*

15. Do you ever use the TV to help you fall asleep?
    - No, not in the past 4 weeks 0 ☐
    - Yes, less than once a week 1 ☐
    - Yes, 1-2 times a week 2 ☐
    - Yes, 3-4 times a week 3 ☐
    - Yes, 5 or more times a week 4 ☐

16. Do you ever have a drink of alcohol to help you sleep?
    - No, not in the past 4 weeks 0 ☐
    - Yes, less than once a week 1 ☐
    - Yes, 1-2 times a week 2 ☐
    - Yes, 3-4 times a week 3 ☐
    - Yes, 5 or more times a week 4 ☐

17. Do you ever drink a non-alcoholic beverage like warm milk or herbal tea to help you sleep?
    - No, not in the past 4 weeks 0 ☐
    - Yes, less than once a week 1 ☐
    - Yes, 1-2 times a week 2 ☐
    - Yes, 3-4 times a week 3 ☐
    - Yes, 5 or more times a week 4 ☐

18. Do you ever use a natural or herbal medicine (like melatonin or valerian) to help you sleep?
    - No, not in the past 4 weeks 0 ☐
    - Yes, less than once a week 1 ☐
    - Yes, 1-2 times a week 2 ☐
    - Yes, 3-4 times a week 3 ☐
    - Yes, 5 or more times a week 4 ☐

19. Do you ever use an over-the-counter medicine (like Benadryl or Tylenol PM) to help you sleep?
    - No, not in the past 4 weeks 0 ☐
    - Yes, less than once a week 1 ☐
    - Yes, 1-2 times a week 2 ☐
    - Yes, 3-4 times a week 3 ☐
    - Yes, 5 or more times a week 4 ☐

ID NUMBER:									FORM CODE: SQE VERSION: A 08/10/10	Contact Occasion			SEQ #			

20. Do you ever use a prescription medicine (like trazodone or Ambien) to help you sleep?
    - No, not in the past 4 weeks 0 ☐
    - Yes, less than once a week 1 ☐
    - Yes, 1-2 times a week 2 ☐
    - Yes, 3-4 times a week 3 ☐
    - Yes, 5 or more times a week 4 ☐

21. On a typical day, how many cups of regular coffee (with caffeine) do you drink?
    ☐☐ cups

22. On a typical day, how many cups of regular tea (with caffeine) do you drink?
    ☐☐ cups

23. On a typical day, how many glasses or cans of cola or other soda with caffeine do you drink?
    ☐☐ glasses or cans

24. One a typical day, how many shots, cans or bottles of a caffeinated energy drink do you drink?
    ☐☐ shots, cans or bottles

25. Do you ever use caffeinated drinks (coffee, soda, energy drinks, etc.) to help you stay awake?
    - No, not in the past 4 weeks 0 ☐
    - Yes, less than once a week 1 ☐
    - Yes, 1-2 times a week 2 ☐
    - Yes, 3-4 times a week 3 ☐
    - Yes, 5 or more times a week 4 ☐

Sleep Questionnaire II_Spanish
HCHS/SOL Sleep Ancillary Study

ID NUMBER:									FORM CODE: SQS VERSION: A 10/14/10	Contact Occasion		SEQ #	

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) 0b. Staff ID: ☐☐☐

Instructions: Enter the answer given by the participant for each response. The special value, "Q", is allowed for cases where the response 'Don't know/refused' is not listed as an option.

*Marque la respuesta por cada pregunta que mejor lo/la describa durante **las últimas dos semanas.***

1. Considerando únicamente su propio ritmo, ¿a qué hora se levantaría usted si fuera enteramente libre para planificar el día?

5:00 – 6:30 am	1 ☐
6:30 – 7:45 am	2 ☐
7:45 – 9:45 am	3 ☐
9:45 – 11:00 am	4 ☐
11:00 am – 12:00 (mediodía)	5 ☐

2. Durante la primera media hora después de haberse despertado por la mañana se encuentra usted

Muy cansado	1 ☐
Bastante cansado	2 ☐
Bastante descanzado	3 ☐
Muy descanzado	4 ☐

3. ¿A qué hora de la noche se encuentra usted cansado y siente la necesidad de dormir?

8:00 – 9:00 pm	1 ☐
9:00 – 10:15 pm	2 ☐
10:15 pm – 12:45 am	3 ☐
12:45 – 2:00 am	4 ☐
2:00 – 3:00 am	5 ☐

4. ¿A qué hora del día cree que se encuentra mejor?

5:00 – 8:00 am	1 ☐
8:00– 10:00 am	2 ☐
10:00– 4:45 pm	3 ☐
5:00 – 9:45 pm	4 ☐
10:00– 4:45 am	5 ☐

5. Suele hablarse de personas de tipo "matutino" y "vespertino". ¿De cuál de estos dos tipos se considera usted?

Claramente funciono mejor en la mañana.	1 ☐
Funciono más en la mañana que en la tarde.	2 ☐
Funciono más en la tarde que en la mañana.	3 ☐
Claramente funciono mejor en la tarde.	4 ☐

ID NUMBER:									FORM CODE: SQS VERSION: A 10/14/10	Contact Occasion			SEQ #			

Marque la respuesta por cada pregunta que mejor lo/la describa durante ***las últimas dos semanas.***

6. Indique la severidad de su dificultad para iniciar el sueño.

Ninguna	0 ☐
Ligera	1 ☐
Moderada	2 ☐
Grave	3 ☐
Mucha	4 ☐

7. Indique la severidad de su dificultad para mantener el sueño.

Ninguna	0 ☐
Ligera	1 ☐
Moderada	2 ☐
Grave	3 ☐
Mucha	4 ☐

8. Indique la severidad de que se despierta demasiado pronto:

Ninguna	0 ☐
Ligera	1 ☐
Moderada	2 ☐
Grave	3 ☐
Mucha	4 ☐

9. Indique como está usted de satisfecho/descontento con su patrón de sueño actual:

Muy Satisfecho	0 ☐
Satisfecho	1 ☐
Ni satisfecho ni descontento	2 ☐
No Satisfecho	3 ☐
Muy descontento	4 ☐

10. En las últimas dos semanas, ¿ha tenido problemas con su sueño?

No	0 ☐ → GO TO QUESTION 14
Sí	1 ☐

11. Indique hasta que punto considera que su problema del sueño **INTERFIERE** en su funcionamiento diario (rendimiento en el trabajo o en sus tareas diarias, fatiga, concentración, memoria, estado emocional, etc.):

En absoluto	0 ☐
Un poco	1 ☐
Bastante	2 ☐
Mucho	3 ☐
Muchísimo	4 ☐

12. Indique hasta que punto los demás se dan cuenta de su problema de sueño y de lo que deteriora su calidad de vida:

En absoluto	0 ☐
Un poco	1 ☐
Bastante	2 ☐
Mucho	3 ☐
Muchísimo	4 ☐

ID NUMBER:									FORM CODE: SQS VERSION: A 10/14/10	Contact Occasion			SEQ #			

13. Indique hasta que punto le preocupa su problema de sueño actual:

En absoluto	0 ☐
Un poco	1 ☐
Bastante	2 ☐
Mucho	3 ☐
Muchísimo	4 ☐

14. ¿Tiene una televisión en su cuarto?

No	0 ☐ → GO TO QUESTION 16
Sí	1 ☐

*En esta sección, por favor marque la respuesta por cada pregunta que mejor lo/la describa durante **las últimas cuatro semanas.***

15. ¿Alguna vez usa la televisión para ayudarse a dormir?

No, no en las últimas 4 semanas	0 ☐
Sí, menos de una vez por semana	1 ☐
Sí, 1-2 veces a la semana	2 ☐
Sí, 3-4 veces a la semana	3 ☐
Sí, 5 o más veces a la semana	4 ☐

16. ¿Alguna vez ha tomado un trago de alcohol para ayudarse a dormir?

No, no en las últimas 4 semanas	0 ☐
Sí, menos de una vez por semana	1 ☐
Sí, 1-2 veces a la semana	2 ☐
Sí, 3-4 veces a la semana	3 ☐
Sí, 5 o más veces a la semana	4 ☐

17. ¿Alguna vez ha tomado una bebida no alcohólica como leche caliente o té de hierbas para ayudarse a dormir?

No, no en las últimas 4 semanas	0 ☐
Sí, menos de una vez por semana	1 ☐
Sí, 1-2 veces a la semana	2 ☐
Sí, 3-4 veces a la semana	3 ☐
Sí, 5 o más veces a la semana	4 ☐

18. ¿Alguna vez ha tomado medicinas a base de hierbas o naturales (como melatonina o valeriana) para ayudarse a dormir?

No, no en las últimas 4 semanas	0 ☐
Sí, menos de una vez por semana	1 ☐
Sí, 1-2 veces a la semana	2 ☐
Sí, 3-4 veces a la semana	3 ☐
Sí, 5 o más veces a la semana	4 ☐

19. ¿Alguna vez ha tomado medicamentos sin receta (como Benadryl o Tylenol PM) para ayudarse a dormir?

No, no en las últimas 4 semanas	0 ☐
Sí, menos de una vez por semana	1 ☐
Sí, 1-2 veces a la semana	2 ☐
Sí, 3-4 veces a la semana	3 ☐
Sí, 5 o más veces a la semana	4 ☐

ID NUMBER:									FORM CODE: SQS VERSION: A 10/14/10	Contact Occasion			SEQ #			

20. ¿Alguna vez ha tomado medicamentos con receta (como trazodone o Ambien) para ayudarse a dormir?

No, no en las últimas 4 semanas	0 ☐
Sí, menos de una vez por semana	1 ☐
Sí, 1-2 veces a la semana	2 ☐
Sí, 3-4 veces a la semana	3 ☐
Sí, 5 o mas veces a la semana	4 ☐

21. En un día típico, ¿cuántas tazas de café regular (con cafeína) toma?

☐☐ tazas

22. En un día típico, ¿ cuántas tazas de té regular (con cafeína) toma?

☐☐ tazas

23. En un día típico, ¿ cuántos vasos o latas de cola u otra soda con cafeína toma?

☐☐ vasos o latas

24. En un día típico, ¿ cuántos tragos, latas o botellas de bebidas energéticas con cafeína toma?

☐☐ tragos, latas o botellas

25. ¿Alguna vez usa bebidas con cafeína (café, té, soda, o bebidas energéticas) para ayudarse a mantenerse despierto?

No, no en las últimas 4 semanas	0 ☐
Sí, menos de una vez por semana	1 ☐
Sí, 1-2 veces a la semana	2 ☐
Sí, 3-4 veces a la semana	3 ☐
Sí, 5 o más veces a la semana	4 ☐

Sueño – Sleep Habits in HCHS/SOL

Sleep Questionnaire II (SQE/SQS) Question by Question Instructions

General Instructions:
This section of the interview asks additional questions about sleep patterns and impact of sleep problems. These questions also explore sleep issues more in depth and/or assess different areas of sleep such as circadian rhythms, insomnia, and sleep hygiene.

Question by Question Instructions:

Q1-5. These questions make up the Horne and Östberg Reduced Morningness and Eveningness Questionnaire used to assess the participant's biological rhythm. Emphasize that the responses given in this section should pertain to the PAST 2 WEEKS. The answer choices for Q1, Q3 andQ4 are ranges in clock time. DO NOT present the answer choices to the participant initially. Instead, allow the participant to tell you the time of day and mark the corresponding answer choice. For these questions, if a participant answers a time that is earlier than the earliest answer choice, mark the earliest choice. If a participant answers a time that is later than the latest answer choose, mark the latest choice. If the participant reports a time that corresponds to multiple answer choices, read both answer choices to the participant and ask them to choose the best choice.

Q1. The goal of this question is to understand the timing of the participant's internal clock. Therefore, the question is in regards to what time the participant would wake up from sleep if he/she had no responsibilities (getting to work, taking children to school) to worry about and could organize their own day. Allow the participant to tell you the time of day and mark the corresponding answer choice.

Q2. This question asks how the participant feels after waking at their normal waking time, not the time they chose on Q1.

Q4 A participant's "feeling best" peak is the time when the participant feels the most alert and energized. If the participant is unsure what a "feeling best" peak means, define this term as the time they feel the most alert and full of energy. Allow the participant to tell you the time of day and mark the corresponding answer choice.

Q5 If the participant is unsure what "morning" and "evening" types of people are, define these terms. A "morning" type tends to be more alert and full of energy in the morning whereas an "evening" type tends to be more alert and full of energy in the evening.

Q6-Q13. These questions make up the Insomnia Severity Index. Emphasize that for these questions that the participant is supposed to think about their PAST 2 WEEKS of sleep when answering these questions. Some participants do not have any insomnia symptoms ('no' response to Q10); in this case Q11-13 will be skipped.

Q6. This question refers to the severity of the participant's difficulty getting to sleep after turning off the lights for their longest sleep period.

Q7. This question refers to the severity of the participant's difficulty staying asleep for their longest sleep period. This can be because he/she wakes up frequently or has difficulty falling back to sleep after having woken up.

Q8. This question refers to the severity of the participant's ability to sleep for the entire time set aside for sleep – waking up earlier than they intended or needed to, or earlier than the alarm clock was set – with regards to their longest sleep period.

Q9. This question refers to the participant's overall sleep pattern, not their sleep quality. Their sleep pattern includes when they are able to fall asleep and wake up, duration, and whether they nap. For instance, a participant may not be satisfied with the fact that he is not able to sleep at night, so he has to nap during the day and that impedes him from doing other activities.

Q10. This question assesses whether or not the participant feels like they have any problem with their sleep. This could include poor quality sleep or trouble falling/staying asleep. If participants answer 'no' to this question, skip to Q14

Q11. If participant answers 'yes' to Q10, then ask Q11. This question asks the participant to think of the problem or problems they indicated in Q10 and describe the level to which these problems interfere with their daily functioning.

Q12. If participant answers 'yes' to Q10, then ask Q12. Again, participants are supposed to refer to the problem(s) mentioned in Q10. For this question the participant is asked to describe how noticeable the impairment caused by their sleep problem or problems is to others.

Q13. If participant answers 'yes' to Q10, then ask Q13. Again, participants are supposed to refer to the problem(s) mentioned in Q10. For this question, participants are asked to describe how distressed or worried they are about their sleep problem or problems.

Q14. This question assesses whether the participant has a television in the room that they usually sleep in. The television must be functioning. However, it does not matter whether the participant watches television in that room. If a participant answers 'no' to this question, then skip to Q16.

Q15-20. These questions assess whether the participant uses any activity or supplement to help them fall asleep. Emphasize that this is in the PAST 4 WEEKS. Only mark 'yes' if the participant intentionally does these activities with the purpose of helping them fall or stay asleep.

Q21-22. For these questions emphasize that we are assessing how many cups of CAFFEINATED coffee or tea they may drink in a typical day over the PAST 4 WEEKS. If participant asks for clarification, a cup is 8oz or about the size of a typical, small Styrofoam cup. For example the "venti" (20oz) size from Starbucks would count as 2 cups on these questions. If a participant drinks "half-caf" (half regular and half decaffeinated coffee) then divide however many cups they drink per day by 2 (if this does not equal a whole number round up to the nearest whole number).

Q23. Again, emphasize that the participant should only include caffeinated soda intake per day over the past four weeks. Lemon-lime soda and root-beer, among others, do not usually include caffeine. If the participant asks for clarification, a can of soda is 12oz. If someone drinks a 20oz bottle of soda that would count as 2 glasses or cans of soda. If someone drinks a 2 liter bottle of soda that would count as 5 glasses or cans.

Q24. Again, emphasize that the participant should only count caffeinated energy drinks . Energy drinks come in all sizes, so just record the number of individually packaged (shots, cans, bottles) caffeinated energy drinks that the participant ingests on a typical day.

Acculturation Stress
HCHS/SOL Sleep Ancillary Study

ID NUMBER:									FORM CODE: ATE VERSION: A 04/01/10	Contact Occasion		SEQ #	

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) 0b. Staff ID: ☐☐☐

Instructions: Enter the answer given by the participant for each response. The special value, "Q", is allowed for cases where the response 'Don't know/refused' is not listed as an option.

Acculturation Stress: Hispanic Stress Inventory

Please answer 'yes' or 'no' to indicate whether the following situations have occurred to you during the last 3 months. Then if it did occur to you, indicate how worried or tense the situation made you feel. Remember there is no right or wrong answer so try and be as honest as you can.

1. Because I do not know enough English, it has been difficult for me to interact with others.

No 0 ☐ → **GO TO QUESTION 2**
Yes 1 ☐

1a. How worried or tense have you been about it?

Not at all worried/tense 1 ☐
A little worried/tense 2 ☐
Moderately worried/tense 3 ☐
Very worried/tense 4 ☐
Extremely worried/tense 5 ☐

2. My spouse and I have disagreed on how to bring up our children.

No 0 ☐ → **GO TO QUESTION 3**
Yes 1 ☐
N/A 9 ☐ → **GO TO QUESTION 3**

2a. How worried or tense have you been about it?

