Sueño – Sleep Habits in HCHS

Field Center Procedures

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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.

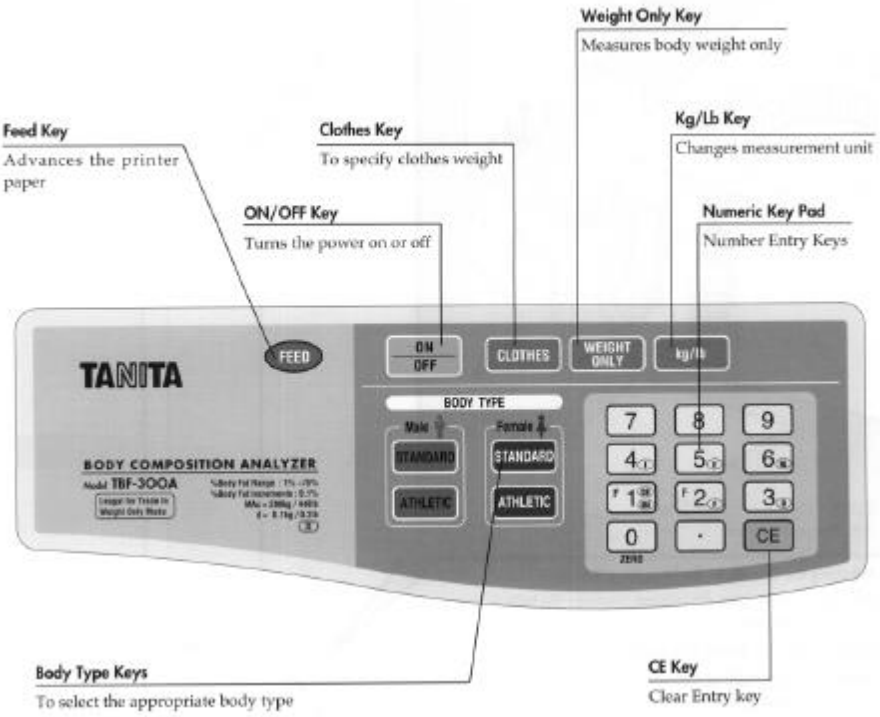
Figure 8-A Position for Standing Height

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."

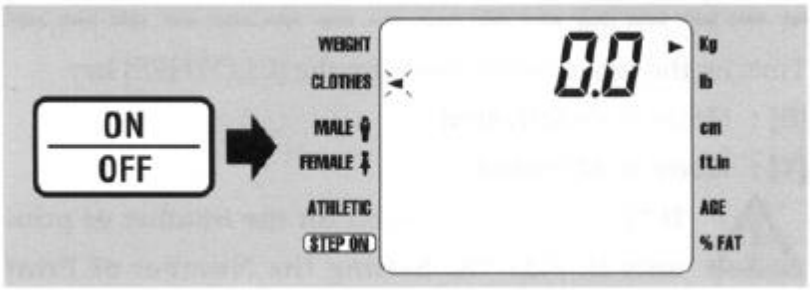
b. Setting the number of print outs and printing language

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.

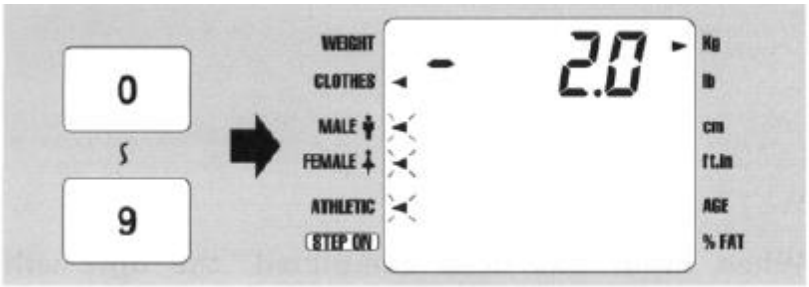
c. Operating Instructions

➔ <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).

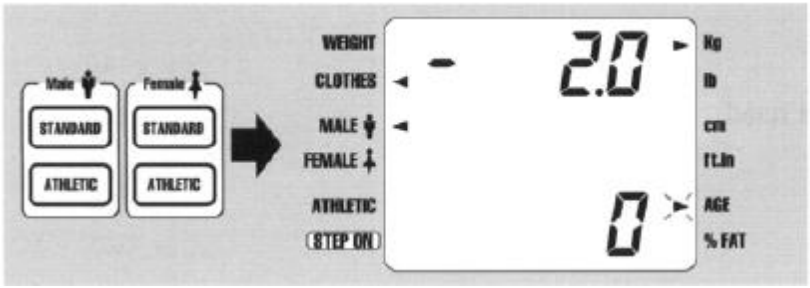
If participant does not have internal electronic device, proceed with the following instructions:



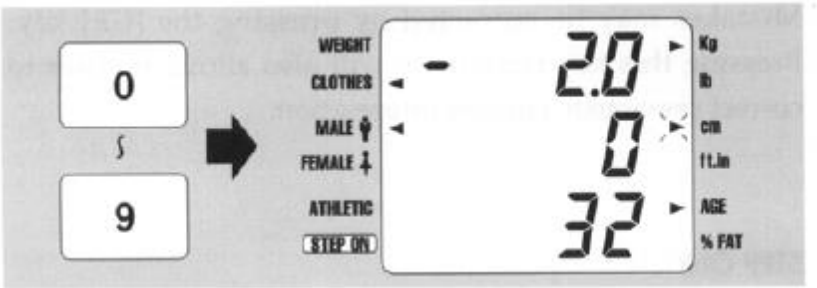
Press ON/OFF key to turn the machine on. Wait until 0.0 and an arrow appear on the screen. Check that the arrow points to "Kg". If arrow point to "lb", press the Kg/Lb key on the control panel and the arrow will shift to "Kg"



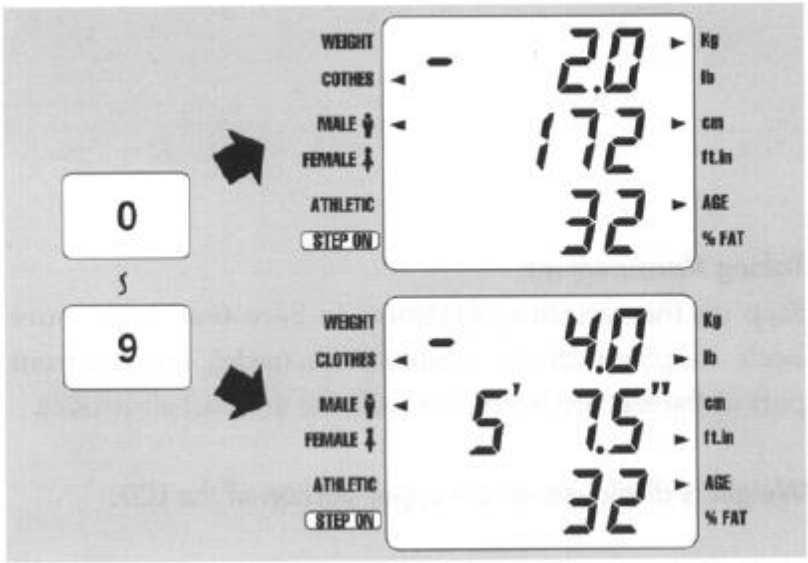
Enter Clothes weight:
1.0 kg using the numeric pad on the control panel



