ROSTERS
Randomized Order Safety Trial Evaluating Resident Schedules

Manual of Operations

CHAPTER 1: PROTOCOL

The ROSTERs protocol can be found in the protocol subfolder

CHAPTER 2: STUDY START-UP

2.1 OVERVIEW

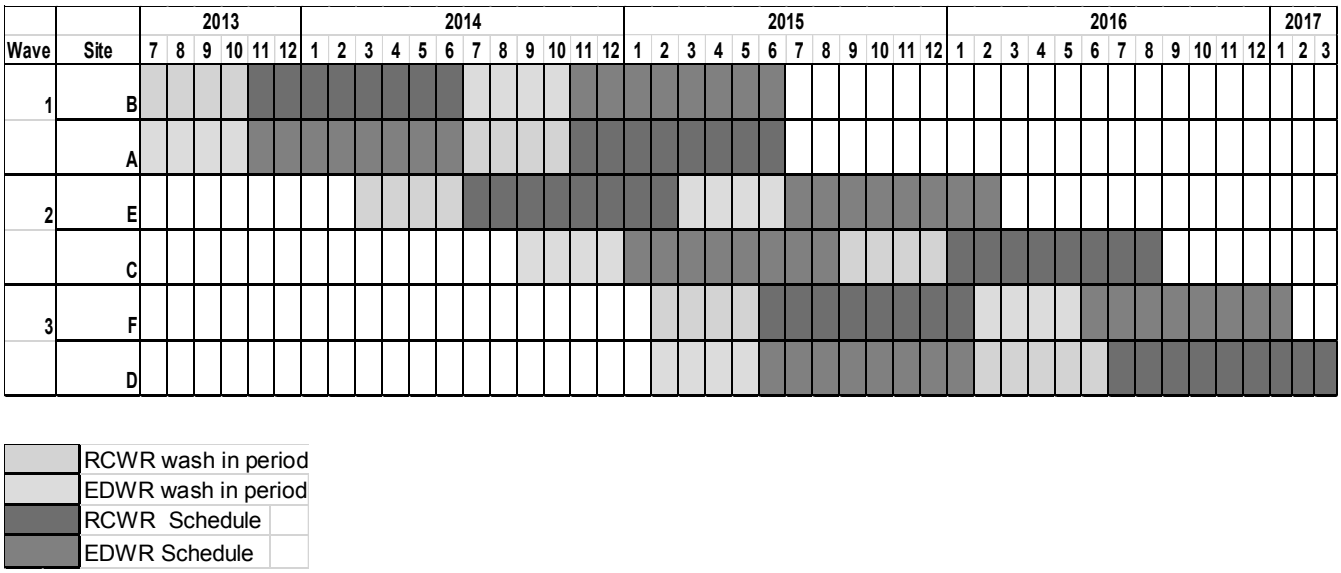
This chapter reviews the activities required of sites prior to their assigned wave as well as activities during the four month wash-in period prior to data collection. These include: IRB approval, strategies for schedule implementation, receiving the necessary equipment, and training staff.

2.2 IRB APPROVAL

Once the data collection forms, operations manual and informed consent template have been approved by the DSMB and finalized versions are available, sites should finalize their informed consent and submit their application to their IRB for approval, or submit a modification, if approval was obtained with draft documents.

2.3 TIMELINE AND SCHEDULE

Sites will be paired and enter the trial in three waves. We anticipate that the wash-in period for the first two sites will begin in July 2013, with data collection beginning in November 2013. Data collection will continue for eight months, followed by a four month wash-out period. Sites will then switch intervention schedules and proceed with another eight months of data collection. It is important that sites adhere to the schedules for the intervention and non-intervention years, so that the months may be seamlessly mapped (eg, July of the intervention schedule may be mapped to July of the traditional (or EDWR) schedule). The second wave and third wave of sites will join the study as indicated in the figure below.



2.4 RESIDENT SUBJECT REQUIREMENTS AND RECRUITMENT

Sites should have at least four full-time residents rotating in the PICU. In sites where there are only three full-time PICU residents, a fourth floating resident may be used, as long as this resident is part of a stable group of four residents. Therefore the floating resident must stay consistent throughout the month of data collection for each batch of participants.

It is expected that approximately 75% of eligible residents will agree to enroll in the trial. Sites should schedule those residents who do not wish to enroll during the four month wash-in period, and the enrollees during the eight months of data collection. To enable proper scheduling, sites will need to recruit residents prior to setting their rotation schedules. Incoming second year residents should be contacted about participation during their first year and incoming third year residents during their second year.

The DSMB requires that all incoming residents be informed that they will be subject to work schedule changes. To meet this requirement, clinical sites should include information about the study in their resident orientations. In addition, a letter or email may be sent to all eligible residents describing the study and inviting their participation. See attached sample recruitment letter in Appendix A

2.5 SCHEDULE IMPLEMENTATION

During the intervention, residents will be scheduled to work in a sequence of shifts in a repeating four day cycle. The approximate schedule will be:
Day 1: ~6:30am to ~5:30pm
Day 2: ~6:30am to ~9:00pm
Day 3/4: ~8:00pm to 10:00am (or 12:00pm at the latest)

In addition to the daily morning rounds, sites will need to implement a structured handoff at the evening shift change, if one is not already in place. A fellow or faculty member will oversee the evening handoff of care, which should occur between 8pm and 9pm. Sites are not required to use the I-PASS handoff, but sites must include these key five elements:

1. **I**llness Severity: Identification as stable, “watcher”, or unstable
2. **P**atient Summary: Summary statement, events leading up to admission, hospital course, ongoing assessment, plan
3. **A**ction List: To do list; timeline and ownership
4. **S**ituation Awareness / Contingency Planning: Know what’s going on; plan for what might happen
5. **S**ynthesis by Receiver: Written reminder to prompt receiver to summarize what was heard during verbal handoff

2.6 EQUIPMENT

Each site will need to have the following equipment as their wash-in period begins, to allow time for staff training.

2.6.1 Tablets

Each site will receive at least two tablets for physician observers to collect data. These tablets will be encrypted and password-protected by the Data Coordinating Center (DCC). Staff will use these tablets to link to online data collection forms.

2.6.2 PC or Laptop

Sites will also need a dedicated PC or laptop to download device data, log into the study website, complete data collection forms and logs.

2.6.3 Actigraphs

The first wave of sites will receive up to eight actigraphs for all resident subjects to wear during the course of their rotations. Specific instructions on the set-up and use of actigraphs are included in Chapter 5.

2.6.4 PVT Testing Station

Sites will need to have a PC or laptop (ideally a different one that used by the study staff) for the Psychomotor Vigilance Testing (PVT) testing. This computer should be in a room or area that is relatively quiet and free of disturbances. Specific instructions on the PVT testing are included in Chapter 7.

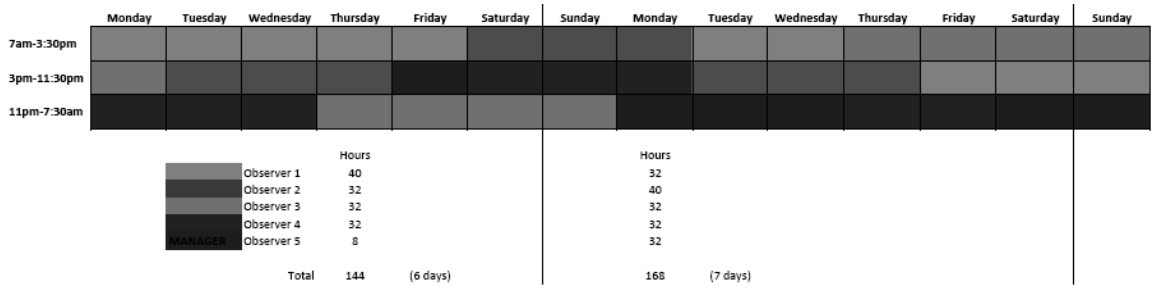
2.7 STAFFING

Sites are expected to have study staff in place during the wash-in period to train and prepare for recruitment of resident subjects. Study staff will include, at a minimum, the lead site investigator, a research nurse, and five physician observers (one of which will serve as the manager of the observers) and a research assistant.

The lead site investigator or research assistant will be responsible for obtaining IRB approval prior to wash-in period and for working out the details of the schedule implementation at their site. They will also be responsible for the initial outreach to incoming residents regarding participation in the study. The research assistant will then follow-up with interested residents to describe the trial in further detail, administer informed consent and ensure that resident subjects complete the Baseline Survey, as well as the End-of-Rotation Survey. The research assistant will also be responsible for instructing residents on completing the daily sleep/work logs and on the use of actigraphs and PVT. They will also be responsible for downloading the device data and transmitting it to the Data Coordinating Center.

The lead physician observer will be responsible for making sure the other four observers are trained and for determining their schedules to ensure that at least one observer is on the unit at all times. The physician observers are responsible for collecting data on any suspected medical errors they observe while on the unit. They will be assigned to observe one resident at a time. Each site should develop an observation schedule which ensures

that all residents are observed for approximately equal amounts of time during their rotations. The observers schedule should also be designed in a way that insures that the observers will not be working extended duration shifts or a shift pattern that could lead to circadian misalignment. Below is an example observer schedule.



The research nurse is responsible for following up on and adding any additional detail to the suspected incidents identified by the physician observers. The research nurse is also responsible for completing suspected event forms for potential medical errors identified by other staff, found in the medical records or otherwise identified or recorded in the hospital database. The research nurse will also be responsible for maintaining a Patient Days Log to track the number of patient days during the trial.