Not at all worried/tense 1 ☐
A little worried/tense 2 ☐
Moderately worried/tense 3 ☐
Very worried/tense 4 ☐
Extremely worried/tense 5 ☐

3. Because of my poor English people have treated me badly.

No 0 ☐ → **GO TO QUESTION 4**
Yes 1 ☐

ID NUMBER:									FORM CODE: ATE VERSION: A 04/01/10	Contact Occasion			SEQ #			

3a. How worried or tense have you been about it?

Not at all worried/tense	1 ☐
A little worried/tense	2 ☐
Moderately worried/tense	3 ☐
Very worried/tense	4 ☐
Extremely worried/tense	5 ☐

4. My children have not respected my authority the way they should.

No	0 ☐	→ **GO TO QUESTION 5**
Yes	1 ☐	
N/A	9 ☐	→ **GO TO QUESTION 5**

4a. How worried or tense have you been about it?

Not at all worried/tense	1 ☐
A little worried/tense	2 ☐
Moderately worried/tense	3 ☐
Very worried/tense	4 ☐
Extremely worried/tense	5 ☐

5. Because I am Latino I have been expected to work harder.

No	0 ☐	→ **GO TO QUESTION 6**
Yes	1 ☐	

5a. How worried or tense have you been about it?

Not at all worried/tense	1 ☐
A little worried/tense	2 ☐
Moderately worried/tense	3 ☐
Very worried/tense	4 ☐
Extremely worried/tense	5 ☐

6. My income has not been sufficient to support my family or myself.

No	0 ☐	→ **GO TO QUESTION 7**
Yes	1 ☐	

6a. How worried or tense have you been about it?

Not at all worried/tense	1 ☐
A little worried/tense	2 ☐
Moderately worried/tense	3 ☐
Very worried/tense	4 ☐
Extremely worried/tense	5 ☐

7. I have felt that my children's ideas about sexuality are too liberal.

No	0 ☐	→ **GO TO QUESTION 8**
Yes	1 ☐	
N/A	9 ☐	→ **GO TO QUESTION 8**

7a. How worried or tense have you been about it?

Not at all worried/tense	1 ☐
A little worried/tense	2 ☐
Moderately worried/tense	3 ☐
Very worried/tense	4 ☐
Extremely worried/tense	5 ☐

ID NUMBER:									FORM CODE: ATE VERSION: A 04/01/10	Contact Occasion			SEQ #			

8. There has been physical violence among members of my family.

No 0 ☐ → **GO TO QUESTION 9**
Yes 1 ☐

8a. How worried or tense have you been about it?

Not at all worried/tense 1 ☐
A little worried/tense 2 ☐
Moderately worried/tense 3 ☐
Very worried/tense 4 ☐
Extremely worried/tense 5 ☐

9. Because I am Latino I have had difficulty finding the type of work I want.

No 0 ☐ → **GO TO QUESTION 10**
Yes 1 ☐

9a. How worried or tense have you been about it?

Not at all worried/tense 1 ☐
A little worried/tense 2 ☐
Moderately worried/tense 3 ☐
Very worried/tense 4 ☐
Extremely worried/tense 5 ☐

10. My children have talked about leaving home.

No 0 ☐ → **GO TO QUESTION 11**
Yes 1 ☐
N/A 9 ☐ → **GO TO QUESTION 11**

10a. How worried or tense have you been about it?

Not at all worried/tense 1 ☐
A little worried/tense 2 ☐
Moderately worried/tense 3 ☐
Very worried/tense 4 ☐
Extremely worried/tense 5 ☐

11. My children have received bad school reports (or bad grades).

No 0 ☐ → **GO TO QUESTION 12**
Yes 1 ☐
N/A 9 ☐ → **GO TO QUESTION 12**

11a. How worried or tense have you been about it?

Not at all worried/tense 1 ☐
A little worried/tense 2 ☐
Moderately worried/tense 3 ☐
Very worried/tense 4 ☐
Extremely worried/tense 5 ☐

12. I have had to watch the quality of my work so others do not think I am lazy.

No 0 ☐ → **GO TO QUESTION 13**
Yes 1 ☐

ID NUMBER:									FORM CODE: ATE VERSION: A 04/01/10	Contact Occasion			SEQ #			

12a. How worried or tense have you been about it?

Not at all worried/tense	1 ☐
A little worried/tense	2 ☐
Moderately worried/tense	3 ☐
Very worried/tense	4 ☐
Extremely worried/tense	5 ☐

13. Because I am Latino it has been hard to get promotions or salary raises.

No	0 ☐	→ **GO TO QUESTION 14**
Yes	1 ☐	

13a. How worried or tense have you been about it?

Not at all worried/tense	1 ☐
A little worried/tense	2 ☐
Moderately worried/tense	3 ☐
Very worried/tense	4 ☐
Extremely worried/tense	5 ☐

14. I had serious arguments with family members.

No	0 ☐	→ **GO TO QUESTION 15**
Yes	1 ☐	

14a. How worried or tense have you been about it?

Not at all worried/tense	1 ☐
A little worried/tense	2 ☐
Moderately worried/tense	3 ☐
Very worried/tense	4 ☐
Extremely worried/tense	5 ☐

15. I have been forced to accept low paying jobs.

No	0 ☐	→ **GO TO QUESTION 16**
Yes	1 ☐	

15a. How worried or tense have you been about it?

Not at all worried/tense	1 ☐
A little worried/tense	2 ☐
Moderately worried/tense	3 ☐
Very worried/tense	4 ☐
Extremely worried/tense	5 ☐

16. There have been conflicts among members of my family.

No	0 ☐	→ **GO TO QUESTION 17**
Yes	1 ☐	

16a. How worried or tense have you been about it?

Not at all worried/tense	1 ☐
A little worried/tense	2 ☐
Moderately worried/tense	3 ☐
Very worried/tense	4 ☐
Extremely worried/tense	5 ☐

ID NUMBER:									FORM CODE: ATE VERSION: A 04/01/10	Contact Occasion			SEQ #			

17. I have felt pressured to learn English.

No 0 ☐ → **END QUESTIONNAIRE**
Yes 1 ☐

17a. How worried or tense have you been about it?

Not at all worried/tense 1 ☐
A little worried/tense 2 ☐
Moderately worried/tense 3 ☐
Very worried/tense 4 ☐
Extremely worried/tense 5 ☐

Acculturation Stress_Spanish
HCHS/SOL Sleep Ancillary Study

ID NUMBER:									FORM CODE: ATS VERSION: A 09/01/10	Contact Occasion		SEQ #	

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) 0b. Staff ID: ☐☐☐

Instructions: Enter the answer given by the participant for each response. The special value, "Q", is allowed for cases where the response 'Don't know/refused' is not listed as an option.

Acculturation Stress: Hispanic Stress Inventory

*Por favor responda "sí" o "no" para indicar si las siguientes situaciones le han ocurrido a usted en los últimos **3 meses**. Si le ocurrieron, indique que tan preocupado o tenso la situación lo ha hecho sentir. Si la situación mencionada no le ha ocurrido, conteste "no". Recuerde, no hay respuestas correctas o incorrectas. Por favor trate de ser honesto(a) con sus respuestas.*

1. Por no saber suficiente inglés ha sido difícil para mí socializar con otros.
   - No 0 ☐ → **GO TO QUESTION 2**
   - Sí 1 ☐

   1a. ¿Qué tan preocupado(a) o tenso(a) ha estado?
   - No preocupado/tenso 1 ☐
   - Un poco preocupado/tenso 2 ☐
   - Moderadamente preocupado/tenso 3 ☐
   - Muy preocupado/tenso 4 ☐
   - Extremadamente preocupado/tenso 5 ☐

2. Mi esposo(a) y yo hemos tenido desacuerdos acerca de cómo criar a nuestros hijos.
   - No 0 ☐ → **GO TO QUESTION 3**
   - Sí 1 ☐
   - N/A 9 ☐ → **GO TO QUESTION 3**

   2a. ¿Qué tan preocupado(a) o tenso(a) ha estado?
   - No preocupado/tenso 1 ☐
   - Un poco preocupado/tenso 2 ☐
   - Moderadamente preocupado/tenso 3 ☐
   - Muy preocupado/tenso 4 ☐
   - Extremadamente preocupado/tenso 5 ☐

3. Debido a mi mal inglés, la gente me ha tratado mal.
   - No 0 ☐ → **GO TO QUESTION 4**
   - Sí 1 ☐

3a. ¿Qué tan preocupado(a) o tenso(a) ha estado?

No preocupado/tenso	1 ☐
Un poco preocupado/tenso	2 ☐
Moderadamente preocupado/tenso	3 ☐
Muy preocupado/tenso	4 ☐
Extremadamente preocupado/tenso	5 ☐

4. Mis hijos(as) no han respetado mi autoridad en la forma que deberían.

No	0 ☐	→ **GO TO QUESTION 5**
Sí	1 ☐	
N/A	9 ☐	→ **GO TO QUESTION 5**

4a. ¿Qué tan preocupado(a) o tenso(a) ha estado?

No preocupado/tenso	1 ☐
Un poco preocupado/tenso	2 ☐
Moderadamente preocupado/tenso	3 ☐
Muy preocupado/tenso	4 ☐
Extremadamente preocupado/tenso	5 ☐

5. Debido a que soy latino(a) se ha esperado que trabaje más duro.

No	0 ☐	→ **GO TO QUESTION 6**
Sí	1 ☐	

5a. ¿Qué tan preocupado(a) o tenso(a) ha estado?

No preocupado/tenso	1 ☐
Un poco preocupado/tenso	2 ☐
Moderadamente preocupado/tenso	3 ☐
Muy preocupado/tenso	4 ☐
Extremadamente preocupado/tenso	5 ☐

6. Mis ingresos no han sido suficientes para mantener a mi familia o a mí mismo/a.

No	0 ☐	→ **GO TO QUESTION 7**
Sí	1 ☐	

6a. ¿Qué tan preocupado(a) o tenso(a) ha estado?

No preocupado/tenso	1 ☐
Un poco preocupado/tenso	2 ☐
Moderadamente preocupado/tenso	3 ☐
Muy preocupado/tenso	4 ☐
Extremadamente preocupado/tenso	5 ☐

7. He sentido que las ideas de mis hijos(as) acerca de la sexualidad son demasiado liberales.

No	0 ☐	→ **GO TO QUESTION 8**
Sí	1 ☐	
N/A	9 ☐	→ **GO TO QUESTION 8**

7a. ¿Qué tan preocupado(a) o tenso(a) ha estado?

No preocupado/tenso	1 ☐
Un poco preocupado/tenso	2 ☐
Moderadamente preocupado/tenso	3 ☐
Muy preocupado/tenso	4 ☐
Extremadamente preocupado/tenso	5 ☐

8. Ha habido violencia física entre miembros de mi familia.

No	0 ☐	→ **GO TO QUESTION 9**
Sí	1 ☐	

8a. ¿Qué tan preocupado(a) o tenso(a) ha estado?

No preocupado/tenso	1 ☐
Un poco preocupado/tenso	2 ☐
Moderadamente preocupado/tenso	3 ☐
Muy preocupado/tenso	4 ☐
Extremadamente preocupado/tenso	5 ☐

9. Debido a que soy latino(a) he tenido dificultad para encontrar el tipo de trabajo que quiero.

No	0 ☐	→ **GO TO QUESTION 10**
Sí	1 ☐	

9a. ¿Qué tan preocupado(a) o tenso(a) ha estado?

No preocupado/tenso	1 ☐
Un poco preocupado/tenso	2 ☐
Moderadamente preocupado/tenso	3 ☐
Muy preocupado/tenso	4 ☐
Extremadamente preocupado/tenso	5 ☐

10. Mis hijos(as) han hablado acerca de irse de la casa.

No	0 ☐	→ **GO TO QUESTION 11**
Sí	1 ☐	
N/A	9 ☐	→ **GO TO QUESTION 11**

10a. ¿Qué tan preocupado(a) o tenso(a) ha estado?

No preocupado/tenso	1 ☐
Un poco preocupado/tenso	2 ☐
Moderadamente preocupado/tenso	3 ☐
Muy preocupado/tenso	4 ☐
Extremadamente preocupado/tenso	5 ☐

11. Mis hijos(as) han recibido malas calificaciones en la escuela.

No	0 ☐	→ **GO TO QUESTION 12**
Sí	1 ☐	
N/A	9 ☐	→ **GO TO QUESTION 12**

11a. ¿Qué tan preocupado(a) o tenso(a) ha estado?

No preocupado/tenso	1 ☐
Un poco preocupado/tenso	2 ☐
Moderadamente preocupado/tenso	3 ☐
Muy preocupado/tenso	4 ☐
Extremadamente preocupado/tenso	5 ☐

12. He tenido que ser cuidadoso(a) con la calidad de mi trabajo para que otros no piensen que soy un(a) perezoso(a).

No	0 ☐	→ **GO TO QUESTION 13**
Sí	1 ☐	

12a. ¿Qué tan preocupado(a) o tenso(a) ha estado?

No preocupado/tenso	1 ☐
Un poco preocupado/tenso	2 ☐
Moderadamente preocupado/tenso	3 ☐
Muy preocupado/tenso	4 ☐
Extremadamente preocupado/tenso	5 ☐

13. Debido a que soy latino(a), ha sido difícil obtener ascensos o aumentos de salario.

No	0 ☐	→ **GO TO QUESTION 14**
Sí	1 ☐	

13a. ¿Qué tan preocupado(a) o tenso(a) ha estado?

No preocupado/tenso	1 ☐
Un poco preocupado/tenso	2 ☐
Moderadamente preocupado/tenso	3 ☐
Muy preocupado/tenso	4 ☐
Extremadamente preocupado/tenso	5 ☐

14. He tenido pleitos serios con miembros de mi familia.

No	0 ☐	→ **GO TO QUESTION 15**
Sí	1 ☐	

14a. ¿Qué tan preocupado(a) o tenso(a) ha estado?

No preocupado/tenso	1 ☐
Un poco preocupado/tenso	2 ☐
Moderadamente preocupado/tenso	3 ☐
Muy preocupado/tenso	4 ☐
Extremadamente preocupado/tenso	5 ☐

15. Me he visto forzado(a) a aceptar trabajos con salarios bajos.

No	0 ☐	→ **GO TO QUESTION 16**
Sí	1 ☐	

15a. ¿Qué tan preocupado(a) o tenso(a) ha estado?

No preocupado/tenso	1 ☐
Un poco preocupado/tenso	2 ☐
Moderadamente preocupado/tenso	3 ☐
Muy preocupado/tenso	4 ☐
Extremadamente preocupado/tenso	5 ☐

16. Ha habido pleitos entre miembros de mi familia.

No 0 ☐ → **GO TO QUESTION 17**
Sí 1 ☐

16a. ¿Qué tan preocupado(a) o tenso(a) ha estado?

No preocupado/tenso	1 ☐
Un poco preocupado/tenso	2 ☐
Moderadamente preocupado/tenso	3 ☐
Muy preocupado/tenso	4 ☐
Extremadamente preocupado/tenso	5 ☐

17. Me he sentido presionado(a) para aprender inglés.

No 0 ☐ → **END QUESTIONNAIRE**
Sí 1 ☐

17a. ¿Qué tan preocupado(a) o tenso(a) ha estado?

No preocupado/tenso	1 ☐
Un poco preocupado/tenso	2 ☐
Moderadamente preocupado/tenso	3 ☐
Muy preocupado/tenso	4 ☐
Extremadamente preocupado/tenso	5 ☐

Sueño – Sleep Habits in HCHS/SOL

Acculturation Stress (ATE/ATS) Question by Question Instructions

General Instructions: Hispanic Stress Inventory (HIS)

The HSI acculturation stress measure is a 17-item measure created for Latinos that taps stress associated with the process of integrating and existing in a non-native culture. Various aspects of acculturation such as language ability, relationships with children, work opportunities, family conflicts and moral standards are addressed. You should be aware of skip patterns for several of the questions and be sure to follow them as directed. It is important to present all answers to the participant including N/A (Not Applicable). Make sure to tell the participant that N/A (Not Applicable) should be the answer choice given if the participant does not have children in response to questions that ask about children. If the participant says "No" in response to a question asking about children, confirm that the participant is NOT responding this way because they do not have children. Note that all the questions must be read to the participant and request that he/she responded N/A (Not Applicable) regardless of if the participant verbally indicates he/she has no children or is not married.

Q1-Q17a: Read the script exactly as it appears. You may re-read the answer options if the participant requests. When asking these questions, be careful to not comment on respondent's answers and to record answers in a non-judgmental manner. If you are asked about the meaning of specific questions, you should encourage participants to interpret questions in the way that makes the most sense to them. It is critical that you do not provide definitions or interpretations of these questions.