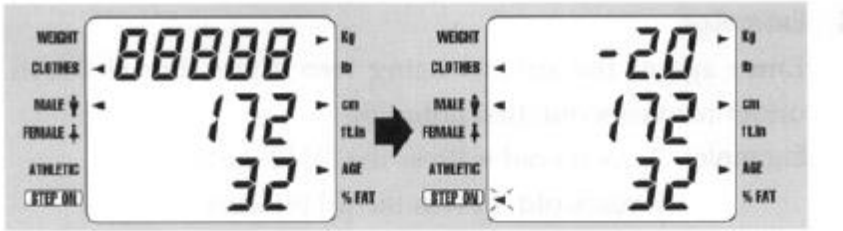
Select Gender and Body type:
Standard Female or Standard Male



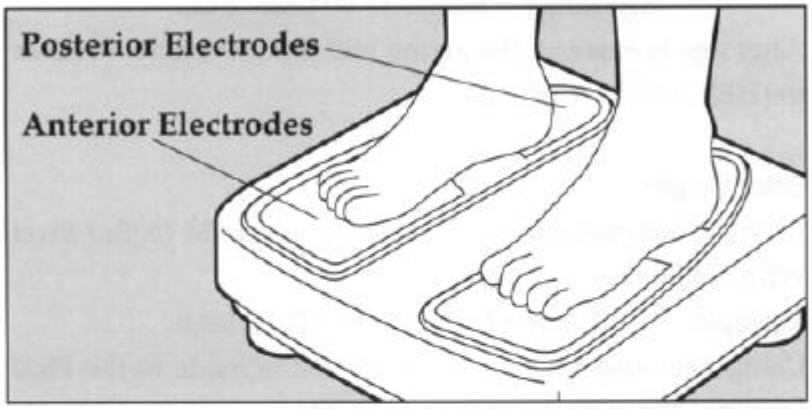
Enter age of participant using the numeric pad of the control panel. After age is entered, the arrow will direct you automatically to enter the height.



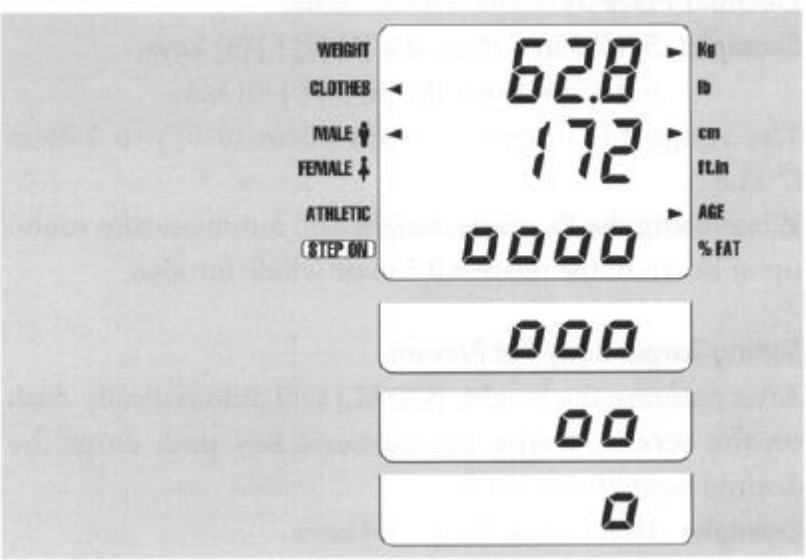
Enter height in cm. For example, for 172 cm, press the [1] [7] [2] keys.



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.

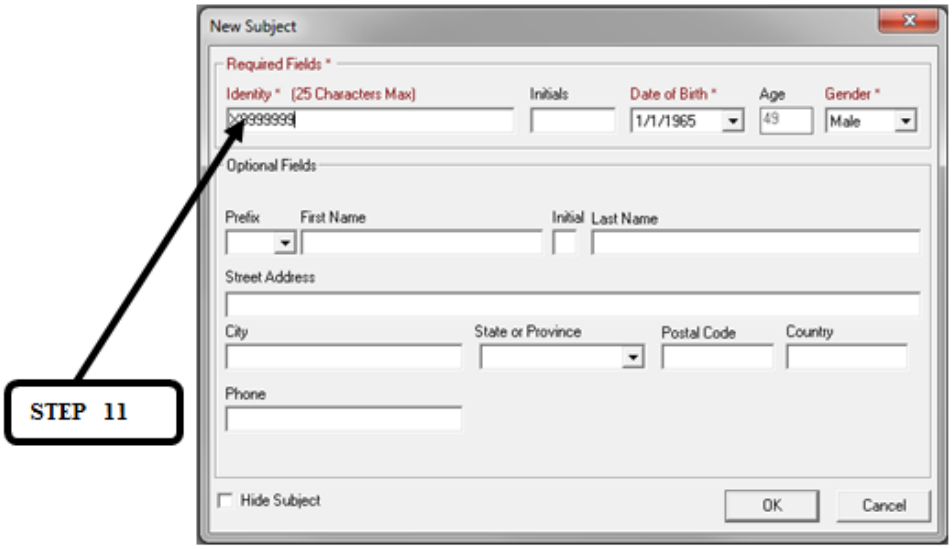
10) Click **Configure**.

*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

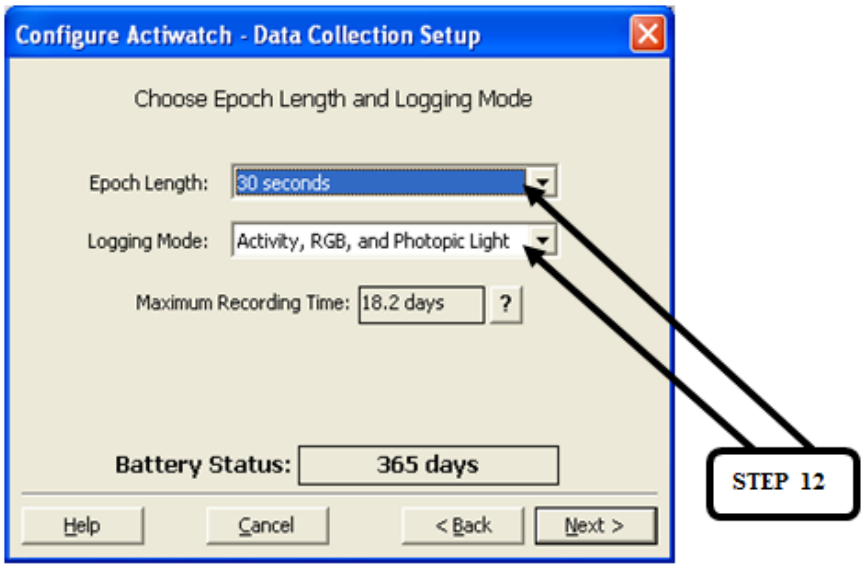


12) Configure the Data Collection Set Up.

- 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



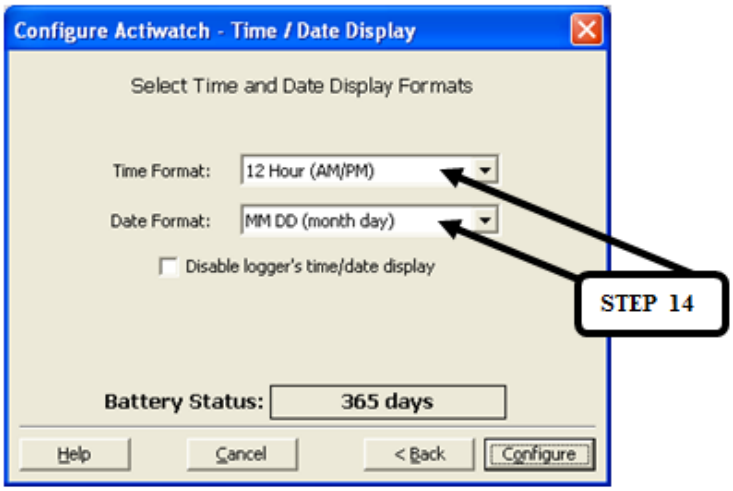
13) Configure the Start Time and Duration

- 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.