All staffing changes must be communicated to the CCC and DCC in a timely manner. This includes any delays in hiring staff prior to data collection and any changes to staff during the data collection period. The CCC and DCC will work with the sites to ensure that there is optimal staff coverage and training during these transitions.

2.8 TRAINING

The Clinical Coordinating Center (CCC) will host a webinars for the physician observers and research nurses during the wash-in periods for each wave of sites. The webinar will provide instruction on how to identify, record and classify medical errors. The training will cover general information on patient safety, definitions of terms and will review a set of test cases. Links to the webinars will be posted to the study website as a reference and a tool for new staff. To ensure inter-rater reliability, at least twice during each 8 month period of data collection, for each wave of sites, the DCC will examine the rates of events by observer at each of the sites to determine if there is significant variability. Re-training of physician observers will occur as needed to ensure consistent reporting of suspected medical errors across staff and sites.

The research assistant, research nurse and physician observers will be trained by the DCC on the use of data collection forms and the study website, where they can address data edits, update data, and access study resources. (See Chapter 10: Data Management and Quality Assurance for more details)

The research assistant will also be trained in the operation of the actigraph and PVT. Training will be conducted by webinars or onsite as feasible.

Lastly, all study staff will be trained to be alert to reportable safety issues related to the resident subjects. These would include serious adverse events, such as hospitalizations, or other health or mental health issues they observe. Details on collecting and reporting this information is included in Chapter 9: Collecting and Reporting Serious Adverse Events. Sites must keep the CCC and DCC informed of any planned staff hires so that additional training sessions may be scheduled to onboard new staff in a timely manner.

APPENDIX A: SAMPLE RECRUITMENT LETTER

Dear Housestaff,

We are conducting a multi-center study of the effects of implementing a sleep and circadian-science based schedule for residents (SCS schedule) on ICU patient safety. Data collected from this study will inform future program improvements, and may have an important impact on local and national policy guidelines related to work hours, health, and safety.

We found in a preliminary randomized controlled trial several years ago that interns working on a traditional schedule with recurrent 30 hour shifts slept 6 hours less per week and made 36% more serious medical errors (including 5 times as many serious diagnostic errors) than interns working an intervention schedule that limited scheduled consecutive work to 16 hours (NEJM, 2004). In light of this and similar findings from other investigators, the Institute of Medicine has called for the elimination of resident work shifts exceeding 16 hours without sleep. Whether implementing shorter work hours will in fact lead to a decrease in rates of preventable adverse events, however, remains uncertain. Furthermore, the optimal manner of reducing work hours remains unclear.

We need the help of housestaff willing to serve as research subjects. Participation would consist of completion of daily sleep and work logs (requires 2 minutes per day) while working in the ICU. You may be asked to wear a watch-like device that measures overall activity for part of the study. We may also collect a saliva sample from you, if you are willing, for future analyses of the relationship between certain genotypes, sleep deprivation, and performance.

During the study, we will be tracking medication errors and adverse drug events in the ICU. This will involve daily direct observation of you while you work by our research team, along with chart review and other methods. We will also be collecting data on work hours, communication between housestaff, motor vehicle accidents, body fluid exposures, general health and your educational experience through a survey. We will compare data gathered in the traditional schedule with data gathered in our SCS intervention schedule. Those in the study cohort who complete both surveys and sleep logs throughout the study period will receive $200.00 compensation for their effort.

All of your responses, as well as all other data collected in the study will be highly confidential. We are seeking a Certificate of Confidentiality from the Department of Health and Human Services that would strongly protect these data.

You will not receive any personal health benefits as a result of your participation. However, results from this study will further the knowledge of the role of fatigue in housestaff safety and quality of patient care, and may provide incentive to re-examine scheduling practices in hospitals and other industries where extended work hours are required.

Participation in this study is entirely voluntary. You are under no obligation to enroll, no explanation is required if you decide for any reason not to enroll, and your decision to enroll will in no way affect your residency evaluations, present or future employment, health care you receive at BWH, or participation in any other opportunities provided by your residency program. You may withdraw from the study at any time without penalty, and no explanation is required if you decide for any reason to withdraw. If you decide to participate, you may choose not to answer any questions or participate in any parts of the study that you do not feel comfortable with.

You may call or email at any time with questions. Please let us know if you wish to participate in the study, learn more, or cannot participate. If you are interested in participating, we would like to meet with you, answer questions, and obtain formal consent. You can contact us at [phone number] or at [email].

Thank you very much,

[Name(s)]
Principal Investigator(s)

CHAPTER 3: ENROLLMENT OF RESIDENT SUBJECTS

3.1 OVERVIEW

All second and third year residents at the pediatric intensive care units (PICUs) of six clinical centers will be invited to enroll in the study. The only exclusion criteria are that the resident is at least 21 years of age. We aim to have 4 participants enrolled each month at the six study sites. We anticipate studying 300 residents in total.

3.2 INFORMED CONSENT

Recruitment of resident subjects is described in Chapter 2. Once a resident agrees to participate, study staff will administer an informed consent. This IRB approved document will outline data collected, potential risks and benefits, timeline for participation, payment, and a separate consent for the collection of salivary samples for genetic analyses.

3.3 RANDOMIZATION

The trial will be conducted in three waves of two clinical sites each. In each wave, one clinical site will be randomly assigned to the SCS intervention arm [also known as a rapidly cycling work roster (RCWR)] and other will continue on the traditional schedule [also known as an extended duration work roster (EDWR)]. Data will be collected on resident subjects in the PICUs for eight months, after which time the two sites will switch assignments. There will be another four month wash-out/wash-in period before the next 8 month wave of data collection begins.

Sites will implement the SCS (or RCWR) intervention schedule as described in Chapter 2. Following consent, resident subjects will be informed of their randomization assignment and will be given their work schedules.

3.4 PARTICIPANT ID AND ACROSTIC

Following randomization, all resident subjects will be assigned a participant ID and acrostic which will be used to identify them throughout the study. The ID is a unique five digit number; each clinical site will have a different one-digit prefix to identify their subjects. The acrostic is a random four letter code which the resident subject or study staff may choose. (More information about assigning IDs and acrostics is included in Chapter 10: Data Management and Quality Assurance.)

Each site will be provided with a log of available IDs to assign and study staff should record the name of each newly enrolled resident for the next available ID number to ensure that IDs are not used more than once. This log should be kept in a secure location.

Study staff should also complete an online **Enrollment Form** on the study website, which includes the ID, acrostic, date of consent, level of consent, rotation start and end dates, and whether they provided a DNA sample.

Lastly, study staff should also communicate the assigned ID and acrostic to the resident and make sure s/he records it in a secure location (eg, a password-protected phone, tablet or lap top). The resident will need this information when completing their forms and sleep diaries.

3.5 FORMS

3.5.1 Baseline Questionnaire

After signing the informed consent, the resident subject will complete a **Baseline Questionnaire**, which includes the following information: contact information for the site, demographics, household composition, specialty program, health status and health conditions, sleep disorders and commuting.

The Baseline Questionnaire will be available in an electronic format on the ROSTERS Resident Portal website: http://rds.sfcc-cpmc.net/

See Baseline Questionnaire in Appendix A.

3.5.2 Sleep/Work Diary and Drive Diary

Each morning, all resident subjects will be required to complete a sleep/work diary, which includes information on their sleep and work schedules. Residents may access the diary via https://ediary.sfcc-cpmc.net/login and the diary may be completed on a PC, tablet or smart phone. The resident will need to know his/her ID and acrostic in order to complete the diary and therefore study staff must ensure that residents maintain this information in a secure location. The DCC will review diary entries on a regular basis to ensure that they are being completed on a daily basis and there are no errors, and report any issues to the sites. Residents should be contacted promptly if a diary is missing or contains an error. Residents may complete or edit diaries going back three days. If changes need to be made to earlier diary entries the DCC will make changes that have been confirmed by the resident.

Study staff should provide the residents with the following instruction regarding completing the dairy. (These instructions are also included in Chapter 5 and on a sample instruction sheet appended to that chapter.)

> *Complete the Sleep/Work Diary to describe your last 24 hours. It should be completed each morning. The first half of the diary contains questions about your sleep and the latter half about the times you were working. Questions 1-5 describe your "main" sleep in bed and Question 6 is for listing any additional sleep (naps). If you remove your actigraph, please annotate that in the space following question 6. For the work portion of the diary, if one or more work shifts have ENDED in the past 24 hours and you have NOT recorded them on previous entries of the diary, please record the time and date that the shift started (which may not have been in the past 24 hours) and the time and date*

that the shift ended. If you did not work in the past 24 hours or if your shift has not yet ended, please check the appropriate box.

All resident subjects that drive themselves to and from work will be asked to complete a drive diary following their commutes to and from work.

3.5.3 End of Rotation Survey

Following their rotation, resident subjects will complete an **End of Rotation Survey**, where they will be asked about their sleep and work habits, motor vehicle experiences, needle sticks and other body fluid exposures, health and mental health status, residency training, quality of life, patient safety, and teamwork.

The End of Rotation Survey is available in an electronic format on the ROSTERS Resident Portal website: http://rds.sfcc-cpmc.net/ and study staff should ensure that it is completed on the last day of the resident's rotation or soon thereafter.