Well-Being Questionnaire
HCHS/SOL Sleep Ancillary Study

ID NUMBER:									FORM CODE: WLE VERSION: A 08/16/10	Contact Occasion		SEQ #	

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ 0b. Staff ID: ☐☐☐

Instructions: Enter the answer given by the participant for each response. The special value, "Q", is allowed for cases where the response 'Don't know/refused' is not listed as an option.

A. CES-D 10

I am going to read a list of some of the ways you may have felt or behaved. Please indicate how often you have felt this way during the past week. Respond by saying "rarely or none of the time', meaning less than one day during the past week, 'some or a little of the time', meaning one to two days during the past week, 'occasionally or a moderate amount of time, meaning three to four days, or 'all of the time' meaning five to seven days. Choose only one of these categories for each item statement I read.

	Rarely or none of the time (<1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of time (3-4 days)	All of the time (5-7 days)
1. I was bothered by things that usually don't bother me.	0 ☐	1 ☐	2 ☐	3 ☐
2. I had trouble keeping my mind on what I was doing.	0 ☐	1 ☐	2 ☐	3 ☐
3. I felt depressed.	0 ☐	1 ☐	2 ☐	3 ☐
4. I felt that everything I did was an effort.	0 ☐	1 ☐	2 ☐	3 ☐
5. I felt hopeful about the future.	0 ☐	1 ☐	2 ☐	3 ☐
6. I felt fearful.	0 ☐	1 ☐	2 ☐	3 ☐
7. My sleep was restless.	0 ☐	1 ☐	2 ☐	3 ☐
8. I was happy.	0 ☐	1 ☐	2 ☐	3 ☐
9. I felt lonely.	0 ☐	1 ☐	2 ☐	3 ☐
10. I could not "get going".	0 ☐	1 ☐	2 ☐	3 ☐

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B. Spielberger Trait Anxiety Scale

I am now going to read you another list of statements. Do not spend too much time on any one statement but give the answer which seems to describe how you generally feel.

	Almost never	Sometimes	Often	Almost always
11. I feel nervous and restless.	0 ☐	1 ☐	2 ☐	3 ☐
12. I feel satisfied with myself.	0 ☐	1 ☐	2 ☐	3 ☐
13. I wish I could be as happy as others seem to be.	0 ☐	1 ☐	2 ☐	3 ☐
14. I feel like a failure.	0 ☐	1 ☐	2 ☐	3 ☐
15. I worry too much over something that really doesn't matter.	0 ☐	1 ☐	2 ☐	3 ☐
16. I lack self-confidence.	0 ☐	1 ☐	2 ☐	3 ☐
17. I feel secure.	0 ☐	1 ☐	2 ☐	3 ☐
18. I feel inadequate.	0 ☐	1 ☐	2 ☐	3 ☐
19. I am a steady person.	0 ☐	1 ☐	2 ☐	3 ☐
20. I get in a state of tension or turmoil as I think over my recent concerns and interests.	0 ☐	1 ☐	2 ☐	3 ☐

Well-Being Questionnaire_Spanish
HCHS/SOL Sleep Ancillary Study

ID NUMBER:									FORM CODE: WLS VERSION: A 08/30/10	Contact Occasion		SEQ #	

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ 0b. Staff ID: ☐☐☐

Instructions: Mark the appropriate box for the response. Unless instructed, mark ONLY one response.

A. CES-D 10

Aquí le presento una lista de frases que describen cómo pudo haberse sentido o comportado. Por favor, indique con qué frecuencia se ha sentido de esta manera durante la semana pasada. Puede responder con 'raramente o ninguna vez', que significa menos de un día a la semana, 'algunas veces o pocas veces, que significa uno a dos días a la semana, 'ocasionalmente o una cantidad de tiempo moderado', que significa tres o cuatro días a la semana o 'la mayor parte del tiempo, que significa cinco a siete días a la semana. Escoja una opción para cada frase.

	Raramente o ninguna vez (<1 día)	Algunas o pocas veces (1-2 días)	Ocasionalmente o una cantidad de tiempo moderado (3-4 días)	La mayor parte del tiempo (5-7 días)
1. Me molestaron cosas que usualmente no me molestan.	0 ☐	1 ☐	2 ☐	3 ☐
2. Tuve dificultad en mantener mi mente en lo que hacía.	0 ☐	1 ☐	2 ☐	3 ☐
3. Me sentí deprimido(a).	0 ☐	1 ☐	2 ☐	3 ☐
4. Sentí que todo lo que hacía era un esfuerzo.	0 ☐	1 ☐	2 ☐	3 ☐
5. Me sentí con esperanza en el futuro.	0 ☐	1 ☐	2 ☐	3 ☐
6. Me sentí con miedo.	0 ☐	1 ☐	2 ☐	3 ☐
7. Mi sueño fue inquieto.	0 ☐	1 ☐	2 ☐	3 ☐
8. Estuve contento(a).	0 ☐	1 ☐	2 ☐	3 ☐
9. Me sentí solo(a).	0 ☐	1 ☐	2 ☐	3 ☐
10. No tuve ganas de hacer nada.	0 ☐	1 ☐	2 ☐	3 ☐

ID NUMBER:								FORM CODE: WLS VERSION: A 08/30/10	Contact Occasion			SEQ #		

B. Spielberger Trait Anxiety Scale

Ahora le voy a presentar otra lista de frases. No tome mucho tiempo en cada frase pero escoja la respuesta que describa mejor cómo se siente generalmente.

	Casi nunca	A veces	A menudo	Casi siempre
11. Me siento nervioso(a) e inquieto(a).	0 ☐	1 ☐	2 ☐	3 ☐
12. Me siento satisfecho(a) conmigo mismo(a).	0 ☐	1 ☐	2 ☐	3 ☐
13. Desearía que pudiera ser tan feliz como otras personas parecen serlo.	0 ☐	1 ☐	2 ☐	3 ☐
14. Siento que soy un fracaso.	0 ☐	1 ☐	2 ☐	3 ☐
15. Me preocupo mucho por algo que realmente no vale la pena.	0 ☐	1 ☐	2 ☐	3 ☐
16. No tengo confianza en mí mismo(a).	0 ☐	1 ☐	2 ☐	3 ☐
17. Me siento seguro(a).	0 ☐	1 ☐	2 ☐	3 ☐
18. Me siento inadecuado(a).	0 ☐	1 ☐	2 ☐	3 ☐
19. Soy una persona estable.	0 ☐	1 ☐	2 ☐	3 ☐
20. Me siento en un estado agitado y tenso cuando pienso en mis preocupaciones e intereses recientes.	0 ☐	1 ☐	2 ☐	3 ☐

Sueño – Sleep Habits in HCHS/SOL

Well Being (WLE/WLS) Question by Question Instructions

General Instructions:
The Well-being questionnaire consists of two brief measures that assess depressive symptoms and "trait anxiety", respectively. Measures included are the Center for Epidemiological Study measure of depression (10- item version) and the Spielberger Trait Anxiety Scale (10-item version) in order to evaluate the relationships between depression and anxiety with sleep in this population. In addition, these measures will allow an assessment of the prevalence of depression and anxiety symptoms among Latinos that have sleep problems.

Question by Question Instructions:
Q1 – Q10:
The CESD 10 is a measure of thoughts or feelings related to recent depression. Interviewers should read the script exactly as it appears on the screen. Emphasis should be placed on the time frame, the PAST WEEK. Interviewers should then read the answers and let respondents know that for each question there will be 4 possible answers – rarely or none of the time (<1 day/week), some or little of the time (1-2 days/week), occasionally or a moderate amount of time (3-4 days/week), or all of the time (5-7 days/week). The number of days per week should be read to help the respondent understand each of the categories. In addition, hand motions to indicate the continuum from the low end of the scale to the high end of the scale can be helpful. Show cards or the instrument itself displaying the Likert scale when describing the answer categories. After describing the answer categories, the interviewer should proceed with asking each question and the corresponding answer categories. The interviewer may re-read the answer options if the participant has problems recalling them or choosing a category. When asking these questions, interviewers should be careful to not comment on respondent's answers and to record answers in a non-judgmental manner.

Q11 –Q20:
Trait anxiety reflects the existence of STABLE individual differences in the tendency to respond with an unpleasant emotional arousal in the anticipation of threatening situations. Interviewers should read the script exactly as it appears on the screen. The respondent should refer to how he or she GENERALLY feels. The interviewer may re-read the answer options if the participant has problems recalling them or choosing a category. BE CAREFUL. In contrast to the CES-D questions in 1-10, there is no reference to a specific time period in these questions. This is because the questions are designed to uncover a stable pattern of behavior. ONLY IF the individual asks for clarification on the time period, the interview can clarify by recommending that the respondent think about the PREVIOUS YEAR. When asking these questions, interviewers should be careful to not comment on respondent's answers and to record answers in a non-judgmental manner.

ACTIWATCH INSTRUCTIONS

About the ActiWatch

What is it doing?

While it may look like a watch, the ActiWatch is actually a very complex and delicate machine. Inside, it has sensors that record when and how the watch moves which can tell us when you are awake and when you are asleep. It also has a light detector that tells us how much light you are exposed to. Wearing the ActiWatch will let us know about your sleep quantity and quality.

It is very important that the ActiWatch is cared for properly. Please follow the instructions on this page as well as those given by staff.

Wearing the ActiWatch

- For the next week, **please wear the ActiWatch as much as possible.**
- **The ActiWatch is waterproof** – it can be worn in the shower and while swimming.
- Wear the ActiWatch on the hand that you do not write with (if you are right handed, wear the watch on your left hand).
- Treat the ActiWatch like an expensive watch. **If you have to take it off, please keep it in a safe place.**
- There is a light sensor on the ActiWatch so please keep it uncovered (by clothing, etc.) as much as possible.
- There is a button on either side of the ActiWatch face. **Please press both buttons for 3 seconds to mark when you are going to sleep and when you wake up.**

Questions or Problems

If you have any questions or problems, call _____ at (_ _ _) _ _ _ - _ _ _ _.

Daily Sleep Log
HCHS/SOL Sleep Ancillary Study

ID NUMBER:										Form Code: DSE Version: A 09/15/10	Contact Occasion			SEQ #		

Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) Day: **0**

Instructions: Please complete this log *EACH MORNING* within one hour after you wake up.

What should I do if I miss a day? *If you forget to fill in the diary, leave the diary blank for that day.*

What do the words "bed", "day" and "night" mean on the diary? *This diary can be used for people who are awake or asleep at unusual times. In the sleep diary, the word "day" is the time when you choose or are required to be awake and the word "night" is the main time you choose to sleep. The term "bed" means the place where you usually sleep.*

Will answering these questions about my sleep keep me awake? *You should not worry about giving exact times, and you should not watch the clock. Just give your best estimate.*

1. What time did you go to bed and try to fall asleep last night? ☐☐:☐☐ ☐ am ☐ pm

2. How much time did it take you to fall asleep? ☐ Hours ☐☐ Minutes

3. Did you wake up during the night? No 0 ☐ Yes 1 ☐

   3a. If yes, how many times? ☐☐ times

4. What time did you get out of bed today? ☐☐:☐☐ ☐ am ☐ pm

5. Did you go to work or school yesterday? No 0 ☐ Yes 1 ☐

6. During the day yesterday, did you take naps or fall asleep for more than 5 minutes? No 0 ☐ Yes 1 ☐

   6a. If yes, at what times did these naps begin? ☐☐:☐☐ ☐ am ☐ pm
   ☐☐:☐☐ ☐ am ☐ pm
   ☐☐:☐☐ ☐ am ☐ pm

REMINDER: Press the buttons on either side of the ActiWatch whenever you try to go to sleep today and whenever you wake up from sleep.

Daily Sleep Log
HCHS/SOL Sleep Ancillary Study

ID NUMBER:										Form Code: DSE Version: A 09/15/10	Contact Occasion			SEQ #		

Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) Day: **1**

Instructions: Please complete this log *EACH MORNING* within one hour after you wake up.

1. What time did you go to bed and try to fall asleep last night? ☐☐:☐☐ ☐ am ☐ pm

2. How much time did it take you to fall asleep? ☐ Hours ☐☐ Minutes

3. Did you wake up during the night? No 0 ☐ Yes 1 ☐

3a. If yes, how many times? ☐☐ times

4. What time did you get out of bed today? ☐☐:☐☐ ☐ am ☐ pm

5. Did you go to work or school yesterday? No 0 ☐ Yes 1 ☐

6. During the day yesterday, did you take naps or fall asleep for more than 5 minutes? No 0 ☐ Yes 1 ☐

6a. If yes, at what times did these naps begin? ☐☐:☐☐ ☐ am ☐ pm
☐☐:☐☐ ☐ am ☐ pm
☐☐:☐☐ ☐ am ☐ pm

REMINDER: Press the buttons on either side of the ActiWatch whenever you try to go to sleep today and whenever you wake up from sleep.

Daily Sleep Log
HCHS/SOL Sleep Ancillary Study

ID NUMBER:										Form Code: DSE Version: A 09/15/10	Contact Occasion			SEQ #		

Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) Day: **2**

Instructions: Please complete this log *EACH MORNING* within one hour after you wake up.

1. What time did you go to bed and try to fall asleep last night? ☐☐:☐☐ ☐ am ☐ pm

2. How much time did it take you to fall asleep? ☐ Hours ☐☐ Minutes

3. Did you wake up during the night? No 0 ☐ Yes 1 ☐

3a. If yes, how many times? ☐☐ times

4. What time did you get out of bed today? ☐☐:☐☐ ☐ am ☐ pm

5. Did you go to work or school yesterday? No 0 ☐ Yes 1 ☐

6. During the day yesterday, did you take naps or fall asleep for more than 5 minutes? No 0 ☐ Yes 1 ☐

6a. If yes, at what times did these naps begin? ☐☐:☐☐ ☐ am ☐ pm
☐☐:☐☐ ☐ am ☐ pm
☐☐:☐☐ ☐ am ☐ pm

REMINDER: Press the buttons on either side of the ActiWatch whenever you try to go to sleep today and whenever you wake up from sleep.

Daily Sleep Log
HCHS/SOL Sleep Ancillary Study

ID NUMBER:										Form Code: DSE Version: A 09/15/10	Contact Occasion			SEQ #		

Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) Day: **3**

Instructions: Please complete this log *EACH MORNING* within one hour after you wake up.

1. What time did you go to bed and try to fall asleep last night? ☐☐:☐☐ ☐ am ☐ pm

2. How much time did it take you to fall asleep? ☐ Hours ☐☐ Minutes

3. Did you wake up during the night? No 0 ☐ Yes 1 ☐

3a. If yes, how many times? ☐☐ times

4. What time did you get out of bed today? ☐☐:☐☐ ☐ am ☐ pm

5. Did you go to work or school yesterday? No 0 ☐ Yes 1 ☐

6. During the day yesterday, did you take naps or fall asleep for more than 5 minutes? No 0 ☐ Yes 1 ☐

6a. If yes, at what times did these naps begin? ☐☐:☐☐ ☐ am ☐ pm
☐☐:☐☐ ☐ am ☐ pm
☐☐:☐☐ ☐ am ☐ pm

REMINDER: Press the buttons on either side of the ActiWatch whenever you try to go to sleep today and whenever you wake up from sleep.

Daily Sleep Log
HCHS/SOL Sleep Ancillary Study

ID NUMBER:										Form Code: DSE Version: A 09/15/10	Contact Occasion			SEQ #		

Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) Day: **4**

Instructions: Please complete this log *EACH MORNING* within one hour after you wake up.

1. What time did you go to bed and try to fall asleep last night? ☐☐:☐☐ ☐ am ☐ pm

2. How much time did it take you to fall asleep? ☐ Hours ☐☐ Minutes

3. Did you wake up during the night? No 0 ☐ Yes 1 ☐

3a. If yes, how many times? ☐☐ times

4. What time did you get out of bed today? ☐☐:☐☐ ☐ am ☐ pm

5. Did you go to work or school yesterday? No 0 ☐ Yes 1 ☐

6. During the day yesterday, did you take naps or fall asleep for more than 5 minutes? No 0 ☐ Yes 1 ☐

6a. If yes, at what times did these naps begin? ☐☐:☐☐ ☐ am ☐ pm
☐☐:☐☐ ☐ am ☐ pm
☐☐:☐☐ ☐ am ☐ pm

REMINDER: Press the buttons on either side of the ActiWatch whenever you try to go to sleep today and whenever you wake up from sleep.

Daily Sleep Log
HCHS/SOL Sleep Ancillary Study

ID NUMBER:										Form Code: DSE Version: A 09/15/10	Contact Occasion			SEQ #		

Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) Day: **5**

Instructions: Please complete this log *EACH MORNING* within one hour after you wake up.