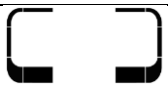
d. Removing the Actigraph

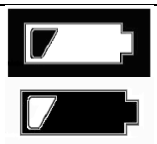
The actigraph does *not* have to be removed when bathing and/or during water sports. Participants should be encouraged to wear the actigraph when showering. It can be worn while showering, bathing, or swimming. When the actigraph or band does get wet, remove the watch and wipe the underlying skin dry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

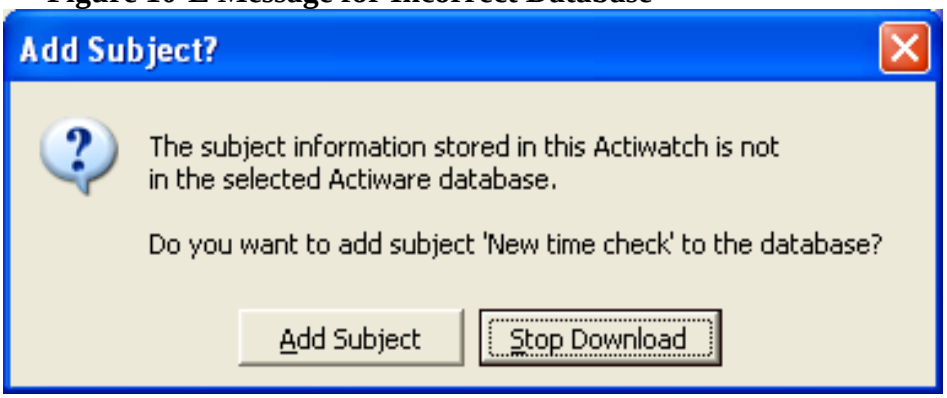
We strongly recommend that actigraph data be processed on a single computer. However, if your site is using more than one computer for actigraph data, please make sure the data is retrieved on the <u>same computer</u> on which the device was configured.

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.

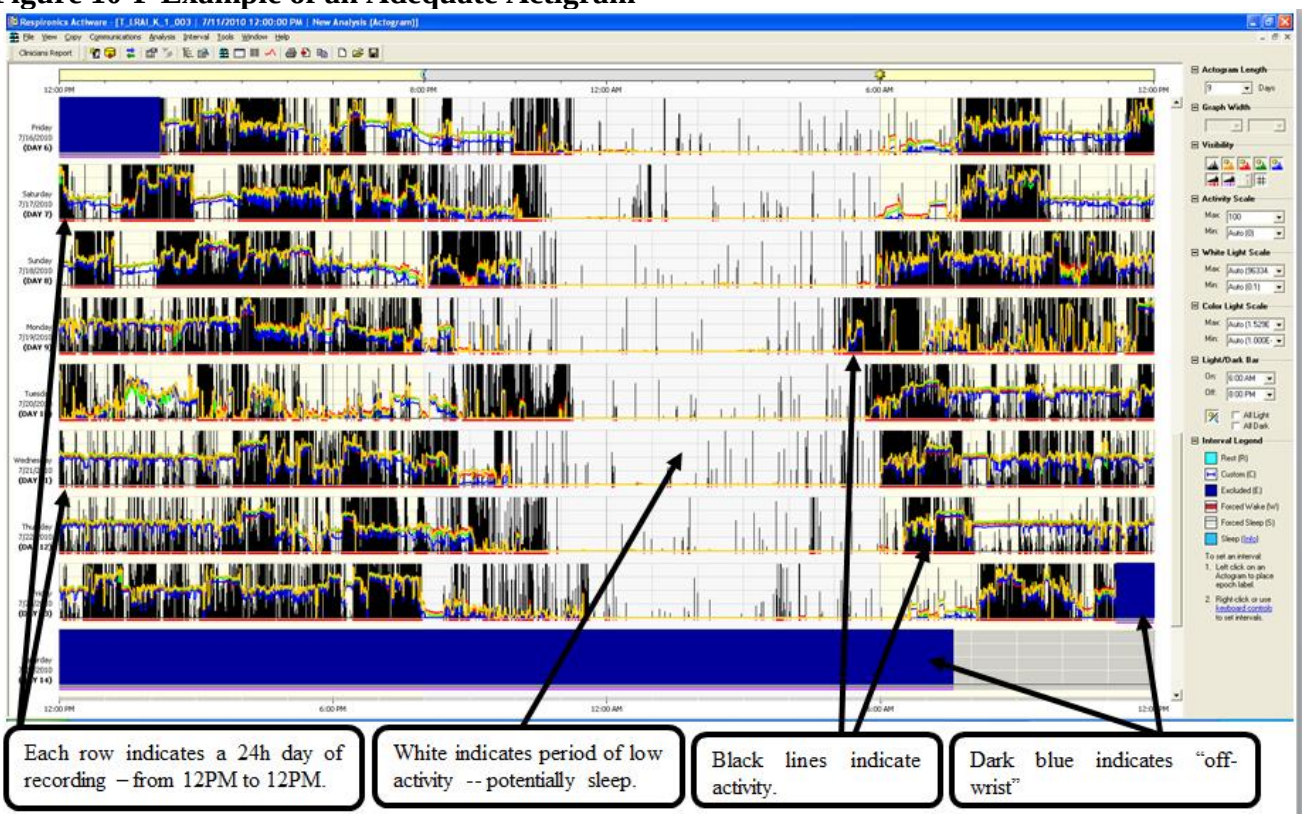
8) Choose one option and click Next.

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.

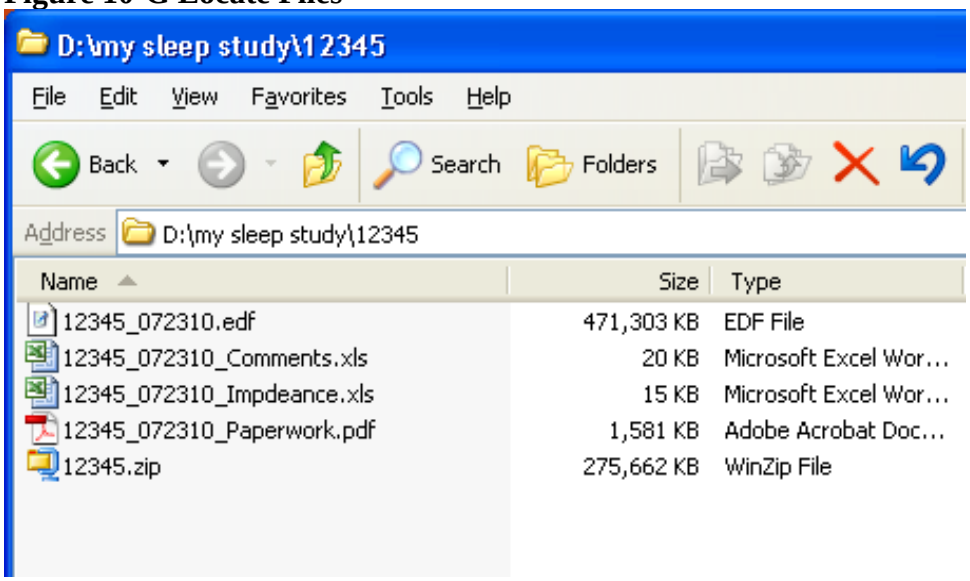
The encrypted zip file should include:

- 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

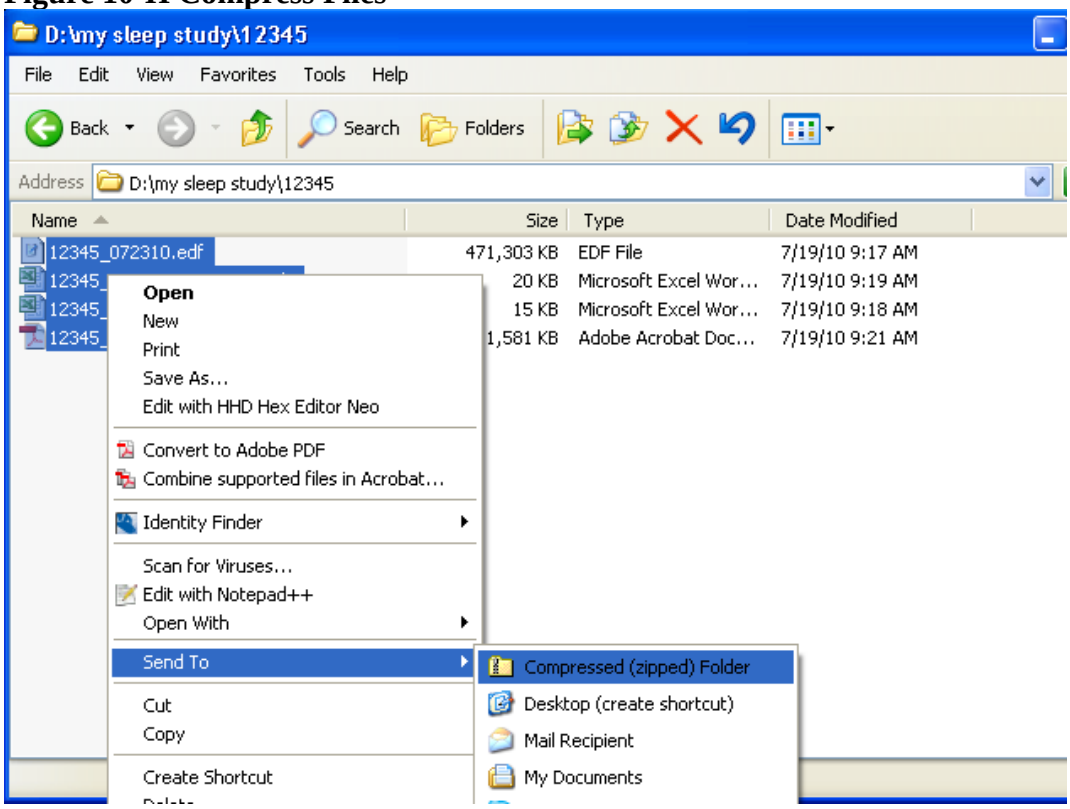
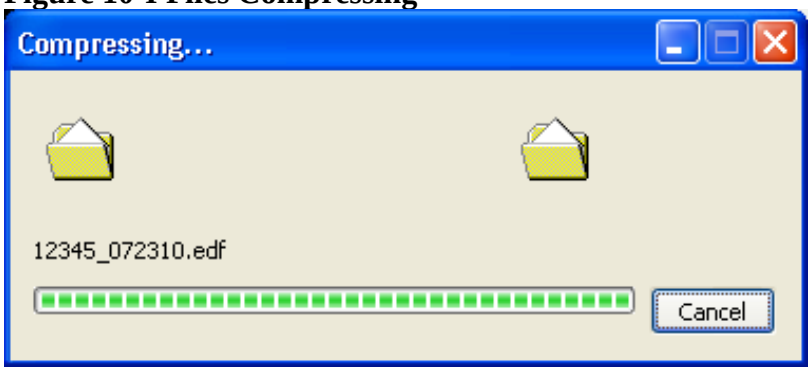
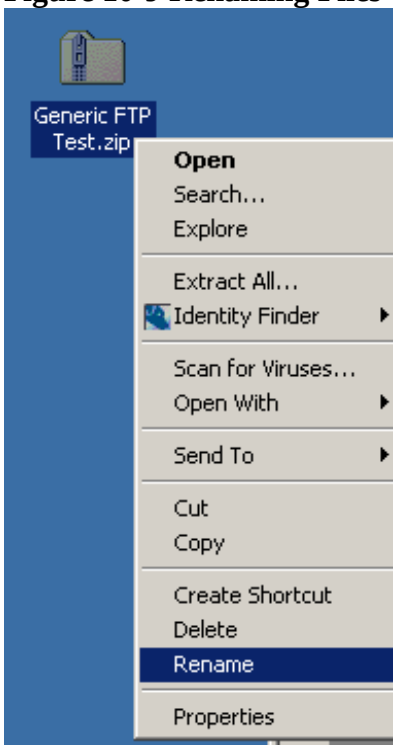


Figure 10-I Files Compressing



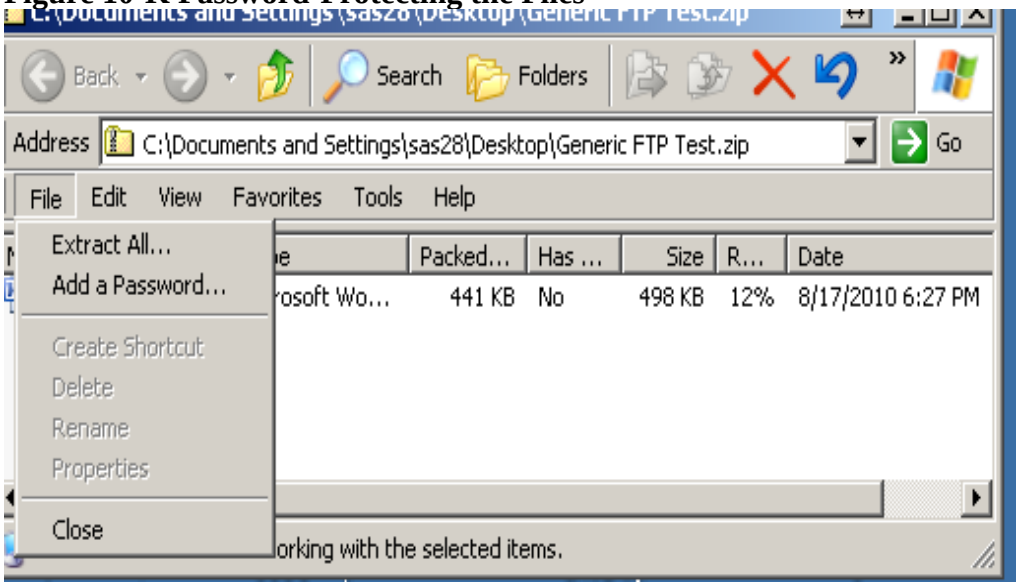
- Rename the file, if needed, to comply with naming conventions. Once the zip archive file appears in the directory, right click on the zip file name and "rename" (see Figure 10-H in the next page)Note the name of the zip file will be the same as the first file in the group selected, or if only one file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

Figure 10-J Renaming Files



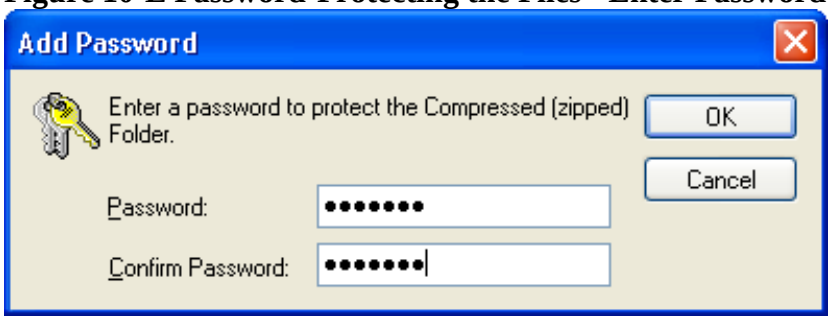
- Open the compressed zip file (double-click on the folder, or right-click and select Open) then select **File --> Add a Password**

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.