IMPORTANT: Question 17 of the End of Rotation Survey is a depression screen and includes the question: "Thought about or wanted to commit suicide?" (17i). If the resident responds with "some of the time," "most of the time" or "all of the time," a subquestion will appear which asks: "Do you have a plan?" If the resident responds "yes", the following text will appear:

> Your response to the previous question causes us to be concerned for your welfare. While your response remains strictly confidential, we urge you to obtain medical evaluation locally. There are many programs available and we encourage you to contact a Mental Healthcare Professional in your area.

If the resident responds that they have thought about suicide "some of the time," "most of the time," or "all of the time," regardless of whether they have a plan, the DCC will contact the site PI, who should in turn contact the Residency Program Director. The site is then expected to follow their protocols for timely intervention and action, in compliance with their organizational rules and standards. The site PI is expected to confirm with the DCC that above procedure has been followed. The DCC will follow-up with the site if they have not received confirmation within one week.
See the End of Rotation Survey in Appendix B.

3.6 ACTIGRAPH AND PVT

Detailed information regarding the operation of these devices is included in Chapters 5, 6 and 7 of the Operations Manual. This section provides an overview of the resident subject responsibilities with regards to wearing the actigraph and performing the PVT tests.

3.6.1 Actigraph

All resident subjects in the first wave of sites will be required to wear an actigraph throughout the duration of their rotation. Residents in the second and third wave may be required to wear the

device as determined by the study investigators. An actigraph is a small wrist worn device which measures activity and ambient light exposure. Site staff will complete an **Actigraphy Checklist** online for each resident, to track when the watch was given to the resident and the serial number of the watch. Site staff will also maintain an **Actigraph Log** locally to track the location and any issues with each of the watches. Subjects will be instructed to only remove the actigraph when necessary (e.g., while swimming or taking a bath) and to make note of these times to record in their daily sleep diaries. Subjects will also be instructed to contact site staff promptly if the battery is low.

Residents will need to check-in with study staff after the first week to download their actigraphy data. Staff should then upload this data to the DCC to ensure that there are no problems with the data collected. If the watch appears to be functioning normally and the resident is wearing the watch consistently, site staff may wait until to the end of the resident's rotation to complete the second and final download. If there are any issues with the data, the DCC may request another interim download.

3.6.2 PVT

The PVT is an established metric of vigilance that is sensitive to sleep deprivation and circadian misalignment. The task requires the participant to look at a computer monitor that is blank except for a small, central, white rectangular box. Periodically numbers will begin to count up in the box. On detection of the numbers, the participant presses a button on a custom controller, the box then once again becomes blank. This repeats for multiple trials over the course of each test. The test to be used in this study will be 10 minutes in duration.

Residents will perform this test during one of their scheduled shifts per week. They will take the test at the start of their shift, every 5 hours and at the end of their shift. Study staff will complete a **PVT Checklist** for each session to record the date and time of the test and any disturbances. The PVT data will be transferred to the DCC after the resident has completed his/her rotation. Please see Chapter 7: PVT for more detailed instructions on administering the PVT tests.

3.7 RESIDENT EDUCATION

As part of the study, participants will have the option of enrolling in an online educational platform entitled OPENPediatrics (Website: http://openpediatrics.org). OPENPediatrics is a free, open access, peer-reviewed, digital learning platform that utilizes the latest in innovative technology to provide robust continuing medical education. Through a feature entitled the Learning Pathways, participants will have access to the ROSTERS curriculum, or a similar ICU learning curriculum approved by each participant's hospital. This curriculum is comprised of 18 lessons by educational experts. Each lesson begins with a pre-test followed by a didactic or procedural demonstration video and concludes with a post-test. This unique format will allow for asynchronous learning, so that participants can complete their educational lessons outside the hospital and apply their knowledge during on-duty hours. OPENPediatrics' robust analytics will allow research staff to track each participant's submissions as they progress through the curriculum. Pre-test and post-test scores as well as duration in each module will allow researchers to note the educational gains made throughout the curriculum, and compare each

participant's results in the control (EDWR) and Sleep and Circadian Science-based (SCS) intervention (RCWR) arms. A vigorous set of security measures will allow the analytic data from the application to be securely passed from the application to the data collection program, Cognos. As standard practice for the OPENPediatrics data storage procedures this data will be stored on IBM's secure servers, and IBM's analytic department will control access to this data. All residents in the unit will have access to the platform so no delineation between non subject residents and subject residents can be made by anyone except each site coordinator who will maintain the only identified list of subjects for the site. Resident data specific to each site will be sent from OPENPediatrics to each site coordinator; the site coordinator will then delete all data associated with non-subject residents. These measures are being taken so only site coordinators have knowledge of which data sets are associated with resident subjects. The team will work with the site PI to de-identify the data by removing the user's name/email. The data will only be stored on password-protected computers. Data will only be reported as de-identified, aggregated data. On their end-of-rotation surveys, they will report their impressions of their educational experience. See Appendix C for detailed instructions on requesting resident data from OPENPediatrics.

3.8 RESIDENT SAES

Serious adverse events will be collected on all enrolled residents during their month-long rotation. The definition of an SAE, and the protocol for completing an SAE Report Form are described in Chapter 9: Collecting and Reporting Serious Adverse Events.

3.9 MODIFYING OR WITHDRAWING CONSENT

A resident may opt during the course of their rotation to modify his/her consent from "full participation" to "observation only" or withdraw consent completely. In either circumstance, study staff should complete an online Withdrawal Form to document the withdrawal date and the reason, and whether consent was modified or withdrawn completely. Study staff should take the time to explore the resident's reason(s) for terminating participation and report any concerns to the site Principal Investigator.

3.10 PROTOCOL DEVIATIONS

If a protocol deviation occurs, study staff should complete an online Protocol Deviation form describing the event. Examples of protocol deviations are enrolling a resident without obtaining a signed informed consent or compromising the confidentiality of an enrolled resident. Please follow your local IRB guidelines for reporting protocol deviations.

APPENDIX A

ROSTERS Baseline Questionnaire

Study ID #	Acrostic	Date Form Completed	Staff ID #
		/ /	

1. Age: ___ years

2. Gender: □ M □ F

3. What is your race?

□ American Indian or Alaskan native

□ Asian

□ Black or African American

□ Native Hawaiian or other Pacific Islander

□ White or Caucasian

□ More than one race: please specify:_____

□ Other: please specify:_____

□ Refused

4. What is your ethnicity?
□ Hispanic or Latino □ Not Hispanic or Latino □ Don't know □ Refused

5. What is your current marital status?
□ married □ separated □ divorced □ widowed/widower □ never married

6a. Who lives in the same household as you? Please check all that apply:
□Child/children □ Spouse/Partner □ Other family members □ Roommate □ Pet

6b. If you have children, how many children live with you? ___ children

7. What year of your residency program are you in?

□ PGY2 □ PGY3

8. Which of the following best describes your specialty program for this year?

□ pediatrics

□ internal medicine/pediatrics

□ internal medicine

□ Other: Please specify_____

9. In general, would you say your health is: *(check one box)*
□ poor □ fair □ good □ very good □ excellent

10. What is your height_____ (feet) ____ (inches) □ Don't know

11. What is your weight_____(pounds) □ Don't know

12. What is your neck circumference (inches)_____ □ Don't know

13. On average, how many hours of sleep do you feel you need to feel rested per 24 hours?
____ hours/24h

14. On average, how many hours of sleep did you get per 24 hours during your final year of medical school?
____ hours/24h

15. Do you have or have you ever had any of the following conditions? *(check the best answer for each question)*

	Never	In the past, but not now	Currently, but not currently on therapy	Currently, receiving therapy	Don't know
High blood pressure	0 □	1 □	2 □	3 □	4 □
Diabetes mellitus	0 □	1 □	2 □	3 □	4 □
Depression	0 □	1 □	2 □	3 □	4 □
Sleep Apnea	0 □	1 □	2 □	3 □	4 □
Sleep Disorders	0 □	1 □	2 □	3 □	4 □
Shift-Work disorder	0 □	1 □	2 □	3 □	4 □

16. Do you snore?
□ Yes
□ No
□ Don't know

If you snore:

16a. Your snoring is:
□ Slightly louder than breathing
□ As loud as talking
□ Louder than talking
□ Very loud – can be heard in adjacent rooms
□ Don't know

16b. How often do you snore?
□ Nearly every day
□ 3-4 times a week
□ 1-2 times a week
□ 1-2 times a month
□ Never or nearly never
□ Don't know

16c. Has your snoring ever bothered other people?
□ Yes
□ No
□ Don't know

16d. Has anyone noticed that you quit breathing during your sleep?
□ Nearly every day
□ 3-4 times a week
□ 1-2 times a week
□ 1-2 times a month
□ Never or nearly never
□ Don't know

17. How often do you feel tired or fatigued after your sleep?
□ Nearly every day
□ 3-4 times a week
□ 1-2 times a week
□ 1-2 times a month
□ Never or nearly never

18. During your waking time, do you feel tired, fatigued or not up to par?
□ Nearly every day
□ 3-4 times a week
□ 1-2 times a week
□ 1-2 times a month
□ Never or nearly never

19. Have you ever nodded off or fallen asleep while driving a vehicle?
□ Yes
□ No

If yes:

19a. How often does this occur?
□ Nearly every day
□ 3-4 times a week
□ 1-2 times a week
□ 1-2 times a month
□ Never or nearly never

20. Do you have high blood pressure?
□ Yes
□ No
□ Don't know

For the following questions, please indicate (by checking the appropriate number) your estimate of any difficulty, provided that it occurred at least three times per week during the last month:

21. Sleep induction (time it takes you to fall asleep after turning-off the lights)
□ 0: No problem
□ 1: Slightly delayed
□ 2: Markedly delayed
□ 3: Very delayed or did not sleep at all

22. Awakenings during the night
□ 0: No problem
□ 1: Minor problem
□ 2: Considerable problem
□ 3: Serious problem or did not sleep at all

23. Final awakening earlier than desired
□ 0: Not earlier
□ 1: A little earlier
□ 2: Markedly earlier
□ 3: Much earlier or did not sleep at all

24. Total sleep duration
□ 0: Sufficient
□ 1: Slightly insufficient
□ 2: Markedly insufficient
□ 3: Very insufficient or did not sleep at all

25. Overall quality of sleep (no matter how long you slept)
0: Satisfactory
1: Slightly unsatisfactory
2: Markedly unsatisfactory
3: Very unsatisfactory or did not sleep at all

26. Sense of well-being during the day
0: Normal
1: Slightly decreased
2: Markedly decreased
3: Very decreased

27. Functioning (physical and mental) during the day
□ 0: Normal
□ 1: Slightly decreased
□ 2: Markedly decreased
□ 3: Very decreased

28. Sleepiness during the day

□ 0: None
□1: Mild
□ 2: Considerable
□ 3: Intense

Commuting

29. How many miles do you live from your workplace? ____ miles

30. What is your predominant means of commuting to and from work? *(check one box)*

- □ driving a car, truck, or van
- □ passenger in a car, truck, or van
- □ driving a motorcycle or motor scooter
- □ public transport
- □ bicycling
- □ walking
- □ other (Please specify_____)

31. How long does your commute take each day? (One direction) ____minutes

Thank you very much for participating in this study, and completing the Baseline Questionnaire.

APPENDIX B

ROSTERS End of Rotation Survey

Study ID #	Acrostic	Date Form Completed	Staff ID #
		/ /	

Thank you very much for participating in our study of work hours. We very much appreciate your investment in this project. This survey will ask you about your work experience, sleep, health and safety incidents over the past month in the ICU. Results will be used for research. Aggregate results may be published, but no data that would make it possible to identify individual respondents will be shared with anyone other than the study personnel. Protection of your confidentiality will be our highest priority.

Except as otherwise noted, all questions on this survey refer to your schedule and experiences **during the last month that you were working in the ICU.** We understand that you may not remember all details perfectly, but please make your best guess. You are free to skip any question you would prefer not to answer, but we encourage you to answer all questions, as complete data will improve the value of the survey

Sleep and Work

1. On average, how many hours of sleep did you get per 24 hours over the past month? ____ hours/24h

2. In the past month, what was the longest number of **continuous** hours you were actually physically at work? (Include protected time for sleep provided during an extended shift) ____ hours

3. In the past month, what was the longest number of continuous hours you went without sleep? ____ hours

4. In the past month, on average, **per week**, how many hours did you spend:

a. participating in direct patient care (examining patients, writing notes, interpreting tests/radiographic studies/pathology specimens, consulting with other physicians, etc.) ___ (0-168) hours

b. in the workplace in duties not related to patient care (other paperwork, scheduling tests, etc.) ___ (0-168) hours

c. in formal structured learning including classes/ laboratories/grand rounds ___ (0-168) hours

d. in self-directed learning outside of the workplace ___ (0-168) hours

e. teaching students or housestaff ___ (0-168) hours

f. in leisure activities outside of the hospital or workplace ___ (0-168) hours

5. Over the past month you were working, how many times did you nod off or fall asleep *(enter 0 if you did not participate in the activity described)*

a. During lectures, seminars, or grand rounds	__Yes	__No	__ NA	If yes,	___times
b. On the telephone	__Yes	__No	__ NA	If yes,	___times
c. During rounds	__Yes	__No	__ NA	If yes,	___times
d. While talking to or examining a patient	__Yes	__No	__ NA	If yes,	___times

e. During Surgery or while doing a procedure __Yes __No __ NA If yes, ___times
f. While stopped in traffic __Yes __No __ NA If yes, ___times
g. While driving __Yes __No __ NA If yes, ___times

Motor Vehicle Experiences: Accidents, and Near Misses

6. In the past month, did you have any motor vehicle accidents, crashes or near misses in which you were driving? __yes __no

a. IF YES, how many did you have? _____ incidents(s)

Please fill out the following data for each near incident:

	Accident or Near miss #1	Accident or Near miss #2	Accident or Near miss #3	Accident or Near miss #4	Accident or Near miss #5	Accident or Near miss #6
Was this an accident or a near miss?	☐ Accident ☐ Near miss	☐ Accident ☐ Near mi	☐ Accident ☐ ea r mis	☐ Accident ☐ Near miss	☐ Accident ☐ Near mi	☐ Accident ☐ Near mis
Did the incident occur while driving to work?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ o	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ o
Did the incident occur while driving away from work?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ o	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ o
What was the date of the incident?	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___
About what time did the incident occur (to the nearest hour)?	__ __(hour)	__ __(hour)	__ __(hour)	__ __(hour)	__ __(hour)	__ __(hour)

(If you have been involved in more than six driving incidents, *please provide a phone number if you are willing to have one of our staff contact you for more information. _____)*

Needle sticks and other body fluid exposures

7. In the past month, did you personally have an occupational exposure to potentially contaminated blood or other body fluid? __ yes __ no

7a. IF YES, How many incidents? ____ incident(s)

8. In the past month did you cause any occupational exposure to potentially contaminated blood or other body fluid to others? __yes __no

8a. IF YES, how many incidents? ____ incident(s)

	Needle stick and other body fluid exposure #1	Needle stick and other body fluid exposure #2	Needle stick and other body fluid exposure #3	Needle stick and other body fluid exposure #4	Needle stick and other body fluid exposure #5	Needle stick and other body fluid exposure #6
What was the date of the incident?	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___	___/___/___
About what time did the incident occur (to the nearest hour)?	__ __(hour)	__ __(hour)	__ __(hour)	__ __(hour)	__ __(hour)	__ __(hour)
How many hours were you **at work** before this incident	____hours	____hour	____hour	____hours	____hour	____hour
How many hours were you **awake** before this incident	____hours	____hour	____hour	____hours	____hour	____hours

(If you have been involved in more than six body fluid exposures, *please provide a phone number if you are willing to have one of our staff contact you for more information. _____)*

Health

9. On average over the past 3 months, how many drinks of the following did you have **per day**?

a. coffee _____ (# cups)
b. tea _____ (# cups)
c. caffeinated soft drinks _____ (# glasses)
d. beer _____ (# 12oz glasses)
e. wine _____ (# glasses)
f. liquor _____ (# shots)

10. Do you currently smoke cigarettes? □ Yes □ No

10a. If yes, how many cigarettes do you smoke?

□ 1–4 cigarettes per day
□ 5–14 cigarettes per day
□ 15–24 cigarettes per day
□ 25–34 cigarettes per day
□ 35 or more cigarettes per day

11. Over the past month, how many days in total did you take any type of the following **to get to or stay asleep**?

a. prescription medication: Y/N; if Yes, name of medication: _____ ____ (0-30) days
b. non-prescription medication: Y/N; if Yes, name of medication: _____ ____ (0-30) days
c. herbal or health food medication: Y/N; if Yes, name of medication: _____ ____ (0-30) days

12. Over the past month, how many days in total did you take any type of the following any type of the following **to stay awake**?

a. prescription medication: Y/N; if Yes, name of medication: _____ ____ (0-30) days
b. non-prescription medication: Y/N; if Yes, name of medication: _____ ____ (0-30) days
c. herbal or health food medication: Y/N; if Yes, name of medication: _____ ____ (0-30) days

13. Over the past month, how many days in total did you take any type of the following any of the following medications (**for any reason**)

a. anti-histamines: Y/N; if Yes, how many days? ____ (0-30) days
b. benzodiazapines: Y/N; if Yes, how many days? ____ (0-30) days
c. selective serotonin reuptake inhibitors (SSRI): Y/N; if Yes, how many days? ____ (0-30) days
d. other antidepressants: Y/N; if Yes, how many days? ____ (0-30) days

14. In the past month, how many unscheduled days off work did you have (i.e. sick days, personal emergencies, etc.) ____ (0-30) days

15. In the past month, on average how many hours per week did you spend doing vigorous exercise (i.e. long enough to work up a sweat)? ____ (0-168) hours

16. Over the past month, for about how many days in total did you suffer from upper respiratory illnesses? ____ (0-30) days

17. Over the past two weeks, how often have you: *(check the best answer for each question)*

	None or little of the time	Some of the time	Most of the time	All of the time
a. Been feeling low in energy, slowed down?	☐	☐	☐	☐
b. Been blaming yourself for things?	☐	☐	☐	☐
c. Had poor appetite?	☐	☐	☐	☐
d. Had difficulty falling asleep, staying asleep?	☐	☐	☐	☐
e. Been feeling hopeless about the future?	☐	☐	☐	☐
f. Been feeling blue?	☐	☐	☐	☐
g. Been feeling no interest in things?	☐	☐	☐	☐
h. Had feelings of worthlessness?	☐	☐	☐	☐
i. Thought about or wanted to commit suicide?	☐	☐	☐	☐
→ If Some, Most or All, require subquestion: Do you have a plan? Y / N*				
j. Had difficulty concentrating or making decisions?	☐	☐	☐	☐

***NOTE: For 17i above, the subquestion will be hidden on electronic version—and will only appear if resident responds with Some/Most/All.**

If the Resident responds with "Some of the time," "Most of the time," or "All of the time," to question 17i, regardless of whether they respond "Yes" or "No" to "Do you have a plan?", the following message will appear on the form: "Your response to the previous questions causes us to be concerned for your welfare. All reports of suicide ideation will be reported to your site PI, who should in turn contact the Residency Program Director. The site will then follow their protocols for timely intervention and action, in compliance with their organizational rules and standards."