1. What time did you go to bed and try to fall asleep last night? ☐☐:☐☐ ☐ am ☐ pm

2. How much time did it take you to fall asleep? ☐ Hours ☐☐ Minutes

3. Did you wake up during the night? No 0 ☐ Yes 1 ☐

3a. If yes, how many times? ☐☐ times

4. What time did you get out of bed today? ☐☐:☐☐ ☐ am ☐ pm

5. Did you go to work or school yesterday? No 0 ☐ Yes 1 ☐

6. During the day yesterday, did you take naps or fall asleep for more than 5 minutes? No 0 ☐ Yes 1 ☐

6a. If yes, at what times did these naps begin? ☐☐:☐☐ ☐ am ☐ pm
☐☐:☐☐ ☐ am ☐ pm
☐☐:☐☐ ☐ am ☐ pm

REMINDER: Press the buttons on either side of the ActiWatch whenever you try to go to sleep today and whenever you wake up from sleep.

Daily Sleep Log
HCHS/SOL Sleep Ancillary Study

ID NUMBER:										Form Code: DSE Version: A 09/15/10	Contact Occasion			SEQ #		

Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

Day: **6**

Instructions: Please complete this log *EACH MORNING* within one hour after you wake up.

1. What time did you go to bed and try to fall asleep last night? ☐☐:☐☐ ☐ am ☐ pm

2. How much time did it take you to fall asleep? ☐ Hours ☐☐ Minutes

3. Did you wake up during the night? No 0 ☐ Yes 1 ☐

   3a. If yes, how many times? ☐☐ times

4. What time did you get out of bed today? ☐☐:☐☐ ☐ am ☐ pm

5. Did you go to work or school yesterday? No 0 ☐ Yes 1 ☐

6. During the day yesterday, did you take naps or fall asleep for more than 5 minutes? No 0 ☐ Yes 1 ☐

   6a. If yes, at what times did these naps begin? ☐☐:☐☐ ☐ am ☐ pm
   ☐☐:☐☐ ☐ am ☐ pm
   ☐☐:☐☐ ☐ am ☐ pm

REMINDER: Press the buttons on either side of the ActiWatch whenever you try to go to sleep today and whenever you wake up from sleep.

Daily Sleep Log
HCHS/SOL Sleep Ancillary Study

ID NUMBER:										Form Code: DSE Version: A 09/15/10	Contact Occasion			SEQ #		

Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) Day: **7**

Instructions: Please complete this log *EACH MORNING* within one hour after you wake up.

1. What time did you go to bed and try to fall asleep last night? ☐☐:☐☐ ☐ am ☐ pm

2. How much time did it take you to fall asleep? ☐ Hours ☐☐ Minutes

3. Did you wake up during the night? No 0 ☐ Yes 1 ☐

3a. If yes, how many times? ☐☐ times

4. What time did you get out of bed today? ☐☐:☐☐ ☐ am ☐ pm

5. Did you go to work or school yesterday? No 0 ☐ Yes 1 ☐

6. During the day yesterday, did you take naps or fall asleep for more than 5 minutes? No 0 ☐ Yes 1 ☐

6a. If yes, at what times did these naps begin? ☐☐:☐☐ ☐ am ☐ pm
☐☐:☐☐ ☐ am ☐ pm
☐☐:☐☐ ☐ am ☐ pm

REMINDER: Press the buttons on either side of the ActiWatch whenever you try to go to sleep today and whenever you wake up from sleep.

INSTRUCCIONES DEL ACTIWATCH

Sobre el ActiWatch

¿Qué está haciendo?

Aunque parezca un reloj, el ActiWatch es una máquina compleja y delicada. Adentro, tiene censores que registran cuándo y cómo el reloj se mueve que nos puede decir cuando está despierto y cuando está dormido. También tiene un detector de luz que nos dice a cuanta luz usted está expuesto. Usando el ActiWatch nos dejara saber sobre la cantidad y calidad de su sueño.

Es muy importante que el ActiWatch sea cuidado apropiadamente. Por favor siga las instrucciones en esta página y las que le dará el personal.

Usando el ActiWatch

- Por la próxima semana, **use el ActiWatch todo lo posible, por favor.**
- **El ActiWatch es a prueba de agua** – se puede usar en la ducha y mientras esté nadando.
- Use el ActiWatch en la mano con la cual no escribe (si escribe con la mano derecha, use el reloj en su mano izquierda)
- Trate el ActiWatch como un reloj caro. **Si tiene que quitárselo, por favor guárdelo en un lugar seguro.**
- Hay un censor de luz en el ActiWatch, entonces por favor manténgalo descubierto (de ropa, etc.) todo lo posible.
- Hay un botón en cada lado del ActiWatch. **Por favor oprima los dos botones durante 3 segundos para marcar cuando se va a ir a dormir y cuando se levanta.**

Preguntas o Problemas

Si tiene alguna pregunta o algún problema, llame a _____al (_ _ _) _ _ _ - _ _ _ _.

Daily Sleep Log
Sueño – Sleep Habits in HCHS_Spanish

ID NUMBER:										Form Code: DSS Version: A 10/11/10	Contact Occasion			SEQ #		

Fecha: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) Día: 0

Instrucciones: Por favor complete este cuestionario *CADA MAÑANA* dentro de una hora después que se levante.

¿Qué debo hacer si me olvido de un día? *Si se le olvida llenar el diario, déjelo en blanco por ese día.*

¿Qué quieren decir las palabras "cama", "día" y "noche" en el diario? *Este diario puede ser usado por personas que están despiertos o dormidos durante horas irregulares. En el diario de sueño, la palabra "día" es la hora que escoge o que tiene que estar despierto y la palabra "noche" es la hora principal que escoge dormirse. La palabra "cama" se refiere al lugar donde usualmente duerme.*

¿Responder estas preguntas sobre mi sueño me mantendrá despierto? *No debe preocuparse por dar la hora exacta, y no debe mirar el reloj. Simplemente estime la hora lo mejor que pueda.*

1. ¿A qué hora se acostó y trató de dormirse anoche? ☐☐:☐☐ ☐ am ☐ pm

2. ¿Cuánto tiempo le tomó dormirse? ☐ Horas ☐☐ Minutos

3. ¿Se levantó durante la noche? No 0 ☐ Sí 1 ☐

   3a. Si es así, ¿cuántas veces? ☐☐ veces

4. ¿A qué hora se levantó de la cama hoy? ☐☐:☐☐ ☐ am ☐ pm

5. ¿Fue al trabajo o a la escuela ayer? No 0 ☐ Sí 1 ☐

6. Durante el día de ayer, ¿tomó alguna siesta o se durmió más de 5 minutos? No 0 ☐ Sí 1 ☐

   6a. Si es así, ¿a qué hora comenzaron las siestas? ☐☐:☐☐ ☐ am ☐ pm
   ☐☐:☐☐ ☐ am ☐ pm
   ☐☐:☐☐ ☐ am ☐ pm

RECUERDO: Oprima los botones en cada lado del ActiWatch cuando sea que trate de irse a dormir hoy y cuando se levante de su sueño.

Daily Sleep Log
Sueño – Sleep Habits in HCHS

ID NUMBER:										Form Code: DSS Version: 10/11/10	Contact Occasion			SEQ #		

Fecha: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) Día: 1

Instrucciones: Por favor complete este cuestionario *CADA MAÑANA* dentro de una hora después que se levante.

1. ¿A qué hora se acostó y trató de dormirse anoche? ☐☐:☐☐ ☐ am ☐ pm

2. ¿Cuánto tiempo le tomó dormirse? ☐ Horas ☐☐ Minutos

3. ¿Se levantó durante la noche? No 0 ☐ Sí 1 ☐

3a. Si es así, ¿cuántas veces? ☐☐ veces

4. ¿A qué hora se levantó de la cama hoy? ☐☐:☐☐ ☐ am ☐ pm

5. ¿Fue al trabajo o a la escuela ayer? No 0 ☐ Sí 1 ☐

6. Durante el día de ayer, ¿tomó alguna siesta o se durmió más de 5 minutos? No 0 ☐ Sí 1 ☐

6a. Si es así, ¿a qué hora comenzaron las siestas? ☐☐:☐☐ ☐ am ☐ pm
☐☐:☐☐ ☐ am ☐ pm
☐☐:☐☐ ☐ am ☐ pm

RECUERDO: Oprima los botones en cada lado del ActiWatch cuando sea que trate de irse a dormir hoy y cuando se levante de su sueño.

Daily Sleep Log
Sueño – Sleep Habits in HCHS

ID NUMBER:										Form Code: DSS Version: 10/11/10	Contact Occasion			SEQ #		

Fecha: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) Día: 2

Instrucciones: Por favor complete este cuestionario *CADA MAÑANA* dentro de una hora después que se levante.

1. ¿A qué hora se acostó y trató de dormirse anoche? ☐☐:☐☐ ☐ am ☐ pm

2. ¿Cuánto tiempo le tomó dormirse? ☐ Horas ☐☐ Minutos

3. ¿Se levantó durante la noche? No 0 ☐ Sí 1 ☐

   3a. Si es así, ¿cuántas veces? ☐☐ veces

4. ¿A qué hora se levantó de la cama hoy? ☐☐:☐☐ ☐ am ☐ pm

5. ¿Fue al trabajo o a la escuela ayer? No 0 ☐ Sí 1 ☐

6. Durante el día de ayer, ¿tomó alguna siesta o se durmió más de 5 minutos? No 0 ☐ Sí 1 ☐

   6a. Si es así, ¿a qué hora comenzaron las siestas? ☐☐:☐☐ ☐ am ☐ pm
   ☐☐:☐☐ ☐ am ☐ pm
   ☐☐:☐☐ ☐ am ☐ pm

RECUERDO: Oprima los botones en cada lado del ActiWatch cuando sea que trate de irse a dormir hoy y cuando se levante de su sueño.

Daily Sleep Log
Sueño – Sleep Habits in HCHS

ID NUMBER:										Form Code: DSS Version: 10/11/10	Contact Occasion			SEQ #		

Fecha: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) Día: 3

Instrucciones: Por favor complete este cuestionario *CADA MAÑANA* dentro de una hora después que se levante.

1. ¿A qué hora se acostó y trató de dormirse anoche? ☐☐:☐☐ ☐ am ☐ pm

2. ¿Cuánto tiempo le tomó dormirse? ☐ Horas ☐☐ Minutos

3. ¿Se levantó durante la noche? No 0 ☐ Sí 1 ☐

   3a. Si es así, ¿cuántas veces? ☐☐ veces

4. ¿A qué hora se levantó de la cama hoy? ☐☐:☐☐ ☐ am ☐ pm

5. ¿Fue al trabajo o a la escuela ayer? No 0 ☐ Sí 1 ☐

6. Durante el día de ayer, ¿tomó alguna siesta o se durmió más de 5 minutos? No 0 ☐ Sí 1 ☐

   6a. Si es así, ¿a qué hora comenzaron las siestas? ☐☐:☐☐ ☐ am ☐ pm
   ☐☐:☐☐ ☐ am ☐ pm
   ☐☐:☐☐ ☐ am ☐ pm

RECUERDO: Oprima los botones en cada lado del ActiWatch cuando sea que trate de irse a dormir hoy y cuando se levante de su sueño.

Daily Sleep Log
Sueño – Sleep Habits in HCHS

ID NUMBER:										Form Code: DSS Version: 10/11/10	Contact Occasion			SEQ #		

Fecha: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

Día: 4

Instrucciones: Por favor complete este cuestionario *CADA MAÑANA* dentro de una hora después que se levante.

1. ¿A qué hora se acostó y trató de dormirse anoche? ☐☐:☐☐ ☐ am ☐ pm

2. ¿Cuánto tiempo le tomó dormirse? ☐ Horas ☐☐ Minutos

3. ¿Se levantó durante la noche? No 0 ☐ Sí 1 ☐

   3a. Si es así, ¿cuántas veces? ☐☐ veces

4. ¿A qué hora se levantó de la cama hoy? ☐☐:☐☐ ☐ am ☐ pm

5. ¿Fue al trabajo o a la escuela ayer? No 0 ☐ Sí 1 ☐

6. Durante el día de ayer, ¿tomó alguna siesta o se durmió más de 5 minutos? No 0 ☐ Sí 1 ☐

   6a. Si es así, ¿a qué hora comenzaron las siestas? ☐☐:☐☐ ☐ am ☐ pm
   ☐☐:☐☐ ☐ am ☐ pm
   ☐☐:☐☐ ☐ am ☐ pm

RECUERDO: Oprima los botones en cada lado del ActiWatch cuando sea que trate de irse a dormir hoy y cuando se levante de su sueño.

Daily Sleep Log
Sueño – Sleep Habits in HCHS

ID NUMBER:										Form Code: DSS Version: 10/11/10	Contact Occasion			SEQ #		

Fecha: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) Día: 5

Instrucciones: Por favor complete este cuestionario *CADA MAÑANA* dentro de una hora después que se levante.

1. ¿A qué hora se acostó y trató de dormirse anoche? ☐☐:☐☐ ☐ am ☐ pm

2. ¿Cuánto tiempo le tomó dormirse? ☐ Horas ☐☐ Minutos

3. ¿Se levantó durante la noche? No 0 ☐ Sí 1 ☐

3a. Si es así, ¿cuántas veces? ☐☐ veces

4. ¿A qué hora se levantó de la cama hoy? ☐☐:☐☐ ☐ am ☐ pm

5. ¿Fue al trabajo o a la escuela ayer? No 0 ☐ Sí 1 ☐

6. Durante el día de ayer, ¿tomó alguna siesta o se durmió más de 5 minutos? No 0 ☐ Sí 1 ☐

6a. Si es así, ¿a qué hora comenzaron las siestas? ☐☐:☐☐ ☐ am ☐ pm
☐☐:☐☐ ☐ am ☐ pm
☐☐:☐☐ ☐ am ☐ pm

RECUERDO: Oprima los botones en cada lado del ActiWatch cuando sea que trate de irse a dormir hoy y cuando se levante de su sueño.

Daily Sleep Log
Sueño – Sleep Habits in HCHS

ID NUMBER:										Form Code: DSS Version: 10/11/10	Contact Occasion			SEQ #		

Fecha: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

Día: 6

Instrucciones: Por favor complete este cuestionario *CADA MAÑANA* dentro de una hora después que se levante.

1. ¿A qué hora se acostó y trató de dormirse anoche? ☐☐:☐☐ ☐ am ☐ pm

2. ¿Cuánto tiempo le tomó dormirse? ☐ Horas ☐☐ Minutos

3. ¿Se levantó durante la noche? No 0 ☐ Sí 1 ☐

   3a. Si es así, ¿cuántas veces? ☐☐ veces

4. ¿A qué hora se levantó de la cama hoy? ☐☐:☐☐ ☐ am ☐ pm

5. ¿Fue al trabajo o a la escuela ayer? No 0 ☐ Sí 1 ☐

6. Durante el día de ayer, ¿tomó alguna siesta o se durmió más de 5 minutos? No 0 ☐ Sí 1 ☐

   6a. Si es así, ¿a qué hora comenzaron las siestas? ☐☐:☐☐ ☐ am ☐ pm
   ☐☐:☐☐ ☐ am ☐ pm
   ☐☐:☐☐ ☐ am ☐ pm

RECUERDO: Oprima los botones en cada lado del ActiWatch cuando sea que trate de irse a dormir hoy y cuando se levante de su sueño.

Daily Sleep Log
Sueño – Sleep Habits in HCHS

ID NUMBER:										Form Code: DSS Version:10/11/10	Contact Occasion			SEQ #		

Fecha: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) Día: 7

Instrucciones: Por favor complete este cuestionario *CADA MAÑANA* dentro de una hora después que se levante.

1. ¿A qué hora se acostó y trató de dormirse anoche? ☐☐:☐☐ ☐ am ☐ pm

2. ¿Cuánto tiempo le tomó dormirse? ☐ Horas ☐☐ Minutos

3. ¿Se levantó durante la noche? No 0 ☐ Sí 1 ☐

3a. Si es así, ¿cuántas veces? ☐☐ veces

4. ¿A qué hora se levantó de la cama hoy? ☐☐:☐☐ ☐ am ☐ pm

5. ¿Fue al trabajo o a la escuela ayer? No 0 ☐ Sí 1 ☐

6. Durante el día de ayer, ¿tomó alguna siesta o se durmió más de 5 minutos? No 0 ☐ Sí 1 ☐

6a. Si es así, ¿a qué hora comenzaron las siestas? ☐☐:☐☐ ☐ am ☐ pm
☐☐:☐☐ ☐ am ☐ pm
☐☐:☐☐ ☐ am ☐ pm

RECUERDO: Oprima los botones en cada lado del ActiWatch cuando sea que trate de irse a dormir hoy y cuando se levante de su sueño.