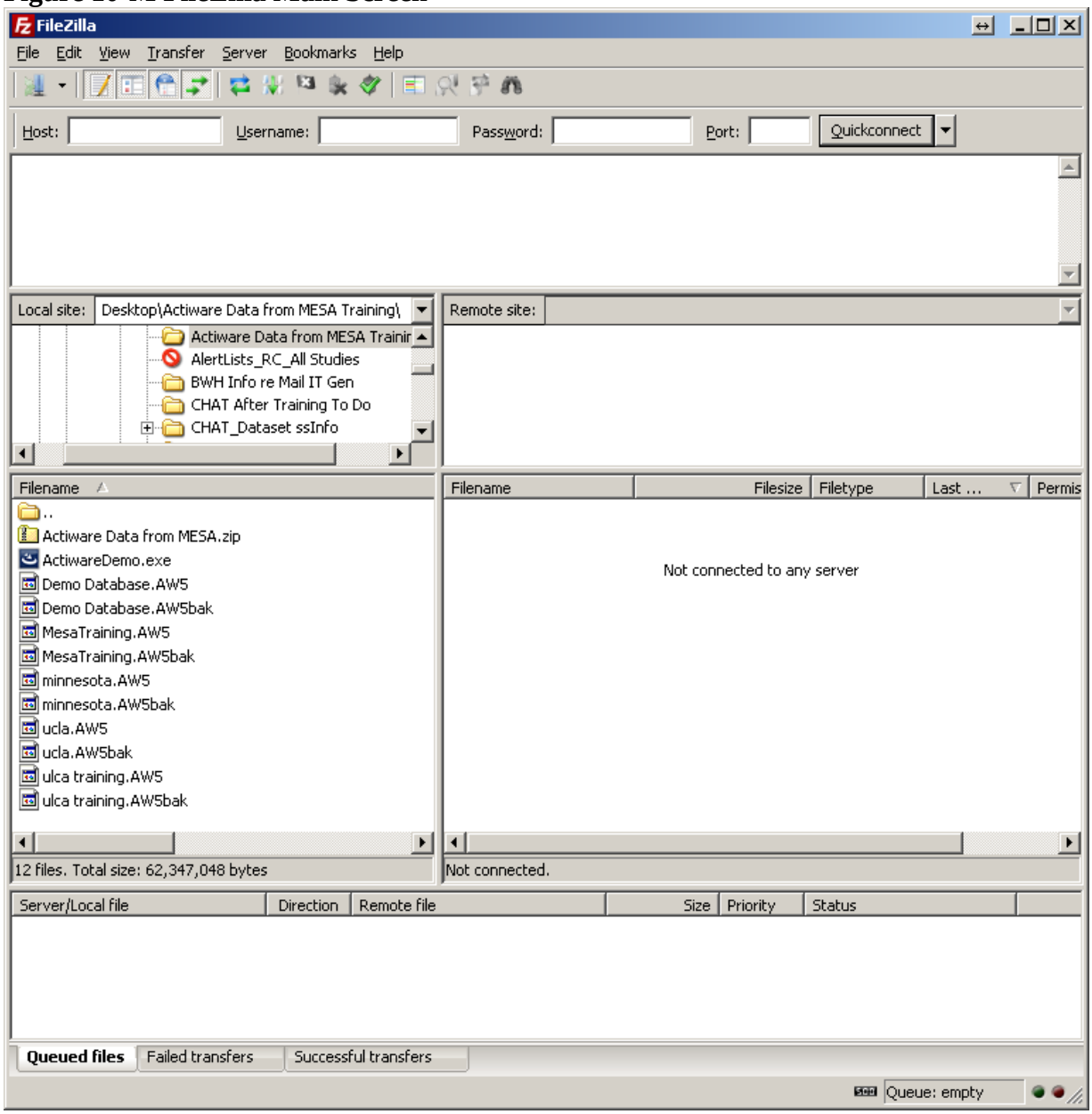
10.5.2. Using FileZilla to Upload/Transfer Data to BWH Reading Center