18. **Please indicate how frequently you feel the following:** *(check the best answer for each question)*

	Never	A few times a year or less	Once a month or less	A few times a month	Once a week	A few times a week	Every day
a. I feel emotionally drained from my work	☐	☐	☐	☐	☐	☐	☐
b. I feel used up at the end of the workday	☐	☐	☐	☐	☐	☐	☐
c. I feel fatigued when I get up in the morning and have to face another day on the job	☐	☐	☐	☐	☐	☐	☐
d. I can easily understand how my patients and their families feel about things	☐	☐	☐	☐	☐	☐	☐
e. I feel I treat some patients and/or their families as if they were impersonal objects	☐	☐	☐	☐	☐	☐	☐
f. Working with people all day is really a strain for me	☐	☐	☐	☐	☐	☐	☐
g. I deal very effectively with the problems of my patients and their families	☐	☐	☐	☐	☐	☐	☐
h. I feel burned out from my work	☐	☐	☐	☐	☐	☐	☐
i. I feel I'm positively influencing other people's lives through my work	☐	☐	☐	☐	☐	☐	☐
j. I've become more callous toward people since I took this job	☐	☐	☐	☐	☐	☐	☐
k. I worry that this job is hardening me emotionally	☐	☐	☐	☐	☐	☐	☐
l. I feel very energetic	☐	☐	☐	☐	☐	☐	☐
m. I feel frustrated by my job	☐	☐	☐	☐	☐	☐	☐
n. I feel I'm working too hard on my job	☐	☐	☐	☐	☐	☐	☐
o. I don't really care what happens to some patients and/or their families	☐	☐	☐	☐	☐	☐	☐
p. Working with people directly puts too much stress on me	☐	☐	☐	☐	☐	☐	☐
q. I can easily create a relaxed atmosphere with my patients and their families	☐	☐	☐	☐	☐	☐	☐
r. I have accomplished many worthwhile things in this job	☐	☐	☐	☐	☐	☐	☐
s. I feel like I'm at the end of my rope	☐	☐	☐	☐	☐	☐	☐
t. In my work, I deal with emotional problems very calmly	☐	☐	☐	☐	☐	☐	☐
u. I feel my patients and/or their families blame me for some of their problems	☐	☐	☐	☐	☐	☐	☐

Residency Training

19. To what extent did your training this year offer you the opportunity to obtain the following knowledge and skills? *(check the best answer for each question)*

	None	A little	Some	Quite a bit	A lot
a. Interviewing patients	☐	☐	☐	☐	☐
b. Physical examination	☐	☐	☐	☐	☐
c. Generating a differential diagnosis	☐	☐	☐	☐	☐
d. Verbal presentation of patients	☐	☐	☐	☐	☐
e. Working with patients and families	☐	☐	☐	☐	☐
f. Working with nursing staff	☐	☐	☐	☐	☐
g. Ability to make decisions independently	☐	☐	☐	☐	☐
h. General procedure competency (IVs, lines, LPs, etc.)	☐	☐	☐	☐	☐
i. Organization and efficiency of work	☐	☐	☐	☐	☐
j. Application of pathophysiology to clinical medicine	☐	☐	☐	☐	☐
k. Appropriate use of lab tests	☐	☐	☐	☐	☐
l. Appropriate use of radiology exams	☐	☐	☐	☐	☐
m. Ethical decision-making in patient care	☐	☐	☐	☐	☐
n. Searching the medical literature	☐	☐	☐	☐	☐
o. Evaluating evidence from medical literature	☐	☐	☐	☐	☐

DAY-TO-DAY ACTIVITIES

20. How often during the <u>past month</u> did you: *(check the best answer for each question)*

	Never	Less than once per month	At least once per month	At least once per week	More than once per week	Daily
a. Skip at least one meal per day while working?	☐	☐	☐	☐	☐	☐
b. Receive belittling or humiliating treatment from a resident, attending, or nurse?	☐	☐	☐	☐	☐	☐
c. Work despite an illness?	☐	☐	☐	☐	☐	☐
d. Trade off personal or family obligations in favor of work?	☐	☐	☐	☐	☐	☐
e. Jeopardize a spousal or partner relationship due to work?	☐	☐	☐	☐	☐	☐

QUALITY OF WORK EXPERIENCE

21. In the context of what you expected from your residency, please assess your experience in the following areas during the past month: *(circle the best answer for each question)*

	Extremely Dissatisfied	Somewhat Dissatisfied	Neutral	Satisfied	Extremely Satisfied
a. Work hours	□	□	□	□	□
b. Work load while on duty	□	□	□	□	□
c. Clinical Supervision by residents	□	□	□	□	□
d. Clinical supervision by attending physicians	□	□	□	□	□
e. Amount of bedside teaching	□	□	□	□	□
f. Having appropriate autonomy in clinical decisions	□	□	□	□	□
g. Sense of professionalism	□	□	□	□	□
h. Time to study independently and pursue clinical questions	□	□	□	□	□
i. Time to attend didactic teaching sessions (e.g. grand rounds, team rounds, etc.)	□	□	□	□	□
j. Time to pursue research or other professional interests	□	□	□	□	□
k. Level of physical stress	□	□	□	□	□
l. Time for recreation and physical exercise	□	□	□	□	□
m. Level of psychological stress	□	□	□	□	□
n. Sense of ownership of the patients on your team	□	□	□	□	□
o. Knowledge and understanding of the daily care plan for the patients on your team	□	□	□	□	□
p. Basic knowledge gained on core critical care topics	□	□	□	□	□

SUPERVISION, SLEEP, AND PATIENT SAFETY

22. On average over the last month, how often, if ever, did you care for patients WITHOUT what you considered adequate supervision from an attending physician?

□ never □ less than once per month □ at least once per month
□ at least once per week □ more than once per week □ almost daily

23. On average over the last month, how often, if ever, did you personally work in what you considered an impaired condition?

□ 0 times □ 1-3 times □ 4-6 times □ 7-9 times □ ≥10 times

TEAMWORK AND SIGN OUT

24. How many times during your last month working did you receive erroneous information during a sign out, or team rounds?

☐ 0 times ☐ 1-3 times ☐ 4-6 times ☐ 7-9 times ☐ ≥10 times

25. How often during your last month working was critical information omitted during a sign-out you received?

☐ 0 times ☐ 1-3 times ☐ 4-6 times ☐ 7-9 times ☐ ≥10 times

26. Overall, how would you rate the quality of communication you received during your last month working?

☐ poor ☐ fair ☐ good ☐ very good ☐ excellent

27. Overall, how would you rate the quality of teamwork between yourself and your colleagues during your last month working?

☐ poor ☐ fair ☐ good ☐ very good ☐ excellent

28. Overall, please rate the quality of your work experience on your last month in the ICU

☐ poor ☐ fair ☐ good ☐ very good ☐ excellent

29. Overall, please rate the quality of your educational experience on your last month in the ICU

☐ poor ☐ fair ☐ good ☐ very good ☐ excellent

Thank you very much for completing this survey!

CHAPTER 4: COLLECTING MEDICAL ERRORS AND ADVERSE EVENTS

4.1 OVERVIEW

Medical errors and adverse events will be collected using the four following methods: (1) continuous observation; (2) voluntary and solicited reports; (3) collection of formal incident reports; and (4) chart surveillance. An adverse event is any harm due to medical care (or the absence or medical care); a medical error is something that goes wrong in the care delivery process, whether it causes harm or not.

4.2 CONTINUOUS OBSERVATION

Physician observers and research nurses will be responsible for collecting data on medical errors and adverse events. Five physician observers will conduct direct observation of residents 24 hours per day, 7 days per week, and will document medical errors and adverse events on a tablet-based **Suspected Event Form** (Appendix A). The research nurse will then gather follow-up data while conducting their daily chart reviews and add information to these event forms.

4.2.1 Observer Shift Summaries and Missed Observation Shift Forms

In order to document observation time on the units, physician observers are required to submit an Observer Shift Summary form following each shift which details the start and end dates and times of their shifts and which enrolled resident(s) they observed. If a shift is missed or the site was unable to schedule a physician observer, the research assistant should complete a Missed Observation Shift form for the hours missed. In the comment section of the form, the site should include one of the following reasons for the missed shift: (1) physician observer sick; (2) no physician observer scheduled; (3) holiday; (4) no enrolled resident scheduled; (5) other. We encourage sites to schedule physician observers even when there is no enrolled resident scheduled as appropriate for your unit. Physician observers could observe rounds and/or observe from a central nurses station.

4.3 COLLECTION OF FORMAL INCIDENT REPORTS

In each hospital, formal incident reports will be collected if permitted; if any institutions will not allow access to these data, we will request that duplicate study reports be filed by clinical staff on our study units when they complete formal reports. In addition, in any hospitals with computerized adverse event detection systems, the computerized AE monitors will also be interrogated for study-unit events.

Nurse data extractors will collect additional information on each incident identified and submit Event Forms online for suspected incidents.