Sueño Actigraph Watch Log

Site:___________________________________

Study ID	Serial Number	Date Given	Date Sender to Return	Date Actually Returned	Download and Reviewed	Number of Days of Valid Data	Is it Greater Than Five Days?	If not, Reason for Incomplete Data	Was Study Repeated?	Any Download Errors	Was Raw Data and Sleep Log Sent to Reading Center	Date Sent to Reading Center

Study Failure Form
HCHS/SOL Sueño Study

To be completed by Reading Center Staff:

Date Failed (MM/DD/YY): ☐☐/☐☐/☐☐
ID Number: ☐☐☐☐☐☐☐☐
Staff Initials: ☐☐☐
Contact Occasion: ☐

Failure Reason:
- ○ Fewer than 5 days of valid data
- ○ Data corruption/ technical failure
- ○ Other (*specify in notes below)*

Notes:

To be completed by Field Site Staff:

Date Contacted Participant (MM/DD/YY): ☐☐/☐☐/☐☐
Staff Number: ☐☐☐

Participant Status:
- ○ Willing to Repeat Study
- ○ Unwilling to Repeat Study
- ○ Unable to Contact
- ○ Other (*specify in notes below)*

Notes:

Important: *Submit completed form to the Reading Center*

<Letterhead>
SUEÑO – Sleep Ancillary to the Hispanic Community Health Study/Study of Latinos

<Date>
<Name>
<Address>

Dear <Name>,

Thank you for your participation in the Sueño study – an ancillary study to the Hispanic Community Health Study – Study of Latinos. The results from the actigraph that you wore suggest that on average during your main sleep period, you obtain <___> hours of sleep and are awake for <___> hours.

On the back of this letter, please find general tips about healthy sleep habits. In general, most people feel their best if they get 7-8 hours of sleep per night. However, this can vary a lot from person to person. If you think you are not sleeping as well as you should, you feel tired during the day, or have trouble getting to sleep, you should talk to your doctor.

Once again, thank you for your involvement with this study. We hope it will help us learn more about the sleep patterns in Hispanic-Americans/Latinos and how sleep might be important for overall health.

Sincerely,

[Name of local PI]

[Field Center name]

SUEÑO – Sleep Ancillary to the Hispanic Community Health Study/Study of Latinos

Ten Healthy Sleep Tips

1. Maintain a regular bed time and wake time schedule including on weekends.

2. Establish a regular, relaxing bedtime routine such as soaking in a hot bath and then reading a book or listening to soothing music.

3. Create an environment that encourages sleep by making sure the place you sleep is dark, quiet, comfortable and cool.

4. Sleep on a comfortable mattress and pillows.

5. Avoid watching television, using the computer or doing work in your bedroom.

6. Finish eating at least 2-3 hours before your regular bedtime.

7. Exercise regularly. It is best to complete your workout at least a few hours before bedtime.

8. Avoid drinks that contain caffeine (coffee, tea, soft drinks) close to bedtime. They can keep you awake.

9. Avoid products that contain nicotine (cigarettes). Used close to bedtime, they can lead to poor quality sleep.

10. Avoid alcohol close to bedtime.

<Letterhead>
SUEÑO – Sleep Ancillary to the Hispanic Community Health Study-Study of Latinos

<Date>
<Name>
<Address>

Dear <Name>,

Gracias por su participación en el estudio Sueño – un estudio auxiliar del Estudio Sobre Salud de la Comunidad Hispana/Estudio de Latinos. Los resultados del actígrafo que usó sugieren que durante el período principal de sueño, usted obtiene en promedio <___> horas de sueño, y está <___> horas despierto.

Atrás de esta página, por favor vea los consejos generales sobre los hábitos de dormir saludables. En general, la mayoría de personas se sienten mejor si duermen 7-8 horas cada noche. Sin embargo, esto puede variar mucho de persona a persona. Si usted piensa que no está durmiendo como debería, se siente cansado durante el día, o tiene problemas para dormirse, debe hablar con su doctor.

Una vez más, gracias por su participación en este estudio. Esperamos que nos ayude aprender más sobre los hábitos de dormir en los hispano-americanos y como el dormir puede ser importante para la salud en general.

Sinceramente,

[Name of local PI]

[Field Center name]

SUEÑO – Sleep Ancillary to the Hispanic Community Health Study – Study of Latinos

Diez Consejos para el Sueño Saludable

1. **Mantener una hora consistente para acostarse y levantarse, incluyendo los fines de semana.**
2. **Establecer una rutina de dormir y relajada como un baño caliente y después leer un libro o escuchar música calmante.**
3. **Crear un medioambiente que fomente el sueño, asegurándose que el lugar en donde duerma sea oscuro, silencioso, cómodo, y fresco.**
4. **Dormir en un colchón cómodo y con almohadas cómodas.**
5. **Evitar ver la televisión, usar la computadora, o trabajar en su habitación.**
6. **Terminar de comer por lo menos 2 ó 3 horas antes de su hora de la hora habitual en la que se acuesta.**
7. **Hacer ejercicio regularmente. Es mejor hacer ejercicio por lo menos un par de horas antes de la hora de dormir.**
8. **Evitar bebidas que contengan cafeína (café, té, refrescos) cerca de la hora de dormir. Pueden mantenerlo/la despierto/a.**
9. **Evitar productos que contengan nicotina (cigarrillos). Si se consumen cerca de la hora de acostarse, pueden causar mala calidad del sueño.**
10. **Evitar el alcohol cerca de la hora de acostarse.**

Sueño Unanticipated Adverse Event Form

ID Number: ☐☐☐☐☐☐☐☐ Contact Occasion: ☐☐

Instructions: *This form should be completed* ***within a week*** *if the Principal Investigator at your site determines the AE constitutes an unanticipated adverse event (UAE).*

Form Completion Date: ☐☐/☐☐/☐☐ Staff ID: ☐☐☐

Principal Investigator: ☐☐☐☐☐☐☐☐☐☐ Field Center: ☐☐☐☐☐☐☐☐☐☐

Date AE Occurred: ☐☐/☐☐/☐☐

Date Field Center Became Aware: ☐☐/☐☐/☐☐

Indicate whether the event is: ☐ Ongoing ☐ Resolved

Is this type of event foreseen in the Informed Consent or study MOP?

☐ Yes ☐ No ☐ Don't know

Likelihood of Relationship to Participation in Sueño:

- ☐ Definitely related
- ☐ Possibly related
- ☐ Not related

Severity of the Event:

- ☐ Mild
- ☐ Moderate
- ☐ Severe

Describe the Event:

Describe What Action was Taken:

Sueño – Sleep Habits in HCHS

Database Dictionary

April 30, 2014

Table of Contents

1. ADMINISTRATIVE

1.1 SAWA1 (Participant ID)

The first digit is a letter that identifies the Field Center (FC) where sleep data was collected. The 7-digit numerical string that follows the letter is the unique identifier for the participant.

1.2 SAWA2 (Contact Occasion)

Contact occasion 1 is the first time the subject participated in the study. Contact occasion 2 is the second time the subject participated in the study.

Value 1 = Contact 1
Value 2 = Contact 2

1.3 SAWA3 (Field Center ID)

Value 1 = Bronx, NY
Value 2 = Chicago, IL
Value 3 = Miami, FL
Value 4 = San Diego, CA

1.4 SAWA4 (Valid/Invalid Recording)

A valid status means that at least 5 of the days that make up the recording meet minimum quality criteria.

Value 1 = Valid
Value 2 = Invalid

1.5 SAWA5 (Invalid Reason Code)

The main reason for a recording not having 5 or more days of valid data.

Value 1 = Less than 5 days of valid data due to device not being worn properly
Value 2 = Technical failure
Value 3 = Acute illness

1.6 SAWA6 (Actigraph Unit ID)

The last 4 numbers of the unique serial number of the actigraph.

1.7 SAWA7 (Participant Actigraphy Status)

The status of a participant's willingness to repeat the study when their first contact occasion was invalid.

Value 1 = Willing to Repeat
Value 2 = Unwilling to Repeat
Value 3 = Unable to Contact
Value 4 = Not Asked to Repeat
Value 8 = Pending
Value 9 = Permanently Missing

1.8 SAWA8 (Sleep Journal/Log Status)

Binary variable showing whether the Reading Center (RC) received the daily sleep log.

Value 0 = No
Value 1 = Yes

1.9 SAWA12 (Actigram Start Date)
The date on which the actigraph started recording wrist activity as identified by the scorer.

1.10 SAWA13 (Actigram Start Time)
The clock time at which the actigraph started recording wrist activity, as identified by the scorer.

1.11 SAWA14 (Actigram End Date)
The calendar date on which the actigraph stopped recording wrist activity, as identified by the scorer.

1.12 SAWA15 (Actigram End Time)
The clock time at which the actigraph stopped recording wrist activity, as identified by the scorer.

1.13 SAWA340 (Daylight Savings Time Overlap)
This variable identifies studies that overlap with spring or fall daylight savings time.

Value 0 = No overlap
Value 1 = Overlaps with spring daylight savings time
Value 2 = Overlaps with fall daylight savings time

1.14 SAWA341 (Original Epoch Length)
The length of the epoch selected when the actigraph was configured to start recording data. Per study protocol, the default epoch length should be 30 seconds. However, a small percentage of studies were recorded in 15 second epochs. These recordings were recalculated to use 30 second epochs for consistent analysis.

1.15 SAWA342 (Version of Actiware Software)
The version of the Actiware software that was used to download, score, and export actigram data.

Value 1 = 5.59.0015
Value 2 = 5.7

2. NUMBER OF DAYS

2.1 SAWA329 (Number of Days Logged in Sleep Diary)
This is the number of daily sleep log entries on which the participant reported a bed time and/or a wake time. This refers to the number of days for which the participant reported nightly sleep (or lack thereof).

2.2 SAWA332 (Number Work Days Logged in Sleep Diary)
This is the number of daily sleep log entries on which the participant reported going to work or school.

2.3 SAWA9 (Number of Good/Valid Days)
The number of valid 24 hour intervals that meet minimum quality criteria.

2.4 SAWA10 (Number of Valid Weekday Days)
The number of days with valid actigraphy data that start on Sunday through Thursday.

2.5 SAWA11 (Number of Valid Weekend Days)
The number of days with valid actigraphy data that start on Friday or Saturday.

2.6 SAWA343 (Number of Good/Valid Workdays)

The number of days with valid actigraphy data on which the participant self-reported as having attended work or school in the daily sleep log.

2.7 SAWA344 (Number of Good/Valid Non-workdays)

The number of days with valid actigraphy data on which the participant self-reported as not having attended work or school.

2.8 SAWA47 (Number of Days with Sleep/Rest Data)

This is the number of valid main rest intervals in the recording that meet quality criteria. Main rest intervals are the intervals of time between the epoch at which the participant went to bed and the epoch at which the participant got out of bed, as marked by the scorer. It refers to the participant's "nightly" time in bed, including time awake and asleep.

2.9 SAWA94 (Number of Weekdays with Sleep/Rest Data)

This is the number of main rest intervals that end on a calendar Monday through Friday.

2.10 SAWA141 (Number of Weekends with Sleep/Rest Data)

This is the number of main rest intervals that end on a calendar Saturday or Sunday.

2.11 SAWA188 (Number of Workdays with Sleep/Rest Data)

This is the number of main rest intervals that directly precede the subject going to work or school, as self-reported in the daily sleep log.

2.12 SAWA235 (Number of Non-workdays with Sleep/Rest Data)

This is the number of main rest intervals that directly precede the subject not going to work or school, as self-reported in the daily sleep log.

2.13 SAWA282 (Number of Reliable Days with Sleep/Rest Data)

This is the number of main rest intervals for which the sum of the quality score for in bed and out of bed times is 5 or 6. Bed times are given a reliability score between 1 and 3:

Value -8 = Not Applicable
Value -1 = Flag/ Confusion
Value 0 = No Evidence of Sleep
Value 1 = Unreliable
Value 2 = Somewhat reliable
Value 3 = Mostly reliable

3. DURATION

3.1 SAWA16 (Average Main Rest Duration)

This is the average duration of main rest intervals across all days, in minutes. This variable is similar to SAWA50; however, SAWA16 is generated by Actiware software before data optimization.

3.2 SAWA50 (Average Main Rest Duration)

This is the average duration of main rest intervals across all days, in minutes. This refers to the amount of time, on average, that a person spent between getting in bed and getting out of bed, including times when the person was momentarily up at night.

3.3 SAWA97 (Average Weekday Main Rest Duration)
This is the average duration of main rest intervals across all weekday days.

3.4 SAWA144 (Average Weekend Main Rest Duration)
This is the average duration of main rest intervals across all weekend days.

3.5 SAWA191 (Average Workday Main Rest Duration)
This is the average duration of main rest intervals across all workday days.

3.6 SAWA238 (Average Non-workday Main Rest Duration)
This is the average duration of main rest intervals across all non-workday days.

3.7 SAWA285 (Average Reliable Day Main Rest Duration)
This is the average duration of main rest intervals across all reliable days.

3.8 SAWA18 (Average Sleep Duration)
This is the average duration of time between sleep onset and sleep offset across all main rest intervals, in minutes. This variable is similar to SAWA152; however, SAWA18 is generated by Actiware software before data optimization.

3.9 SAWA52 (Average Sleep Duration)
This is the average duration of time between sleep onset and sleep offset across all main rest intervals, in minutes. This refers to the average length of time between when the person fell asleep and when they woke up.

3.10 SAWA32 (Average Weekday Sleep Duration)
This is the average duration of time between sleep onset and sleep offset across all weekday main rest intervals. This variable is similar to SAWA99; however, SAWA32 is derived from Actiware variable SAWA18 before data optimization.

3.11 SAWA99 (Average Weekday Sleep Duration)
This is the average duration of time between sleep onset and sleep offset across all weekday main rest intervals.

3.12 SAWA31 (Average Weekend Sleep Duration)
This is the average duration of time between sleep onset and sleep offset across all weekend main rest intervals, in minutes. This variable is similar to SAWA146; however, SAWA31 is derived from Actiware variable SAWA18 before data optimization.

3.13 SAWA146 (Average Weekend Sleep Duration)
This is the average duration of time between sleep onset and sleep offset across all weekend main rest intervals, in minutes.

3.14 SAWA193 (Average Workday Sleep Duration)
This is the average duration of time between sleep onset and sleep offset across all workday main rest intervals, in minutes.

3.15 SAWA240 (Average Non-Workday Sleep Duration)

This is the average duration of time between sleep onset and sleep offset across all non-workday main rest intervals, in minutes.

3.16 SAWA287 (Average Reliable Day Sleep Duration)

This is the average duration of time between sleep onset and sleep offset across all reliable day main rest intervals, in minutes.

3.17 SAWA45 (Average Sleep Time)

This is the average amount of time spent asleep across all main rest intervals with sleep, in hours. This variable is similar to the Sueño calculated variable SAWA54; however, SAWA45 is calculated based on data generated by Actiware software before data cleaning and imputation.

3.18 SAWA54 (Average Sleep Time)

This is the average amount of time, in minutes, spent asleep between the sleep onset and sleep offset times across all main rest intervals with sleep.

3.19 SAWA36 (Average Weekday Sleep Time)

This is the average amount of time spent asleep across all weekday main rest intervals with sleep, in minutes. This variable is similar to the Sueño calculated variable SAWA101; however, SAWA36 is calculated based on data generated by Actiware software before data cleaning and imputation.

3.20 SAWA101 (Average Weekday Sleep Time)

This is the average amount of time, in minutes, spent asleep between the sleep onset and sleep offset times across all weekday main rest intervals with sleep.

3.21 SAWA35 (Average Weekend Sleep Time)

This is the average amount of time spent asleep across all weekend main rest intervals with sleep, in hours. This variable is similar to the Sueño calculated variable SAWA148; however, SAWA35 is calculated based on data generated by Actiware software before data cleaning and imputation.

3.22 SAWA148 (Average Weekend Sleep Time)

This is the average amount of time, in minutes, spent asleep between the sleep onset and sleep offset times across all weekend main rest intervals with sleep.

3.23 SAWA195 (Average Workday Sleep Time)

This is the average amount of time, in minutes, spent asleep between the sleep onset and sleep offset times across all workday main rest intervals with sleep.

3.24 SAWA242 (Average Non-workday Sleep Time)

This is the average amount of time, in minutes, spent asleep between the sleep onset and sleep offset times across all non-workday main rest intervals with sleep.

3.25 SAWA289 (Average Reliable Day Sleep Time)

This is the average amount of time, in minutes, spent asleep between the sleep onset and sleep offset times across all reliable day main rest intervals with sleep.

3.26 SAWA48 (Average Sleep Duration in Main Rest and Naps)

This is the average total sleep time, in minutes, within the main rest interval and naps, across all days. This is the sum of sleep time in sleep intervals (sleep onset to sleep offset) and naps across all days, divided by the total number of days in the recording.

3.27 SAWA95 (Average Weekday Sleep Duration in Main Rest and Naps)
This is the average total sleep time across all weekday days.

3.28 SAWA142 (Average Weekend Sleep Duration in Main Rest and Naps)
This is the average total sleep time across all weekend days.