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

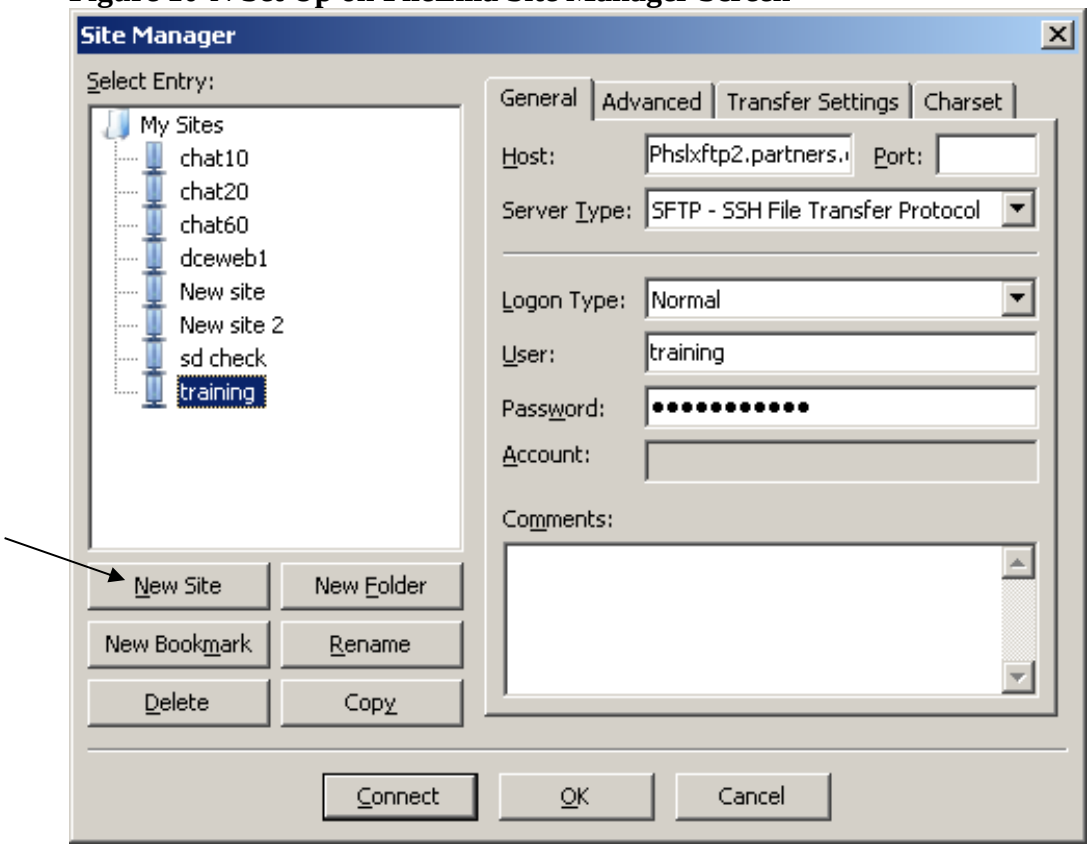
Figure 10-M FileZilla Main Screen



- 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



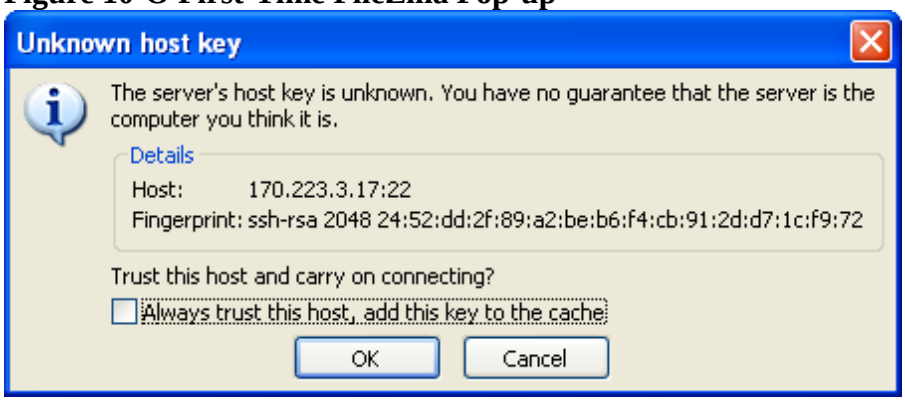
Once a new site is set up and appropriate information is filled in it can be used to connect whenever needed.

- **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

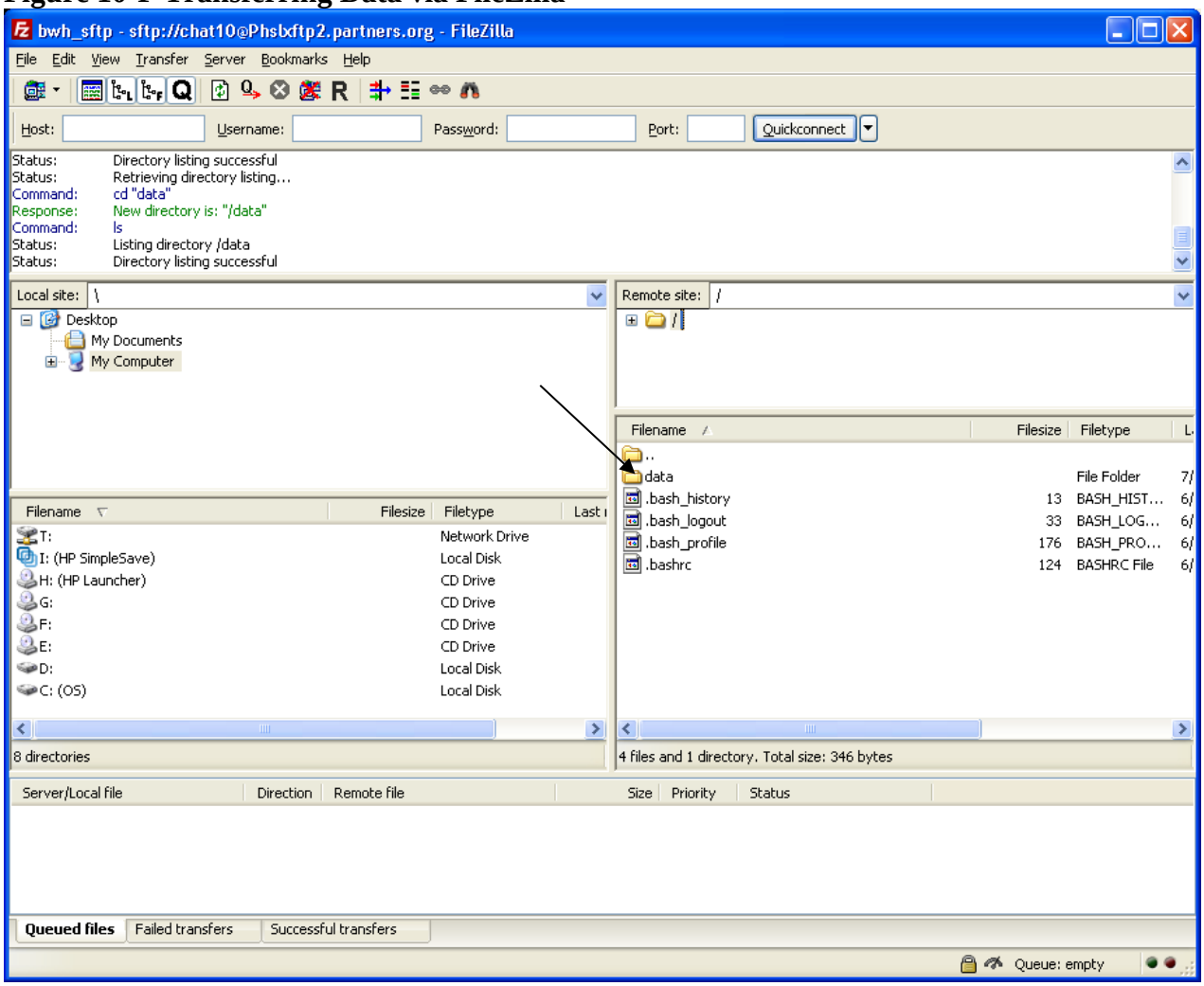
using the information provided, you will automatically be connected to a root folder specific to your site.

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.

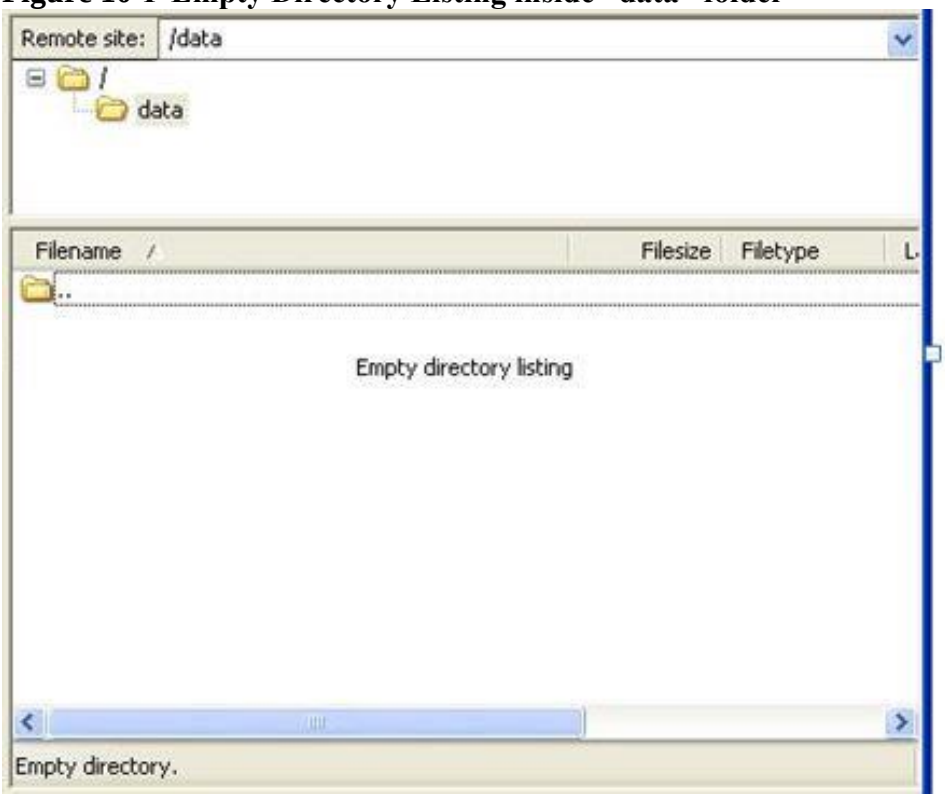
Figure 10-P Transferring Data via FileZilla