4.4 CHART SURVEILLANCE

As alluded to above, the research nurse will serve as the focal point for data collection and organization, and will follow up and review all data collected by observers, reported

by staff, and detected via incident reporting systems. In addition to coordinating collection from other sources, reviewers will examine all orders and charts five days per week using a focused version of the **Institute for Healthcare Improvement (IHI) Global Trigger Tool** (consisting of the intensive care module, cares module, and medication module triggers) to increase the sensitivity of adverse event detection (Appendix B). Reviews on Monday will include a review of the weekend. Data collected for each incident will include a description and classification of the event, patient information, services and personnel involved, and additional work resulting from the event. Medication incidents will further include name, dose, route and category of the drug involved. In addition, subject codes will be recorded for incidents involving resident research subjects, to allow for subsequent sub-analyses investigating the relationship between sleep and work schedules and the occurrence of specific types of events.

4.5 VOLUNTARY AND SOLICITED REPORTS

Forms will be made available and prominently posted in the PICUs to facilitate voluntary reporting of possible errors and events by nurses and other clinical staff. The Incident Reporting Form for Staff will include the following information: patient name, patient ID number, location of incident, staff name (optional), date and time of incident and a brief description.

Chart reviewers will also request reports from staff of errors and adverse events 5 days per week. Any reported error or event will be pursued by the nurse data extractors, who will collect additional information.

Using the **Incident Reporting Forms for Staff** (Appendix C) and any reports of errors and adverse events detected during chart review, the nurse data extractors will complete an online Event Form, accessed via the study website, for all suspected incidents.

4.6 CLASSIFICATION OF ERRORS AND ADVERSE EVENTS

A group of independent physician reviewers will be recruited across sites to review all reported events. Reviewers will be trained to calibrate their assessment of events. Each reported event will be reviewed by two physician reviewers who will classify events as errors, potential adverse events (near misses), or adverse events using a **Physician Reviewer Classification Form** (Appendix D). All events will be rated on severity using the modified NCC-MERP scale. Preventability will be rated using a four point Likert scale. Disagreements will be resolved by discussion. Events for which consensus cannot be reached will be re-rated by a third reviewer. Pre-discussion inter-rater reliability will be evaluated with the Kappa statistic.

4.7 IDENTIFICATION OF PATIENT RISK FACTORS

Clinical and demographic data for all patients admitted to study units will be collected by the research nurse from patient records and institutional administrative databases during

lulls in unit activity. Severity of illness will be assessed using ICD-9 codes, which will be collected and submitted via the Patient ICD-9 Code form (Appendix E) following the patients' discharge from the PICU. The ICD-9 codes will be analyzed to determine severity of illness.

4.8 COLLECTION OF PATIENT DAYS

The research nurse or research assistant will be responsible for collecting data on the unit census during the course of the trial. Staff will maintain a **Patient Days Log** (Excel spreadsheet, Appendix F) which includes the following information: patient study ID, patient acrostic, patient name, medical record number (optional), admission date, discharge date, observed PICU length of stay, age and gender.

The study IDs will be pre-filled in the log and data for each new patient should be entered by the next consecutive ID. If a patient returns to the unit, s/he should be assigned the same ID. Staff may insert a new row in the spreadsheet to add this previously used ID.

Once the patient has been discharged from the unit, staff should complete an electronic Patient Days Log form, which can be found on the study website. The form includes all the fields present on the log EXCEPT the patient's name, and MRN, which are not transferred to the DCC.

4.9 FORM SUBMISSION TIMELINES

The forms detailed in this chapter should be submitted according to the timelines below:

- Suspected Event Forms: Forms which are initiated by the physician observers and saved should be reviewed and submitted by the research nurse within one week of the form initiation.
- Patient Days Log Form: Sites should review their internal patient days log and hospital database on a weekly basis to determine which patients have been discharged from the hospital. Forms should then be submitted for all discharged patients.
- Observer Shift Summaries: Physician observers should complete forms following each shift and no more than three days later.
- Missed Observation Shift Forms: Research assistants should complete forms on the day of the missed shift and no more than one week later.

APPENDIX A

ROSTERS Suspected Event Form

Instructions: The Physician Observers should complete the first half of the form, through Q13 (the Incident, Resident and Patient IDs may be completed by the Research Nurse if not known); the Research Nurse should review the entire form and complete Q14-19 and any other unanswered questions.

1. Incident ID #: ____ ____ ____ ____ ____ ____*(assign next available ID number(2 digit site code + unique 4 digit number))*
2. Date of Incident: ___ ___/___ ___/___ ___ ___ ___ *(MM/DD/YYYY)*
3. Time of incident: ___ ___ : ___ ___ □ AM □ PM □ Don't know
4. Resident Acrostic: ___ ___ ___ ___ □ Not a resident subject
5. Resident Subject ID: __ __ __ __ __ __ __ □ Not a resident subject
6. Patient Study Acrostic ___ ___ ___ ___ *(Refer to Patient Days Log)*
7. Patient Study ID: ___ ___ ___ ___ ___ ___ ___ *(Refer to Patient Days Log)*
8. Source of error recognition *(may choose more than one)*:
   - □ Direct Observation (e.g., on rounds)
   - □ Resident subject report
   - □ Other staff report
   - □ Formal hospital incident report
   - □ Chart review
   - □ Other: *please specify:*_____
9. Descriptive information concerning the suspected harm or error, including period leading up to, during and following the incident. If suspected harm, please emphasize data that helps determine if 1) reported episode was due to medical care (as opposed to underlying disease process); 2) whether harm could have been prevented or mitigated. If suspected error, please emphasize data that helps determine whether the error could have caused harm, and the severity of potential harm.

10. NCC-MERP Index Harm level (preliminary)

A: {Circumstances or events that have the capacity to cause error}

no harm
- □ B: An error that did not reach the patient
- □ C: An error that reached the patient but did not cause harm
- □ D: An error that reached the patient and required monitoring or intervention to confirm that it resulted in no harm to the patient

harm
- □ E: Temporary harm to the patient and required intervention
- □ F: Temporary harm to the patient and required prolonged hospitalization
- □ G: Permanent patient harm
- □ H: Intervention required to sustain life
- □ I: Patient death

APPENDIX A

11. If harm level was classified as **B**, **C**, or **D**, was the incident preventable?

- ☐ 1 Definitely preventable
- ☐ 2 Probably preventable
- ☐ 3 Probably not preventable
- ☐ 4 Definitely not preventable

12. If incident <u>probably or definitely preventable</u>, position of provider who made primary error?

- ☐ 1 intern
- ☐ 2 resident – study subject
- ☐ 3 resident – not a study subject
- ☐ 4 fellow
- ☐ 5 staff physician
- ☐ 6 medical student
- ☐ 7 nurse
- ☐ 8 pharmacist
- ☐ 9 other clinical staff

13. Incident category (pick one best answer):

- ☐ 1 Medication-related
- ☐ 2 Procedure-related
- ☐ 3 Diagnostic test-related or Related to History and Physical (incorrect, delayed, or omitted)
- ☐ 4 Related to therapy other than medication or procedure; describe:_____
- ☐ 5 Nosocomial infection
- ☐ 6 Other; describe:_____

Complete appropriate error subcategory below

13a. If there was an error (i.e., incident was preventable or could have been mitigated more effectively), what was the error category (pick one best answer):

<u>Medication-related</u>

- ☐ 1.1 Wrong medication
- ☐ 1.2 Wrong dose
- ☐ 1.3 Wrong set limits or administered outside limits (ordered and/or policy limits)
- ☐ 1.4 Wrong rate
- ☐ 1.5 Wrong concentration / preparation error
- ☐ 1.6 Wrong patient
- ☐ 1.7 Wrong duration
- ☐ 1.8 Wrong frequency
- ☐ 1.9 Known allergy to medication
- ☐ 1.10 Drug-drug interaction
- ☐ 1.11 Wrong time of day
- ☐ 1.12 Omitted medication
- ☐ 1.13 Med order not discontinued
- ☐ 1.14 Duplicate order / med
- ☐ 1.15 Wrong route
- ☐ 1.16 Other medication error, describe _____

<u>Procedure-related</u>

- ☐ 2.1 Wrong procedure performed
- ☐ 2.2 Necessary procedure not performed
- ☐ 2.3 Wrong site (e.g., wrong-side surgery or procedure)
- ☐ 2.4 Wrong patient

Complete Q14 and Q15 below.