3.29 SAWA189 (Average Workday Sleep Duration in Main Rest and Naps)
This is the average total sleep time across all workday days.

3.30 SAWA236 (Average Non-workday Sleep Duration in Main Rest and Naps)
This is the average total sleep time across non-workdays.

3.31 SAWA283 (Average Reliable Sleep Duration in Main Rest and Naps)
This is the average total sleep time across all reliable days.

3.32 SAWA19 (Average Sleep Onset Latency)
This is the average duration, in minutes, between time in bed and sleep onset, across all main rest intervals with sleep. This variable is similar to SAWA56; however, SAWA19 is generated by Actiware software before data optimization.

3.33 SAWA56 (Average Sleep Onset Latency)
This is the average duration of time, in minutes, between time in bed and sleep onset, across all main rest intervals with sleep. This variable refers to the amount of time that a person spent in bed before falling asleep.

3.34 SAWA103 (Average Weekday Sleep Onset Latency)
This is the average duration of time, in minutes, between time in bed and sleep onset, across all weekday main rest intervals with sleep.

3.35 SAWA150 (Average Weekend Sleep Onset Latency)
This is the average duration of time, in minutes, between time in bed and sleep onset, across all weekend main rest intervals with sleep.

3.36 SAWA197 (Average Workday Sleep Onset Latency)
This is the average duration of time, in minutes, between time in bed and sleep onset, across all workday main rest intervals with sleep.

3.37 SAWA244 (Average Non-workday Sleep Onset Latency)
This is the average duration of time, in minutes, between time in bed and sleep onset, across all non-workday main rest intervals with sleep.

3.38 SAWA291 (Average Reliable Day Sleep Onset Latency)
This is the average duration of time, in minutes, between time in bed and sleep onset, across all reliable day main rest intervals with sleep.

3.39 SAWA20 (Average Snooze Time)

This is the average duration of time, in minutes, between sleep offset and out of bed time, across all main rest intervals with sleep. This variable is similar to SAWA58; however, SAWA20 is generated by Actiware software before data optimization.

3.40 SAWA58 (Average Snooze Time)
This is the average duration of time, in minutes, between sleep offset and out of bed time, across all main rest intervals with sleep. This variable refers to the amount of time, on average, that a person spent in bed after waking up, until they got out of bed.

3.41 SAWA105 (Average Weekday Snooze Time)
This is the average duration of time, in minutes, between sleep offset and out of bed time, across all weekday main rest intervals with sleep.

3.42 SAWA152 (Average Weekend Snooze Time)
This is the average duration of time, in minutes, between sleep offset and out of bed time, across all weekend main rest intervals with sleep.

3.43 SAWA199 (Average Workday Snooze Time)
This is the average duration of time, in minutes, between sleep offset and out of bed time, across all workday main rest intervals with sleep.

3.44 SAWA246 (Average Non-workday Snooze Time)
This is the average duration of time, in minutes, between sleep offset and out of bed time, across all non-workday main rest intervals with sleep.

3.45 SAWA293 (Average Reliable Day Snooze Time)
This is the average duration of time, in minutes, between sleep offset and out of bed time, across all reliable day main rest intervals with sleep.

3.46 SAWA22 (Average WASO Actiware)
This is the average wake time from sleep onset to sleep offset, in minutes, across all main rest intervals with sleep. This variable is similar to SAWA57; however, SAWA22 is generated by Actiware software before data optimization.

3.47 SAWA57 (Average WASO)
This is the average amount of wake time from sleep onset to sleep offset, in minutes, across all main rest intervals with sleep. This variable refers to the total amount of time that a person spent awake after falling asleep and before waking up for the day.

3.48 SAWA104 (Average Weekday WASO)
This is the average amount of wake time from sleep onset to sleep offset across all weekday main rest intervals with sleep.

3.49 SAWA151 (Average Weekend WASO)
This is the average amount of wake time from sleep onset to sleep offset, in minutes, across all weekend main rest intervals with sleep.

3.50 SAWA198 (Average Workday WASO)
This is the average amount of wake time from sleep onset to sleep offset, in minutes, across all workday main rest intervals with sleep.

3.51 SAWA245 (Average Non-workday WASO)
This is the average amount of wake time from sleep onset to sleep offset, in minutes, across all non-workday main rest intervals with sleep.

3.52 SAWA292 (Average Reliable Day WASO)
This is the average amount of wake time from sleep onset to sleep offset, in minutes, across all reliable day main rest intervals with sleep.

3.53 SAWA46 (Average Wake Time in Main Rest Intervals)
This is the average amount of wake time across all main rest intervals. This variable is similar to SAWA59; however, SAWA46 is generated by Actiware software before data optimization.

3.54 SAWA59 (Average Wake Time in Main Rest Intervals)
This is the average amount of wake time, in minutes, across all main rest intervals. This refers to the amount of time that a person spent awake between getting in bed and getting out of bed.

3.55 SAWA106 (Average Wake Time in Weekday Main Rest Intervals)
This is the average amount of wake time, in minutes, across all weekday main rest intervals.

3.56 SAWA153 (Average Wake Time in Weekend Main Rest Intervals)
This is the average amount of wake time, in minutes, across all weekend main rest intervals.

3.57 SAWA200 (Average Wake Time in Workday Main Rest Intervals)
This is the average amount of wake time, in minutes, across all workday main rest intervals.

3.58 SAWA247 (Average Wake Time in Non-workday Main Rest Intervals)
This is the average amount of wake time, in minutes, across all non-workday main rest intervals.

3.59 SAWA294 (Average Wake Time in Reliable Day Main Rest Intervals)
This is the average amount of wake time, in minutes, across all reliable day main rest intervals.

4. SLEEP QUALITY

4.1 SAWA21 (Average Sleep Efficiency in Main Rest Intervals)
This is the average percentage of time spent asleep within each main rest interval, across all main rest intervals of at least one minute duration. This variable is similar to the Sueño calculated variable SAWA60; however, SAWA21 is generated automatically by Actiware before data optimization.

4.2 SAWA60 (Average Sleep Efficiency in Main Rest Intervals)
This is the average percentage of time spent asleep within each main rest interval, across all main rest intervals of at least one minute duration. This refers to the average percentage of time in bed that a person spent asleep.

4.3 SAWA107 (Average Sleep Efficiency in Weekday Main Rest Intervals)
This is the average percentage of time spent asleep within weekday main rest intervals.

4.4 SAWA154 (Average Sleep Efficiency in Weekend Main Rest Intervals)
This is the average percentage of time spent asleep within weekend main rest intervals**.**

4.5 SAWA201 (Average Sleep Efficiency in Workday Main Rest Intervals)
This is the average percentage of time spent asleep within workday main rest intervals.

4.6 SAWA248 (Average Sleep Efficiency in Non-workday Main Rest Intervals)
This is the average percentage of time spent asleep within non-workday main rest intervals.

4.7 SAWA295 (Average Sleep Efficiency in Reliable Main Rest Intervals)
This is the average percentage of time spent asleep within reliable day main rest intervals.

4.8 SAWA24 (Average Sleep Maintenance Efficiency)
This is the average percentage of time spent asleep between sleep onset and sleep offset across all main rest intervals with sleep. This variable is similar to the Sueño calculated variable SAWA62; however, SAWA24 is generated automatically by Actiware before data optimization.

4.9 SAWA62 (Average Sleep Maintenance Efficiency)
This is the average percentage of time spent asleep between sleep onset and sleep offset across all main rest intervals with sleep. This refers to the percentage of time that a person spent asleep between the time they first fell asleep and the time they woke up for the day.

4.10 SAWA34 (Average Weekday Sleep Maintenance Efficiency)
This is the average percentage of time spent asleep between sleep onset and sleep offset across all weekday main rest intervals with sleep. This variable is similar to variable SAWA109; however, SAWA34 is derived from Actiware variable SAWA24 before data optimization.

4.11 SAWA109 (Average Weekday Sleep Maintenance Efficiency)
This is the average percentage of time spent asleep between sleep onset and sleep offset across all weekday main rest intervals with sleep.

4.12 SAWA33 (Average Weekend Sleep Maintenance Efficiency)
This is the average percentage of time spent asleep between sleep onset and sleep offset across all weekend main rest intervals with sleep. This variable is similar to variable SAWA156; however, SAWA33 is derived from Actiware variable SAWA24 before data optimization.

4.13 SAWA156 (Average Weekend Sleep Maintenance Efficiency)

This is the average percentage of time spent asleep between sleep onset and sleep offset across all weekend main rest intervals with sleep.

4.14 SAWA203 (Average Workday Sleep Maintenance Efficiency)
This is the average percentage of time spent asleep between sleep onset and sleep offset across all workday main rest intervals with sleep**.**

4.15 SAWA250 (Average Non-Workday Sleep Maintenance Efficiency)
This is the average percentage of time spent asleep between sleep onset and sleep offset across all non-workday main rest intervals with sleep.

4.16 SAWA297 (Average Reliable Day Sleep Maintenance Efficiency)
This is the average percentage of time spent asleep between sleep onset and sleep offset across all reliable day main rest intervals with sleep.

4.17 SAWA23 (Average Wake Bouts in Sleep Intervals)
This is the average number of continuous periods of wake, at least 30 seconds long, between sleep onset and sleep offset across all main rest intervals with sleep. This variable is similar to variable SAWA66; however, SAWA23 is generated by Actiware software before data optimization.

4.18 SAWA66 (Average Wake Bouts in Sleep Intervals)
This is the average number of continuous periods of wake, at least 30 seconds long, between sleep onset and sleep offset across all main rest intervals with sleep. This refers to the number of times that a person woke up during the night, after having initially fallen asleep and before finally waking up for the day. Note that this variable does not take the length of each wake bout into account.

4.19 SAWA113 (Average Wake Bouts in Weekday Sleep Intervals)
This is the average number of continuous periods of wake between sleep onset and sleep offset across all weekday main rest intervals with sleep.

4.20 SAWA160 (Average Wake Bouts in Weekend Sleep Intervals)
This is the average number of continuous periods of wake between sleep onset and sleep offset across all weekend main rest intervals with sleep.

4.21 SAWA207 (Average Wake Bouts in Workday Sleep Intervals)
This is the average number of continuous periods of wake between sleep onset and sleep offset across all workday main rest intervals with sleep.

4.22 SAWA254 (Average Wake Bouts in Non-workday Sleep Intervals)
This is the average number of continuous periods of wake between sleep onset and sleep offset across all non-workday main rest intervals with sleep.

4.23 SAWA301 (Average Wake Bouts in Reliable Day Sleep Intervals)
This is the average number of continuous periods of wake between sleep onset and sleep offset across all reliable day main rest intervals with sleep.

4.24 SAWA25 (Average Sleep Bouts in Sleep Intervals)
This is the average number of continuous periods of sleep, at least 30 seconds long, between sleep onset and sleep offset across all main rest intervals of at least one minute duration. This variable is similar to variable SAWA65; however, SAWA25 is generated by Actiware software before data optimization.

4.25 SAWA65 (Average Sleep Bouts in Sleep Intervals)

This is the average number of continuous periods of sleep, at least 30 seconds long, between sleep onset and sleep offset across all main rest intervals of at least one minute duration. This refers to the number of times that a person fell asleep during the night. Note that this variable does not take the length of each sleep bout into account.

4.26 SAWA112 (Average Sleep Bouts in Weekday Sleep Intervals)
This is the average number of continuous periods of sleep between sleep onset and sleep offset across all weekday main rest intervals.

4.27 SAWA159 (Average Sleep Bouts in Weekend Sleep Intervals)
This is the average number of continuous periods of sleep between sleep onset and sleep offset across all weekend main rest intervals.

4.28 SAWA206 (Average Sleep Bouts in Workday Sleep Intervals)
This is the average number of continuous periods of sleep between sleep onset and sleep offset across all workday main rest intervals.

4.29 SAWA253 (Average Sleep Bouts in Non-workday Sleep Intervals)
This is the average number of continuous periods of sleep between sleep onset and sleep offset across all non- workday main rest intervals.

4.30 SAWA300 (Average Sleep Bouts in Reliable Day Sleep Intervals)
This is the average number of continuous periods of sleep between sleep onset and sleep offset across all reliable day main rest intervals.

4.31 SAWA26 (Average of Sleep Fragmentation in Main Sleep Intervals)
This is the average fragmentation index across all main rest intervals with sleep. This variable is similar to variable SAWA64; however, SAWA26 is generated by Actiware software before data optimization.

4.32 SAWA64 (Average Sleep Fragmentation in Main Sleep Intervals)
This is the average fragmentation index across all main rest intervals with sleep. The fragmentation index of a sleep interval = [(sum of mobile epochs in sleep period / sum of all epochs in sleep period) + (number of immobile bouts that last 1 minute or less in sleep period / total number of immobile bouts in sleep period)] x100%. This refers to the sum of the percentage of the time that a person was mobile during the sleep interval and the percentage of all immobile bouts ≤1min in the sleep interval. The fragmentation index provides information on the quality of a person's sleep.

4.33 SAWA111 (Average Sleep Fragmentation in Weekday Main Sleep Intervals)
This is the average fragmentation index across all weekday main rest intervals with sleep.

4.34 SAWA158 (Average Sleep Fragmentation in Weekend Main Sleep Intervals)
This is the average sleep fragmentation index across all weekend main rest intervals with sleep.

4.35 SAWA205 (Average Sleep Fragmentation in Workday Main Sleep Intervals)
This is the average sleep fragmentation index across all workday main rest intervals with sleep.

4.36 SAWA252 (Average Sleep Fragmentation in Non-workday Main Sleep Intervals)
This is the average sleep fragmentation index across all non- workday main rest intervals with sleep.

4.37 SAWA299 (Average Sleep Fragmentation in Reliable Main Sleep Intervals)
This is the average of the fragmentation indexes across all reliable day main rest intervals with sleep.

5. SLEEP TIMING

5.1 SAWA330 (Average Time In Bed per Sleep Diary)
This is the average time at which the participant self-reported going to bed across all days in the daily sleep log.

5.2 SAWA331 (Average Time Out of Bed per Sleep Diary)
This is the average time at which the participant self-reported getting out of bed across all days in the daily sleep log.

5.3 SAWA37 (Average Time in Bed)
This is the average clock start time of all main rest intervals. This variable is similar to SAWA78; however SAWA37 is calculated based on data generated by Actiware software before data optimization.

5.4 SAWA78 (Average Time in Bed)
This is the average clock start time of all main rest intervals. This refers to the time, on average, in which the participant went to bed to try to fall asleep across all main rest intervals.

5.5 SAWA39 (Average Weekday Time in Bed)
This is the average clock start time for all weekday main rest intervals. This variable is similar to SAWA125; however SAWA39 is calculated based on data generated by Actiware software before data optimization.

5.6 SAWA125 (Average Weekday Time in Bed)
This is the average clock start time for all weekday main rest intervals.

5.7 SAWA40 (Average Weekend Time in Bed)
This is the average clock start time for all weekend main rest intervals. This variable is similar to the Sueño generated variable SAWA172; however SAWA40 is calculated based on data generated by Actiware software before data optimization.

5.8 SAWA172 (Average Weekend Time in Bed)
This is the average clock start time for all weekend main rest intervals.

5.9 SAWA219 (Average Workday Time in Bed)
This is the average clock start time for all workday main rest intervals.

5.10 SAWA266 (Average Non-Workday Time in Bed)
This is the average clock start time for all non- workday main rest intervals.

5.11 SAWA313 (Average Time in Bed on Reliable Days)
This is the average clock start time for all reliable day main rest intervals.

5.12 SAWA84 (Average Time Out of Bed)
This is the average clock end time of all main rest intervals. This refers to the time, on average, at which a person got out bed for the day, across all main rest intervals.

5.13 SAWA131 (Average Time Out of Bed on Weekdays)
This is the average clock end time for all weekday main rest intervals.

5.14 SAWA178 (Average Time Out of Bed on Weekends)
This is the average clock end time for all weekend main rest intervals.

5.15 SAWA225 (Average Time Out of Bed on Workdays)
This is the average clock end time for all workday main rest intervals.

5.16 SAWA272 (Average Time Out of Bed on Non-Workdays)
This is the average clock end time for all non-workday main rest intervals.

5.17 SAWA319 (Average Time Out of Bed on Reliable days)
This is the average clock end time for all reliable day main rest intervals.

5.18 SAWA86 (Average Main Rest Interval Midpoint)
This is the average clock time of the epoch that is exactly midway between the start and end times of each main rest interval. This is the midpoint between time in bed and time out of bed, across all main rest intervals.

5.19 SAWA133 (Average Weekday Main Rest Interval Midpoint)
This is the average clock time of the epoch that is exactly midway between the start and end times of each weekday main rest interval.

5.20 SAWA180 (Average Weekend Main Rest Interval Midpoint)
This is the average clock time of the epoch that is exactly midway between the start and end times of each weekend main rest interval.