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

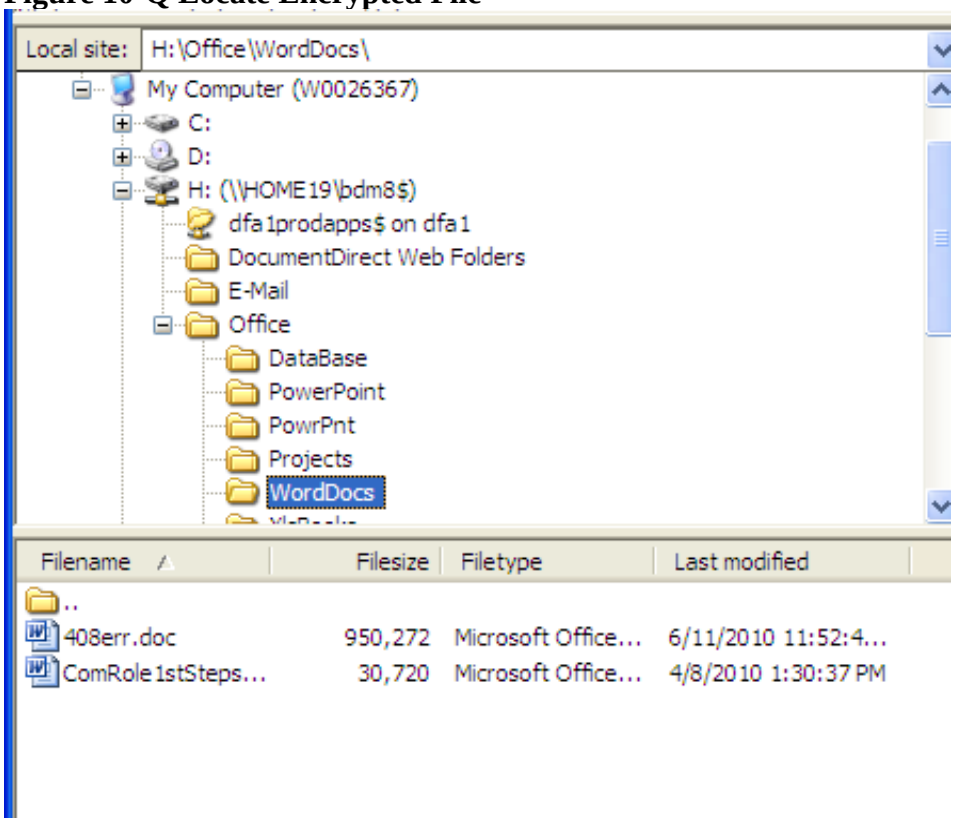


Figure 10-R Upload Encrypted File

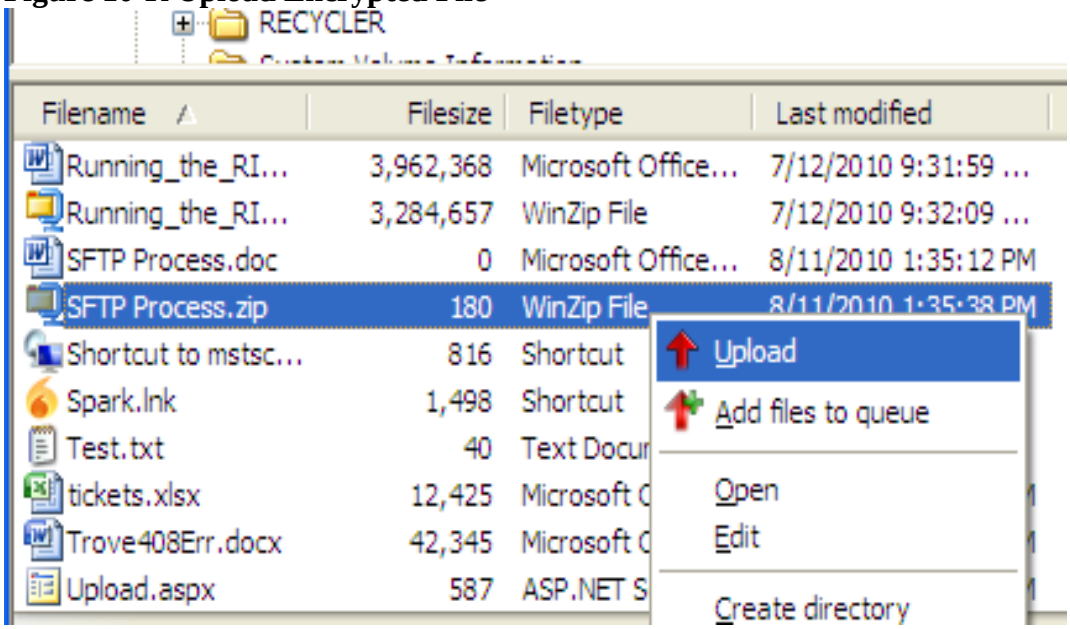
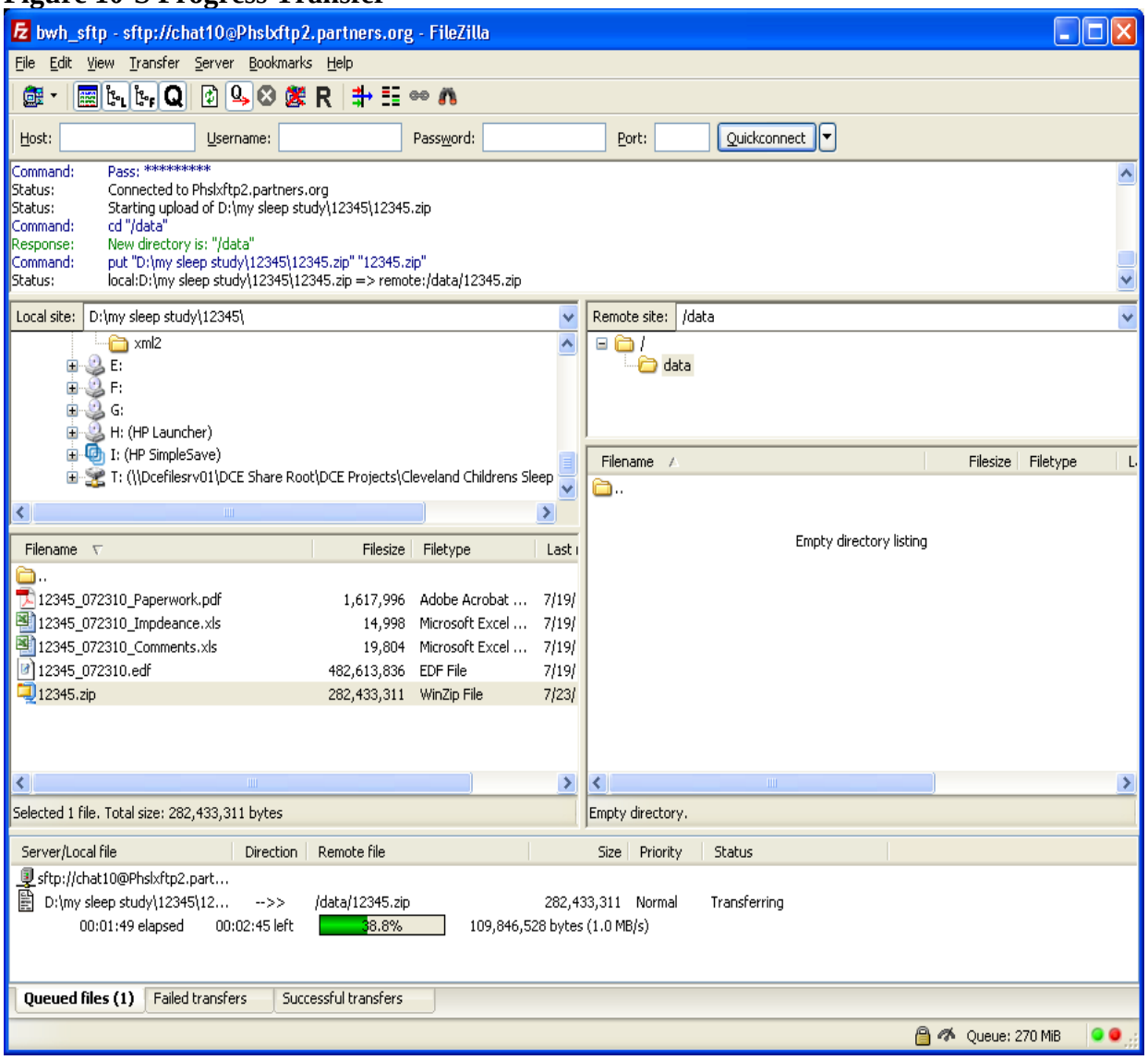