☐ 2.5 Needed equipment or supplies not available
☐ 2.6 Failure to check equipment
☐ 2.7 Defective equipment or supplies
☐ 2.8 Delay in provision or scheduling of service
☐ 2.9 Inadequate patient preparation
☐ 2.10 Other procedural error, describe _____

Related to a therapy/care other than a medication or a procedure
☐ 3.1 Wrong therapy/care
☐ 3.2 Necessary therapy/care not performed
☐ 3.3 Wrong site
☐ 3.4 Wrong patient
☐ 3.5 Needed equipment or supplies not available
☐ 3.6 Failure to check equipment
☐ 3.7 Defective equipment or supplies
☐ 3.8 Delay in provision or scheduling of service
☐ 3.9 Inadequate patient preparation
☐ 3.10 Other therapeutic error, describe _____

Diagnosis-related (delayed, incorrect, or omitted diagnosis)
☐ 4.1 Failure to obtain complete and accurate data from patient history and physical exam
☐ 4.2 Failure to use indicated tests
☐ 4.3 Failure to follow-up test results
☐ 4.4 Failure to act expeditiously on results of tests or findings
☐ 4.5 Misinterpretation of data obtained from history and physical
☐ 4.6 Misinterpretation of test results
☐ 4.7 Other diagnostic error, describe _____

Nosocomial Infection
☐ 5.1 Catheter-related blood stream infection
☐ 5.2 Sepsis/bacteremia unrelated to catheter
☐ 5.3 Ventilator-associated pneumonia
☐ 5.4 Nosocomial pneumonia, not ventilator-related
☐ 5.5 Hospital-acquired UTI
☐ 5.6 Hospital-acquired viral illness
☐ 5.7 Other hospital-acquired infection, describe _____

Other
☐ 6.1 Other category, describe_____

If the incident was medication-related:

14. Name of the drug: _____

15. Category of drug

APPENDIX A

Cardiovascular

□ 1. Beta-blockers
□ 2. Antiarrhythmic
□ 3. Nitrates
□ 4. IV Vasodilator
□ 5. IV Vasoconstrictor / pressor
□ 6. Inotrope
□ 7. Diuretic
□ 8. Digitalis
□ 9. Other antihypertensive agent
□ 10. Antilipemic agent

CNS/Pain/anxiety

□ 11. Non-narcotic analgesic
□ 12. Narcotics analgesic
□ 13. Muscle relaxant
□ 14. Sedative, hypnotic
□ 15. Intravenous anesthetic
□ 16. Anti-seizure
□ 17. Other CNS agents

Infectious Disease

□ 18. Antiviral
□ 19. Antifungal
□ 20. Antibiotic

Intravenous TX

□ 21. IVF
□ 22. Electrolyte concentration
□ 23. Blood products (RBC, plates, FFP)
□ 24. Colloids (albumin, hetastarch)

Gastrointestinal

□ 25. TPN
□ 26. GI-H2 blocker
□ 27. Other GI agent

Other Categories

□ 28. Thrombolytic agent
□ 29. G IIb/IIIa inhibitor
□ 30. Anticoagulant
□ 31. Antitumor
□ 32. Diabetes
□ 33. Antidepressant
□ 34. Antipsychotic
□ 35. Antiasthmatic
□ 36. Immunosuppressants
□ 37. Steroids
□ 38. Diagnostic agent (eg. contrast dye)
□ 39. Antihistamine
□ 40. Other _____

16. Temporal relationship of incident to ICU course:

□ 1 During transport associated with admission to the PICU
□ 2 During admission to unit (initial 30 minutes after arrival)
□ 3 During ongoing routine care
□ 4 During an emergency intervention
□ 5 During a non-emergent procedure
□ 6 During transport to or from procedure or test
□ 7 During transfer out of the unit to a new patient care area
□ 8 Unable to determine
□ 9 Other; describe:_____

17. What was the immediate follow-up response during the 2 hours after the incident?

□ 1 Additional monitoring
□ 2 Change in current medical treatment (eg. increase dosage, decrease dosage or stop current medication)
□ 3 Additional (new) medical treatment (eg. naloxone for oversedation, D10 (dextrose) for insulin excess, transfusion for procedure-related hemorrhage)
□ 4 Additional procedure(s)
□ 5 Additional test(s)
□ 6 Additional consults (describe service/specialty and number of consults below in Q19)

□ 7 No change
□ 8 Other; describe:_____

18. If harm occurred (NCC-MERP level E-I), specific harm code (see Specific Harm Code table): ___ ___ ___ *(Choose from drop down menu)*

18a. If "Other" (899), please describe:_____

19. Final injury / outcome for patient:

	Cares Module Triggers	+	Event Description and Harm Category (E-I)
C1	Transfusion or use of blood products		
C2	Any code or arrest		
C3	Dialysis		
C4	Positive blood culture		
C5	X-ray or Doppler studies for emboli		
C6	Abrupt drop of greater than 25% in hemoglobin or hematocrit		
C7	Patient fall		
C8	Pressure ulcers		
C9	Readmission within 30 days		
C10	Restraint use		
C11	Healthcare-associated infection of any kind		
C12	In-hospital stroke		
C13	Transfer to higher level of care		
C14	Any procedure complication		
C15	Other		
	Surgical Module Triggers		
S1	Return to surgery		
S2	Change in procedure		
S3	Admission to intensive care post-op		
S4	Intubation/reintubation/BiPap in Post Anesthesia Care Unit (PACU)		
S5	X-ray intra-op or in PACU		
S6	Intra-op or post-op death		
S7	Mechanical ventilation greater than 24 hours post-op		
S8	Intra-op epinephrine or norepinephrine		
S9	Post-op troponin level greater than 1.5 ng/ml		
S10	Change of anesthetic during surgery		
S11	Consult requested in PACU		
S12	Pathology report normal or unrelated to diagnosis		
S13	Insertion of arterial or central venous line during surgery		
S14	Operative time greater than 6 hours		
S15	Removal/injury or repair of organ		

	Medication Module Triggers	+	Event Description and Harm Category (E-I)
M1	*Clostridium difficile* positive culture		
M2	Partial thromboplastin time greater than 100 seconds		
M3	International Normalized Ratio (INR) greater than 6		
M4	Glucose less than 50 mg/dl		
M5	Rising BUN or serum creatinine greater than 2 times baseline		
M6	Vitamin K administration		
M7	Benadryl (Diphenhydramine) use		
M8	Romazicon (Flumazenil) use		
M9	Narcan (Naloxone) use		
M10	Anti-emetic use		
M11	Over-sedation/hypotension		
M12	Abrupt medication stop		
M13	Other		
	Intensive Care Module Triggers		
I1	Pneumonia onset		
I2	Readmission to intensive care		
I3	In-unit procedure		
I4	Intubation/reintubation		
	Perinatal Module Triggers		
P1	Apgar score less than 7 at 5 minutes		
P2	Maternal/neonatal transport/transfer		
P3	Magnesium sulfate or terbutaline use		
P4	3rd- or 4th-degree lacerations		
P5	Induction of delivery		
	Emergency Department Module Triggers		
E1	Readmission to ED within 48 hours		
E2	Time in ED greater than 6 hours		

Patient Identifier _____ Total Events _____ Total LOS _____ Write descriptions of the events in greater detail on reverse of Worksheet

[Photocopy Worksheet single-sided. Leave opposite side blank for notes.]

APPENDIX C

Incident number ___ ___-___ ___ ___ ___
(completed by research team)

Patient Safety Study: Incident Reporting Form for Staff

Adverse events, near misses, and medical errors.
(Actual adverse events should be reported by the usual hospital incident reporting system as well)

May be completed by *any* member of the staff (nursing, respiratory therapy, physicians, secretary, etc). Includes corrected orders (verbal or written) or "catches" that may have prevented possible patient injury, unnecessary testing or patient discomfort.

This is a confidential form that will not be part of any patient or hospital records. It will be used only for purposes of quality improvement and research. Only study researchers at your institution will have access to these reports. Clinical staff and other hospital personnel will be provided with no knowledge of specific reports, events or reporters (de-identified summaries may be provided to programs for education, quality improvement, and research purposes).

1. Patient name _____
2. Patient ID # _____
3. Location _____
4. Your name *(optional)* _____
5. Date incident occurred ___ ___ /___ ___ / ___ ___
6 Time incident occurred ___ ___:___ ___ ____AM or ____ PM
7. Please briefly describe the incident (for medications, include name of drug) and, when applicable, what you and the team did to prevent or minimize harm

_____

_____

_____

_____

_____

Thank you!

APPENDIX D

ROSTERS Physician Reviewer Classification Form

1. Incident ID #: ___ ___ ___ ___ ___
2. Incident Date: MM/DD/YYYY
3. Physician Reviewer ID: __ __ __ __
4. Classification of incident

- ☐ 1 Adverse event / harm
- ☐ 2 Intercepted potential adverse event
  Near miss error with potential for harm but was intercepted before reaching patient
- ☐ 3 Non-intercepted potential adverse event
  Near miss error with potential for harm that was not intercepted and fortunately did not result in apparent patient consequence or harm
- ☐ 4 Error with little or no potential for harm
- ☐ 5 Exclusion

5. Harm level _____

no harm (classes 2-4 above)

- ☐ A*: {{Circumstances or events that have the capacity to cause error}}**
- ☐ B: An error that did not reach the patient *(includes some class 2 and some 4 above)*
- ☐ C: An error that reached the patient but did not cause harm *(includes some 3 and some 4 above)*
- ☐ D: An error that reached the patient and required monitoring or intervention to confirm that it resulted in no harm to the patient *(includes some class 3 above)*

harm (class 1 above)

- ☐ E: Temporary harm to the patient and required intervention
- ☐ F: Temporary harm to the patient and required initial or prolonged hospitalization
- ☐ G: Permanent patient harm
- ☐ H: Intervention required to sustain life
- ☐ I: Patient death

Note on Harm Categories (modified from IHI Trigger Tool White Paper): * NOTE: LEVEL A INCIDENTS ARE BEING EXCLUDED FROM THIS STUDY…..All harms due to medical care fall into categories E through I, regardless of whether they are preventable or not. These categories are not progressive (i.e., an event does not have to first meet the definition of E and F before it can be categorized as G). For category E, some intervention is required; the simplest intervention could be observation. For category H, experienced reviewers have found it helpful to define "lifesaving intervention" as that which must be provided in one hour or less in order to prevent death. For example, a patient with a surgical site infection requires antibiotic treatment and one could argue that failure to provide it could lead to sepsis and death. While this may be true, it is unlikely that the antibiotic would need to be provided within one hour to prevent death. However, a patient who develops respiratory depression and arrest from a narcotic requires immediate intervention, such as non-invasive or invasive ventilation; this would be an intervention required to sustain life, even if it was only needed for a few hours. For category I, the event needs only to be contributory to the death.