5.21 SAWA227 (Average Workday Main Rest Interval Midpoint)
This is the average clock time of the epoch that is exactly midway between the start and end times of each workday main rest interval.

5.22 SAWA274 (Average Non-workday Main Rest Interval Midpoint)
This is the average clock time of the epoch that is exactly midway between the start and end times of each non-workday main rest interval.

5.23 SAWA321 (Average Reliable Main Rest Interval Midpoint)
This is the average clock time of the epoch that is exactly midway the start and end times of each reliable day main rest interval.

5.24 SAWA41 (Average Sleep Onset Time)

This is the average time of the first epoch of sleep across all main rest intervals with sleep. This variable is similar to variable SAWA80; however, SAWA41 is calculated based on data generated by Actiware software before data optimization.

5.25 SAWA80 (Average Main Sleep Onset)

This is the average clock time of the first epoch of sleep across all main rest intervals with sleep. This refers to the clock time at which the person first fell asleep for his/her nightly sleep.

5.26 SAWA43 (Average Weekday Sleep Onset)

This is the average clock time of the first epoch of sleep across all weekday main rest intervals with sleep. This variable is similar to variable SAWA127; however, SAWA43 is calculated based on data generated by Actiware software before data optimization.

5.27 SAWA127 (Average Weekday Main Sleep Onset)

This is the average clock time of the first epoch of sleep across all weekday main rest intervals with sleep.

5.28 SAWA44 (Average Weekend Sleep Onset)

This is the average clock time of the first epoch of sleep across all weekend main rest intervals with sleep. This variable is similar to variable SAWA174; however, SAWA44 is calculated based on data generated by Actiware software before data optimization.

5.29 SAWA174 (Average Weekend Main Sleep Onset)

This is the average clock time of the first epoch of sleep across all weekend main rest intervals with sleep.

5.30 SAWA221 (Average Workday Main Sleep Onset)

This is the average clock time of the first epoch of sleep across all workday main rest intervals with sleep.

5.31 SAWA268 (Average Non-workday Main Sleep Onset)

This is the average clock time of the first epoch of sleep across all non-workday main rest intervals with sleep.

5.32 SAWA315 (Average Reliable Day Main Sleep Onset)

This is the average clock time of the first epoch of sleep across all reliable day main rest intervals with sleep.

5.33 SAWA82 (Average Main Sleep Offset)

This is the average clock time of the last epoch of sleep across all main rest intervals with sleep. This refers to the clock time at which the person wakes up for the day.

5.34 SAWA129 (Average Weekday Main Sleep Offset)

This is the average clock time of the last epoch of sleep across all weekday main rest intervals with sleep.

5.35 SAWA176 (Average Weekend Main Sleep Offset)

This is the average clock time of the last epoch of sleep across all weekend main rest intervals with sleep.

5.36 SAWA223 (Average Workday Main Sleep Offset)
This is the average clock time of the last epoch of sleep across all workday main rest intervals with sleep.

5.37 SAWA270 (Average Non-workday Main Sleep Offset)
This is the average clock time of the last epoch of sleep across all non-workday main rest intervals with sleep.

5.38 SAWA317 (Average Reliable Day Main Sleep Offset)
This is the average clock time of the last epoch of sleep across all reliable day main rest intervals with sleep.

5.39 SAWA88 (Average Sleep Interval Midpoint)
This is the average clock time of the epoch that is exactly midway between sleep onset and sleep offset across all main rest intervals with sleep.

5.40 SAWA135 (Average Weekday Sleep Interval Midpoint)
This is the average clock time that is exactly midway between sleep onset and sleep offset across all weekday main rest intervals with sleep.

5.41 SAWA182 (Average Weekend Sleep Interval Midpoint)
This is the average clock time that is exactly midway between sleep onset and sleep offset across all weekend main rest intervals with sleep.

5.42 SAWA229 (Average Workday Sleep Interval Midpoint)
This is the average clock time that is exactly midway between sleep onset and sleep offset across all workday main rest intervals with sleep.

5.43 SAWA276 (Average Non-workday Sleep Interval Midpoint)
This is the average clock time that is exactly midway between sleep onset and sleep offset across all non-workday main rest intervals with sleep.

5.44 SAWA323 (Average Reliable Sleep Interval Midpoint)
This is the average clock time that is exactly midway between sleep onset and sleep offset across all reliable day main rest intervals with sleep.

6. NAPS

6.1 SAWA333 (Percent Diary Days with Naps)
This is the percentage of days in which the participant self-reported in the daily sleep log they took a nap.

6.2 SAWA67 (Days with Any Naps)
This is the number of main rest intervals with at least one nap since the end of the previous main rest interval. This refers to the number of days on which a participant reported taking naps.

6.3 SAWA68 (Days with Naps with Sleep)
This is the number of days that have at least one nap containing any sleep time.

6.4 SAWA69 (Days with Naps with Sleep ≥ 15 Minutes)
This is the number of days that have at least one nap that contains 15 or more minutes of sleep.

6.5 SAWA114 (Weekday Days with Naps)
This is the number of weekdays with at least one nap. This refers to the number of weekdays on which a participant reported taking naps.

6.6 SAWA115 (Weekday Days with Naps with Sleep)
This is the number of weekdays that have at least one nap containing any sleep time.

6.7 SAWA116 (Weekday Days with ≥ 15 Minute Naps)
This is the number of weekdays that have at least one nap that contains 15 or more minutes of sleep.

6.8 SAWA161 (Weekend Days with Naps)
This is the number of weekend days that have at least one nap. This refers to the number of weekend days on which a participant reported taking naps.

6.9 SAWA162 (Weekend Days with Naps with Sleep)
This is the number of weekend days that have at least one nap containing any sleep time.

6.10 SAWA163 (Weekend Days with ≥ 15 Minute Naps)
This is the number of weekend days that have at least one nap that contains 15 or more minutes of sleep.

6.11 SAWA208 (Workday Days with Naps)
This is the number of workdays that have at least one nap. This refers to the number of workday days on which a participant reported taking naps.

6.12 SAWA209 (Workday Days with Naps with Sleep)
This is the number of workdays that have at least one nap containing any sleep time.

6.13 SAWA210 (Workday Days with Naps with Sleep ≥ 15 Minutes)
This is the number of workdays that have at least one nap that contains 15 or more minutes of sleep.

6.14 SAWA255 (Non-workday Days with Naps)
This is the number of non-workdays that have at least one nap. This refers to the number of Non-workday days on which a participant reported taking naps.

6.15 SAWA256 (Non-workday Days with Naps with Sleep)
This is the number of non-workdays that have at least one nap that contains any sleep time.

6.16 SAWA257 (Non-workday Days with Naps with Sleep ≥ 15 Minutes)
This is the number of non-workdays that have at least one nap that contains 15 or more minutes of sleep.

6.17 SAWA302 (Reliable Days with Naps)

This is the number of reliable days that have at least one nap. This refers to the number of reliable days on which a participant reported taking naps.

6.18 SAWA303 (Reliable Days with Naps with Sleep)
This is the number of reliable days that have at least one nap containing any sleep time.

6.19 SAWA304 (Reliable Days with Naps with Sleep ≥ 15 Minutes)
This is the number of reliable days that have at least one nap that contains 15 or more minutes of sleep.

6.20 SAWA70 (Average Number of Naps)
This is the average number of naps per day.

6.21 SAWA71 (Average Number of Naps with Sleep)
This is the average number of naps containing any sleep time across all days.

6.22 SAWA72 (Average Number of Naps with Sleep ≥ 15 Minutes)
This is the average number of naps containing 15 or more minutes of sleep across all days.

6.23 SAWA117 (Average Number of Weekday Naps)
This is the average number of naps across all weekdays.

6.24 SAWA118 (Average Number of Weekday Naps with Sleep)
This is the average number of naps containing any sleep time across all weekdays.

6.25 SAWA119 (Average Number of Weekday Naps with Sleep ≥ 15 Minutes)
This is the average number of naps containing 15 or more minutes of sleep across all weekdays.

6.26 SAWA164 (Average Number of Weekend Naps)
This is the average number of naps across all weekend days.

6.27 SAWA165 (Average Number of Weekend Naps with Sleep)
This is the average number of naps containing any sleep time across all weekend days.
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6.28 SAWA166 (Average Number of Weekend Naps with Sleep ≥ 15 Minutes)
This is the average number of naps containing 15 or more minutes of sleep across all weekend days.
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6.29 SAWA211 (Average Number of Workday Naps)
This is the average number of naps across all workdays.

6.30 SAWA212 (Average Number of Workday Naps with Sleep)
This is the average number of naps containing any sleep time across all workdays.

6.31 SAWA213 (Average Number of Workday Naps with Sleep ≥ 15 Minutes)
This is the average number of naps containing 15 or more minutes of sleep across all workdays.

6.32 SAWA258 (Average Number of Non-workday Naps)

This is the average number of naps across all non-workdays.

6.33 SAWA259 (Average Number of Non-workday Naps with Sleep)
This is the average number of naps containing any sleep time across all non-workdays.

6.34 SAWA260 (Average Number of Non-workday Naps with Sleep ≥ 15 Minutes)
This is the average number of naps containing 15 or more minutes of sleep across all non-workdays.

6.35 SAWA305 (Average Number of Reliable Day Naps)
This is the average number of naps across all reliable days.

6.36 SAWA306 (Average Number of Reliable Day Naps with Sleep)
This is the average number of naps containing any sleep time across all reliable days.

6.37 SAWA307 (Average Number of Reliable Day Naps with Sleep ≥ 15 Minutes)
This is the average number of naps containing 15 or more minutes of sleep across all reliable days.

6.38 SAWA73 (Average Sleep Time per Nap)
This is the average sleep time per nap. This refers to the average length of time spent asleep in each nap.

6.39 SAWA74 (Average Sleep Time per Nap with Sleep)
This is the average sleep time per nap when only naps that contain sleep are counted.

6.40 SAWA75 (Average Sleep Time per Nap with Sleep ≥ 15 Minutes)
This is the average sleep time per nap when only naps containing 15 or more minutes of sleep are counted.

6.41 SAWA120 (Average Sleep Time per Weekday Nap)
This is the average sleep time per weekday nap.

6.42 SAWA121 (Average Sleep Time per Weekday Nap with Sleep)
This is the average sleep time per weekday nap when only naps that contain sleep are counted.

6.43 SAWA122 (Average Sleep Time per Weekday Nap with Sleep ≥ 15 Minutes)
This is the average sleep time per weekday nap when only naps containing 15 or more minutes of sleep are counted.

6.44 SAWA167 (Average Sleep Time per Weekend Nap)
This is the average sleep time per weekend nap.

6.45 SAWA168 (Average Sleep Time per Weekend Nap with Sleep)
This is the average sleep time per weekend nap when only naps that contain sleep are counted.

6.46 SAWA169 (Average Sleep Time per Weekend Nap with Sleep ≥ 15 Minutes)

This is the average sleep time per weekend nap when only naps containing 15 or more minutes of sleep are counted.

6.47 SAWA214 (Average Sleep Time per Workday Nap)
This is the average sleep time per workday nap.

6.48 SAWA215 (Average Sleep Time per Workday Nap with Sleep)
This is the average sleep time per workday nap when only naps that contain sleep are counted.

6.49 SAWA216 (Average Sleep Time per Workday Nap with Sleep ≥ 15 Minutes)
This is the average sleep time per workday nap when only naps containing 15 or more minutes of sleep are counted.

6.50 SAWA261 (Average Sleep Time per Non-Workday Nap)
This is the average sleep time per non-workday nap.

6.51 SAWA262 (Average Sleep Time per Non-Workday Nap with Sleep)
This is the average sleep time per non-workday nap when only naps that contain sleep are counted.

6.52 SAWA263 (Average Sleep Time per Non-Workday Nap with Sleep ≥ 15 Minutes)
This is the average sleep time per non-workday nap when only naps containing 15 or more minutes of sleep are counted.

6.53 SAWA308 (Average Sleep Time per Reliable Day Nap)
This is the average sleep time per reliable day nap.

6.54 SAWA309 (Average Sleep Time per Reliable Day Nap with Sleep)
This is the average sleep time per reliable day nap when only naps that contain sleep are counted.

6.55 SAWA310 (Average Sleep Time per Reliable Day Nap with Sleep ≥ 15 Minutes)
This is the average sleep time per reliable day nap when only naps containing 15 or more minutes of sleep are counted.

6.56 SAWA76 (Average Sleep Time per Day in Naps with Sleep)
This is the average sleep time, in naps per day, across all days.

6.57 SAWA77 (Average Sleep Time per Day with Sleep ≥ 15 Minutes)
This is the average sleep time, in naps per day, across all days when only naps containing 15 or more minutes of sleep are counted.

6.58 SAWA123 (Average Sleep Time per Weekday Nap with Sleep)
This is the average sleep time, in naps per day, across all weekdays.

6.59 SAWA124 (Average Sleep Time per Weekday Nap with Sleep ≥ 15 Minutes)
This is the average sleep time, in naps per day, across all weekdays when only naps containing 15 or more minutes of sleep are counted.

6.60 SAWA170 (Average Sleep Time per Weekend Nap with Sleep)
This is the average sleep time, in naps per day, across all weekend days.

6.61 SAWA171 (Average Sleep Time per Weekend Nap with Sleep ≥ 15 Minutes)
This is the average sleep time, in naps per day, across all weekend days when only naps containing 15 or more minutes of sleep are counted.

6.62 SAWA217 (Average Sleep Time per Workday Nap with Sleep)
This is the average sleep time, in naps per day, across all workdays.

6.63 SAWA218 (Average Sleep Time per Workday Nap with Sleep ≥ 15 Minutes)
This is the average sleep time, in naps per day, across all workdays when only naps containing 15 or more minutes of sleep are counted.

6.64 SAWA264 (Average Sleep Time per Non-workday Nap with Sleep)
This is the average sleep time, in naps per day, across all non-workdays.

6.65 SAWA265 (Average Sleep Time per Non-workday Nap with Sleep ≥ 15 Minutes)
This is the average sleep time, in naps per day, across all non-workdays when only naps containing 15 or more minutes of sleep are counted.

6.66 SAWA311 (Average Sleep Time per Reliable Day Nap with Sleep)
This is the average sleep time, in naps per day, across all reliable days.

6.67 SAWA312 (Average Sleep Time per Reliable Day Nap with Sleep ≥ 15 Minutes)
This is the average sleep time, in naps per day, across all reliable days when only naps containing 15 or more minutes of sleep are counted.

7. VARIABILITY

7.1 SAWA28 (Standard Deviation of Main Rest Duration)
This is the standard deviation across all days of the main rest interval duration, in minutes. This is similar to SAWA51; however, SAWA28 is generated by Actiware software before data optimization.

7.2 SAWA51 (Standard Deviation of Main Rest Duration)
This is the standard deviation across all days of the main rest interval duration, in minutes. This refers to the variability in the nightly amount of time that a person spent in bed across all days.

7.3 SAWA98 (Standard Deviation of Weekday Main Rest Duration)
This is the standard deviation across all weekday main rest interval durations.

7.4 SAWA145 (Standard Deviation of Weekend Main Rest Duration)
This is the standard deviation across all weekend main rest interval durations.

7.5 SAWA192 (Standard Deviation of Workday Main Rest Duration)
This is the standard deviation across all workday main rest interval durations.

7.6 SAWA239 (Standard Deviation of Non-workday Main Rest Duration)
This is the standard deviation across all non-workday main rest interval durations.

7.7 SAWA286 (Standard Deviation of Reliable Day Main Rest Duration)
This is the standard deviation across all reliable day main rest interval durations.

7.8 SAWA29 (Standard Deviation of Main Sleep Duration)
This is the standard deviation across all days of the main sleep interval duration, in minutes. This variable is similar to SAWA53; however, SAWA29 is generated by Actiware software before data optimization.

7.9 SAWA53 (Standard Deviation of Main Sleep Duration)
This is the standard deviation across all days of the main sleep interval duration, in minutes. This refers to the variability in the nightly amount of time between sleep onset and sleep offset.

7.10 SAWA100 (Standard Deviation of Weekday Main Sleep Duration)
This is the standard deviation across all weekday main sleep interval durations.

7.11 SAWA147 (Standard Deviation of Weekend Main Sleep Duration)
This is the standard deviation across all weekend main sleep interval durations.

7.12 SAWA194 (Standard Deviation of Workday Main Sleep Duration)
This is the standard deviation across all workday main sleep interval durations.

7.13 SAWA241 (Standard Deviation of Non-workday Main Sleep Duration)
This is the standard deviation across all non-workday main sleep interval durations.

7.14 SAWA288 (Standard Deviation of Reliable Day Main Sleep Duration)
This is the standard deviation across all reliable day main sleep interval durations.

7.15 SAWA55 (Standard Deviation of Sleep Time)
This is the standard deviation across all days, of sleep time within the main rest interval. This refers to the variability in the nightly amount of sleep.