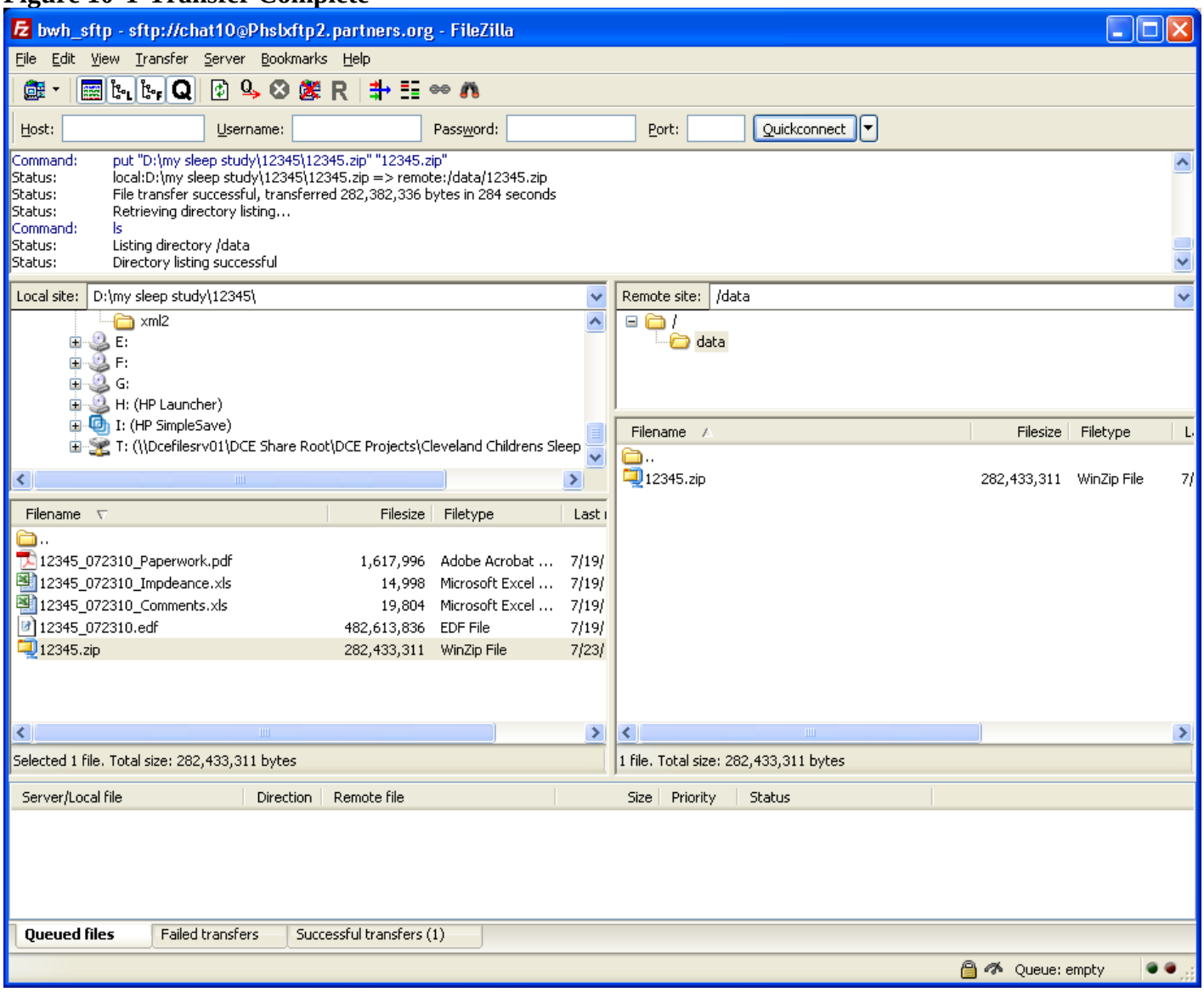


Figure 10-S Progress Transfer



- 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.

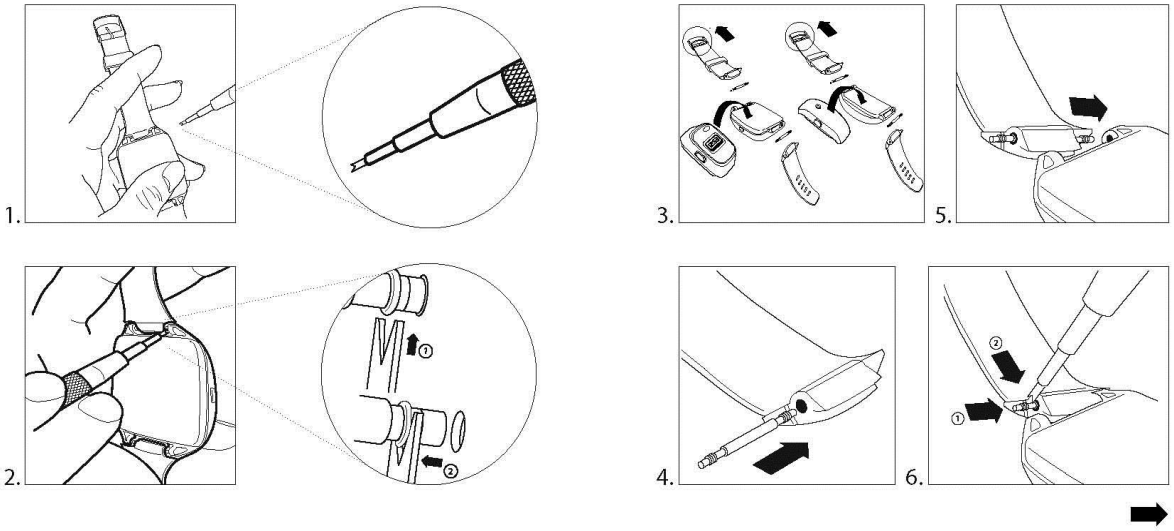
10.6.2. Battery management

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.