7.16 SAWA102 (Standard Deviation of Weekday Sleep Time)
This is the standard deviation across all weekday days, of sleep time within the main rest interval.

7.17 SAWA149 (Standard Deviation of Weekend Sleep Time)
This is the standard deviation across all weekend days, of sleep time within the main rest interval.

7.18 SAWA196 (Standard Deviation of Workday Sleep Time)
This is the standard deviation across all workday days, of sleep time within the main rest interval.

7.19 SAWA243 (Standard Deviation of Non-Workday Sleep Time)
This is the standard deviation across all non-workday days, of sleep time within the main rest interval.

7.20 SAWA290 (Standard Deviation of Reliable Day Sleep Time)
This is the standard deviation across all reliable days, of sleep time within the main rest interval.

7.21 SAWA96 (Standard Deviation of Sleep Duration in Weekday Main Rest and Naps)
This is the standard deviation across all weekdays, of total sleep time.

7.22 SAWA143 (Standard Deviation of Sleep Duration in Weekend Main Rest and Naps)
This is the standard deviation across all weekend days, of total sleep time.

7.23 SAWA190 (Standard Deviation of Sleep Duration in Workday Main Rest and Naps)
This is the standard deviation across all workdays, of total sleep time.

7.24 SAWA237 (Standard Deviation of Sleep Duration in Non-workday Main Rest and Naps)
This is the standard deviation across all non-workdays, of total sleep time.

7.25 SAWA284 (Standard Deviation of Sleep Duration in Reliable Main Rest and Naps)
This is the standard deviation across all reliable days, of total sleep time.

7.26 SAWA38 (Standard Deviation of Average Time in Bed)
This is the standard deviation across all days, of main rest interval start times. This variable is similar to SAWA79; however, SAWA38 is calculated based on data generated by Actiware software before data optimization.

7.27 SAWA79 (Standard Deviation of Time in Bed)
This is the standard deviation across all days, of main rest interval start times. This refers to the variability in the times at which a person went to bed for nightly sleep.

7.28 SAWA126 (Standard Deviation of Weekday Time in Bed)
This is the standard deviation across all weekdays, of main rest interval start time.

7.29 SAWA173 (Standard Deviation of Weekend Time in Bed)
This is the standard deviation across all weekend days, of main rest interval start time.

7.30 SAWA220 (Standard Deviation of Workday Time in Bed)
This is the standard deviation across all workdays, of main rest interval start time.

7.31 SAWA267 (Standard Deviation of Non-Workday Time in Bed)
This is the standard deviation across all non-workdays, of main rest interval start time.

7.32 SAWA314 (Standard Deviation of Reliable Day Time in Bed)
This is the standard deviation across all reliable days, of main rest interval start time.

7.33 SAWA85 (Standard Deviation of Time Out of Bed)
This is the standard deviation across all days, of main rest interval end times. This refers to the variability in the times at which a person gets out of bed, across all days.

7.34 SAWA132 (Standard Deviation of Weekday Time Out of Bed)

This is the standard deviation across all weekdays, of main rest interval end time.

7.35 SAWA179 (Standard Deviation of Weekend Time Out of Bed)
This is the standard deviation across all weekend days, of main rest interval end time.

7.36 SAWA226 (Standard Deviation of Workday Time Out of Bed)
This is the standard deviation across all workdays, of main rest interval end time.

7.37 SAWA273 (Standard Deviation of Non-Workday Time Out of Bed)
This is the standard deviation across all non-workdays, of main rest interval end time.

7.38 SAWA320 (Standard Deviation of Reliable Day Time Out of Bed)
This is the standard deviation across all reliable days, of main rest interval end time.

7.39 SAWA87 (Standard Deviation of Main Rest Midpoints)
This is the standard deviation across all days, of main rest interval midpoint. This refers to the variability in the clock time at which the midpoint between time in bed and time out of bed occurs.

7.40 SAWA134 (Standard Deviation of Weekday Main Rest Midpoints)
This is the standard deviation across all weekdays, of main rest interval midpoint.

7.41 SAWA181 (Standard Deviation of Weekend Main Rest Midpoints)
This is the standard deviation across all weekend days, of main rest interval midpoint.

7.42 SAWA228 (Standard Deviation of Workday Main Rest Midpoints)
This is the standard deviation across all workdays, of main rest interval midpoint.

7.43 SAWA275 (Standard Deviation of Non-workday Main Rest Midpoints)
This is the standard deviation across all non-workdays, of main rest interval midpoint.

7.44 SAWA322 (Standard Deviation of Reliable Main Rest Midpoints)
This is the standard deviation across all reliable days, of main rest interval midpoint.

7.45 SAWA42 (Standard Deviation of Sleep Onset Times)
This is the standard deviation across all days, of the sleep onset time within main rest intervals with sleep. This variable is similar to variable SAWA81; however SAWA42 is calculated based on data generated by Actiware software before data optimization.

7.46 SAWA81 (Standard Deviation of Sleep Onset)
This is the standard deviation across all days, of the sleep onset time within main rest intervals with sleep. This refers to the variability in the clock time at which a person first fell asleep in his/her main sleep period.

7.47 SAWA128 (Standard Deviation of Weekday Sleep Onset)
This is the standard deviation across all weekdays, of the sleep onset time within main rest intervals with sleep.

7.48 SAWA175 (Standard Deviation of Weekend Sleep Onset)

This is the standard deviation across all weekend days, of the sleep onset time within main rest intervals with sleep.

7.49 SAWA222 (Standard Deviation of Workday Sleep Onset)
This is the standard deviation across all workdays, of the sleep onset time within main rest intervals with sleep.

7.50 SAWA269 (Standard Deviation of Non-workday Sleep Onset)
This is the standard deviation across all non-workdays, of the sleep onset time within main rest intervals with sleep.

7.51 SAWA316 (Standard Deviation of Reliable Day Sleep Onset)
This is the standard deviation across all reliable days, of the sleep onset time within main rest intervals with sleep.

7.52 SAWA83 (Standard Deviation of Sleep Offset)
This is the standard deviation across all days, of the sleep offset time within main rest intervals with sleep. This refers to the variability in the clock time at which the person wakes up for the day.

7.53 SAWA130 (Standard Deviation of Weekday Sleep Offset)
This is the standard deviation across all weekdays, of the sleep offset time within main rest intervals with sleep.

7.54 SAWA177 (Standard Deviation of Weekend Sleep Offset)
This is the standard deviation across all weekend days, of the sleep offset time within main rest intervals with sleep.

7.55 SAWA224 (Standard Deviation of Workday Sleep Offset)
This is the standard deviation across all workdays, of the sleep offset time within main rest intervals with sleep.

7.56 SAWA271 (Standard Deviation of Non-workday Sleep Offset)
This is the standard deviation across all non-workdays, of the sleep offset time within main rest intervals with sleep.

7.57 SAWA318 (Standard Deviation of Reliable Day Sleep Offset)
This is the standard deviation across all reliable days, of the sleep offset time within main rest intervals with sleep.

7.58 SAWA89 (Standard Deviation of Main Sleep Midpoint)
This is the standard deviation across all days, of the midpoint between sleep onset and sleep offset within the main rest interval. This refers to the variability in the clock time of a person's midpoint of sleep.

7.59 SAWA136 (Standard Deviation of Weekday Main Sleep Midpoint)
This is the standard deviation across all weekdays, of the midpoint between sleep onset and sleep offset within main rest intervals.

7.60 SAWA183 (Standard Deviation of Weekend Main Sleep Midpoint)

This is the standard deviation across all weekend days, of the midpoint between sleep onset and sleep offset within main rest intervals.

7.61 SAWA230 (Standard Deviation of Workday Main Sleep Midpoint)
This is the standard deviation across all workdays, of the midpoint between sleep onset and sleep offset within main rest intervals.

7.62 SAWA277 (Standard Deviation of Non-workday Main Sleep Midpoint)
This is the standard deviation across all non-workdays, of the midpoint between sleep onset and sleep offset within main rest intervals.

7.63 SAWA324 (Standard Deviation of Reliable Main Sleep Midpoint)
This is the standard deviation across all reliable days, of the midpoint between sleep onset and sleep offset within main rest intervals.

7.64 SAWA61 (Standard Deviation of Main Rest Sleep Efficiency)
This is the standard deviation across all days, of the main rest interval sleep efficiency. This refers to the variability in the proportion of time spent in bed that a person was sleeping, expressed as a percentage.

7.65 SAWA108 (Standard Deviation of Weekday Main Rest Sleep Efficiency)
This is the standard deviation across all weekdays, of the sleep efficiency.

7.66 SAWA155 (Standard Deviation of Weekend Main Rest Sleep Efficiency)
This is the standard deviation across all weekend days, of the sleep efficiency.

7.67 SAWA202 (Standard Deviation of Workday Main Rest Sleep Efficiency)
This is the standard deviation across all workdays, of the sleep efficiency.

7.68 SAWA249 (Standard Deviation of Non-workday Main Rest Sleep Efficiency)
This is the standard deviation across all non-workdays, of the sleep efficiency.

7.69 SAWA296 (Standard Deviation of Reliable Day Main Rest Sleep Efficiency)
This is the standard deviation across all reliable days, of the sleep efficiency.

7.70 SAWA30 (Standard Deviation of Main Rest Sleep Maintenance Efficiency)
This is the standard deviation across all days, of the percentage of sleep time between sleep onset and sleep offset within main rest intervals. This variable is similar to variable SAWA63; however, SAWA30 is generated automatically by Actiware before data optimization.

7.71 SAWA63 (Standard Deviation of Main Sleep Maintenance Efficiency)
This is the standard deviation across all days, of the main rest interval sleep maintenance efficiency. This refers to the variability in the proportion of time between sleep onset and sleep offset that was spent sleeping, expressed as a percentage.

7.72 SAWA110 (Standard Deviation of Weekday Main Sleep Maintenance Efficiency)
This is the standard deviation across all weekdays, of the percentage of sleep time between sleep onset and sleep offset within main rest intervals.

7.73 SAWA157 (Standard Deviation of Weekend Main Sleep Maintenance Efficiency)
This is the standard deviation across all weekend days, of the main rest interval sleep maintenance efficiency.

7.74 SAWA204 (Standard Deviation Main Workday Sleep Maintenance Efficiency)
This is the standard deviation across all workdays, of the main rest interval sleep maintenance efficiency.

7.75 SAWA251 (Standard Deviation of Non-work Main Sleep Maintenance Efficiency)
This is the standard deviation across all non-workdays, of the main rest interval sleep maintenance efficiency.

7.76 SAWA298 (Standard Deviation of Reliable Day Main Sleep Maintenance Efficiency)
This is the standard deviation across all reliable days, of the main rest interval sleep maintenance efficiency.

7.77 SAWA338 (Inter-day Stability)
This is a measure of invariability (or similarity) of sleep wake patterns over a 24-hour period across a 7-day recording. For a variable x(i) that defines sleep-wake status at each epoch i, the inter-day stability is calculated as the proportion of the total variance in x(i) explained by the clock time (in 1-hour bins) that the epoch is in. The inter-day stability can range from 0 (when the 1-hour bins explain none of the variance in sleep-wake status) to 1 (when the 1-hour bins explain all of the variance). Note, that the inter-day stability utilizes the most complete 7 continuous days of recording and is set to missing if 7 consecutive valid days are not present.

For more information, see:

Van Someren EJW et al. Bright light therapy: improved sensitivity to its effects on rest-activity rhythms in Alzheimer patients by application of nonparametric methods. Chronobiol Int 1999; 16(4): 505-18.

7.78 SAWA339 (Intra-day Variability)
This is a measure of the fragmentation of the sleep-wake pattern assessed on an hourly basis across a 7-day recording. It is calculated as the ratio of the mean squares of the difference between the proportion of sleep in all successive hours and the overall variance across all epochs in the 7-day recording. Note, that the intra-day variability utilizes the most complete 7 continuous days of recording and is set to missing if 7 consecutive valid days are not present.

For more information, see:

Van Someren EJW et al. Bright light therapy: improved sensitivity to its effects on rest-activity rhythms in Alzheimer patients by application of nonparametric methods. Chronobiol Int 1999; 16(4): 505-18.

8. LIGHT

8.1 SAWA17 (Average White Light Exposure in Main Rest Intervals)

This is the average white light intensity, in lux, between sleep onset and sleep offset times across all main rest intervals with sleep, as generated by Actiware before data optimization.

8.2 SAWA27 (Average Daily White Light Exposure)
This is the average white light intensity, in lux over the entire day, as generated by Actiware before data optimization.

8.3 SAWA90 (Average White Light Duration above Lux Threshold)
This is the average duration per day that white light intensity was above 1000 lux across all days, in minutes.

8.4 SAWA137 (Average Weekday White Light Duration above Lux Threshold)
This is the average duration per weekday that white light intensity was above 1000 lux.

8.5 SAWA184 (Average Weekend White Light Duration above Lux Threshold)
This is the average duration per weekend day that white light intensity was above 1000 lux.

8.6 SAWA231 (Average Workday White Light Duration above Lux Threshold)
This is the average duration per workday that white light intensity was above 1000 lux.

8.7 SAWA278 (Average Non-workday White Light Duration above Lux Threshold)
This is the average duration per non-workday that white light intensity was above 1000 lux.

8.8 SAWA325 (Average Reliable White Light Duration above Lux Threshold)
This is the average duration per reliable day that white light intensity was above 1000 lux.

8.9 SAWA91 (Average Blue Light Duration above Irradiance Threshold)
This is the average duration per day that blue light intensity was above 1000 μW/cm².

8.10 SAWA138 (Average Weekday Blue Light Duration above Irradiance Threshold)
This is the average duration per weekday that blue light intensity was above 1000 μW/cm².

8.11 SAWA185 (Average Weekend Blue Light Duration above Irradiance Threshold)
This is the average duration per weekend day that blue light intensity was above 1000 μW/cm².

8.12 SAWA232 (Average Workday Blue Light Duration above Irradiance Threshold)
This is the average duration per workday that blue light intensity was above 1000 μW/cm².

8.13 SAWA279 (Average Non-workday Blue Light Duration above Irradiance Threshold)
This is the average duration per non-workday that blue light intensity was above 1000 μW/cm².

8.14 SAWA326 (Average Reliable Blue Light Duration above Irradiance Threshold)
This is the average duration per reliable day that blue light intensity was above 1000 μW/cm².

8.15 SAWA92 (Average Green Light Duration above Irradiance Threshold)
This is the average duration per day that green light intensity was above 1000 μW/cm² across all days, in minutes.

8.16 SAWA139 (Average Weekday Green Light Duration above Irradiance Threshold)
This is the average duration per weekday that green light intensity was above 1000 μW/cm².

8.17 SAWA186 (Average Weekend Green Light Duration above Irradiance Threshold)
This is the average duration per weekend day that green light intensity was above 1000 μW/cm².

8.18 SAWA233 (Average Workday Green Light Duration above Irradiance Threshold)
This is the average duration per workday that green light intensity was above 1000 μW/cm².

8.19 SAWA280 (Average Non-workday Green Light Duration above Irradiance Threshold)
This is the average duration per non-workday that green light intensity was above 1000 μW/cm².

8.20 SAWA327 (Average Reliable Green Light Duration above Irradiance Threshold)
This is the average duration per reliable day that green light intensity was above 1000 μW/cm².

8.21 SAWA93 (Average Red Light Duration above Irradiance Threshold)
This is the average duration per day that red light intensity was above 1000 μW/cm² across all days, in minutes.

8.22 SAWA140 (Average Weekday Red Light Duration above Irradiance Threshold)
This is the average duration per weekday that red light intensity was above 1000 μW/cm².

8.23 SAWA187 (Average Weekend Red Light Duration above Irradiance Threshold)
This is the average duration per weekend day that red light intensity was above 1000 μW/cm².

8.24 SAWA234 (Average Workday Red Light Duration above Irradiance Threshold)
This is the average duration of red light above 1000 μW/cm² across all workdays.

8.25 SAWA281 (Average Non-workday Red Light Duration above Irradiance Threshold)
This is the average duration per non-workday that red light intensity was above 1000 μW/cm².

8.26 SAWA328 (Average Reliable Red Light Duration above Irradiance Threshold)
This is the average duration per reliable day that red light intensity was above 1000 μW/cm².

9. ACTIVITY

9.1 SAWA334 (Average Activity in Active Intervals)
This is the average activity count per minute, across all time spent in an active interval. An active interval is any time outside of a rest interval.

9.2 SAWA335 (Average Activity in Sleep Interval)
This is the average activity count per minute, across all time spent in main sleep intervals (sleep onset to sleep offset).

9.3 SAWA336 (Average Activity in Naps)

This is the average activity count per minute, across all time spent in a nap interval.

9.4 SAWA337 (Average Activity Across all Valid Days)

This is the average activity count per minute, across all days.