5. Was the incident preventable?

- ☐ 1 Definitely preventable
- ☐ 2 Probably preventable
- ☐ 3 Probably not preventable
- ☐ 4 Definitely not preventable

6. If harm, could the harm have been mitigated more effectively than it was?

- ☐ 1 Definitely
- ☐ 2 Probably
- ☐ 3 Probably not
- ☐ 4 Definitely not

APPENDIX E PATIENT ICD ODES FORM

ROSTERS

Pa CD-9 Cod s Form

Staff ID: NNNN *(required)*

Patient ID NNNNN *(required)*

Patient Acrostic: AB D *(required)*

Primary Dia nosis: NNN.NN *(required)*

Secondary Dia nosis (1): NNN.NN

Secondary Dia nosis (2): NNN.NN

Secondary Dia nosis (3): NNN.NN

Secondary Dia nosis (4): NNN.NN

Secondary Dia nosis (5): NNN.NN

Secondary Dia nosis (6): NNN.NN

Secondary Dia nosis (7): NNN.NN

Secondary Dia nosis (8): NNN.NN

Secondary Dia nosis ( ): NNN.NN

Secondary Dia nosis (10): NNN.NN

Secondary Dia nosis (11): NNN.NN

Secondary Dia nosis (12): NNN.NN

Secondary Dia nosis (13): NNN.NN

Secondary Dia nosis (14): NNN.NN

Secondary Dia nosis (15): NNN.NN

 omments: (open text)

APPENDIX F TER PATIENT ID AND DAY LOG

PATIENT UBJECT ID	PATIENT AC TIC (4 letter)	LA T NAME	I T NAME	M N	H PITAL ADMI I ON DATE	H PITAL DISCHARGE DATE	PICU LOS (exclude days where pt was not under observation (eg, transferred temporarily to another unit)) (DAY)	AGE (**YRS** - if >36 mon; **MON** - if >3 mon and <36 mon; **WKS** - if < 3 mon)	GENDE (M/)
N2001									
N2002									
N2003									
N2004									
N2005									
N2006									
N2007									
N2008									
N2009									
N2010									
etc									

APPENDIX F TER PATIENT ID AND DAY LOG

PATIENT UBJECT ID	PATIENT AC TIC (4 letter)	LA T NAME	I T NAME	M N	H PITAL ADMI I ON DATE	H PITAL DISCHARGE DATE	PICU LOS (exclude days where pt was not under observation (eg, transferred temporarily to another unit)) (DAY)	AGE (**YRS** - if >36 mon; **MON** - if >3 mon and <36 mon; **WKS** - if < 3 mon)	GENDE (M/)

CHAPTER 5: ACTIGRAPHY

5.1 OVERVIEW

The equipment that will be used for this study, the Basic Motionlogger-L (Ambulatory Monitoring, Inc, Ardsley, New York) actigraph, is a small wrist-worn device, which measures activity and light exposure. The actigraph should be worn on the non-dominant wrist throughout the duration of the residents' month-long rotation through the PICU. The output from the actigraph supplies information about percent sleep, number of awakenings per night, length of awakenings at night, percent wake, napping behavior (number of naps and length of wake periods between naps) and variables that summarize patterns of circadian rhythms.

The research assistants who have received training in the operation of the actigraphs will need to set up the actigraphs and distribute them to the resident subjects at the time they consent to participation or at the start of their rotation. Residents will be required to check in weekly with the research assistants to download their data. Research assistants, in turn, will send data files from all residents to the DCC on a weekly basis.

5.2 EQUIPMENT AND SUPPLIES

- **Basic Motionlogger-L (Octagonal BASIC)**
- **Motionlogger interface unit and cables**
- **ACT Millennium Software**
- **3 volt Lithium Watch batteries (CR2430)**
- **9-volt batteries (for IU)/or electrical cord**
- **black electrical tape**
- **alcohol swabs**
- **watchbands**

5.3 SETTING UP THE ACT MILLENIUM SOFTWARE

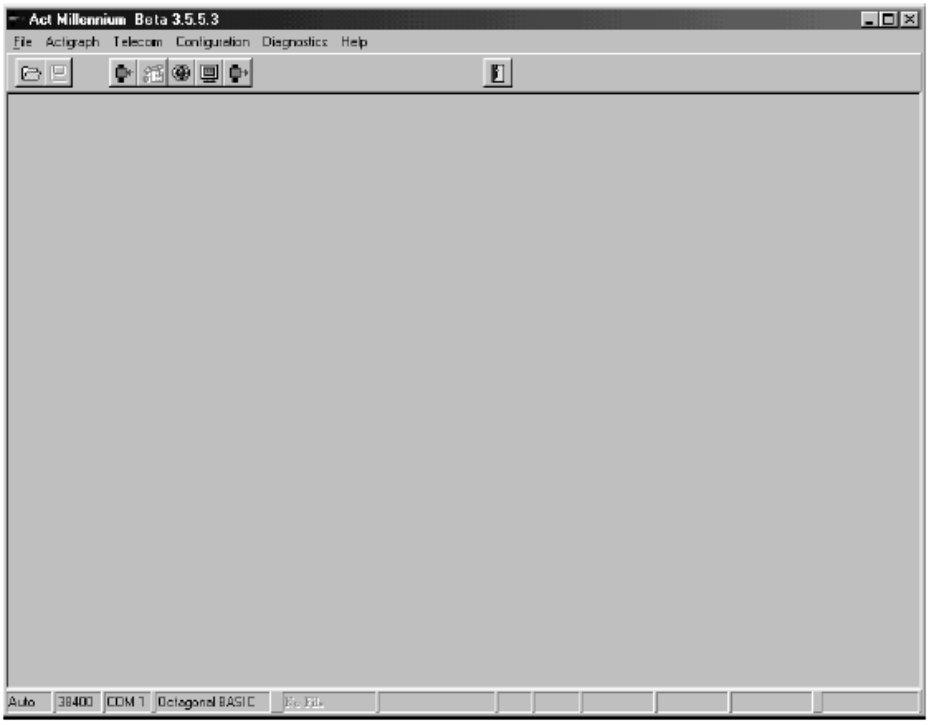
ACT Millenium (ACTME) software is a Windows program that is used to initialize Motionlogger actigraphs, and to download data from the devices.

5.3.1 Installing ACT Millenium (CD-ROM)

1. Insert the ACT Millennium CD-ROM into your CD-ROM drive
2. If your computer supports AutoPlay, installation of the program will begin automatically; just skip to step 6.
3. Double-click on MY COMPUTER on your desktop
4. Double-click on your CD-ROM drive (typically drive D:)
5. If the installer launches, skip to step 6. Otherwise double-click the SETUP icon.
6. Follow the on-screen prompts to complete the installation.

5.3.2 Running ACT Millennium

Clicking on the Windows Start Button, selecting Programs, AMI, ACT Millennium, and finally clicking on the ACT Millennium file can start the software. You may wish to copy and paste the ACT Millennium icon on your desktop, making it easier to start your program. The figure below shows a display of ACT Millennium upon start up.

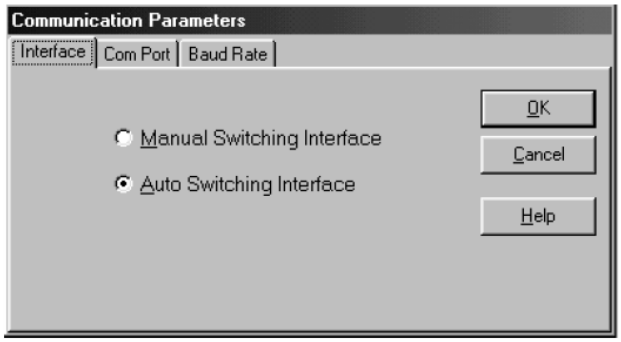


5.3.3 Configuring ACT Millenium

Before proceeding to initialize or download any actigraphs, it would be a good idea to configure ACT Millennium to match existing hardware. This is accomplished by selecting items from the Configuration menu. In addition to editing the configuration, one can save the new configuration, load up the last saved configuration, and reset the configuration to the default values.

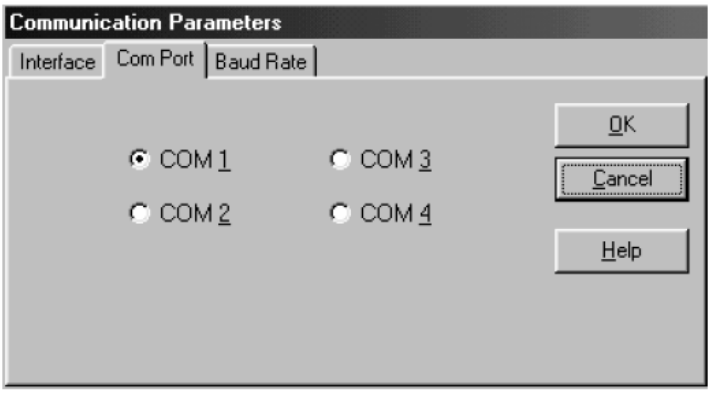
Configuring Communications (Interface Type, Com Port and Baud Rate)

The figure below shows the configuration window when the *Communications* item is selected:



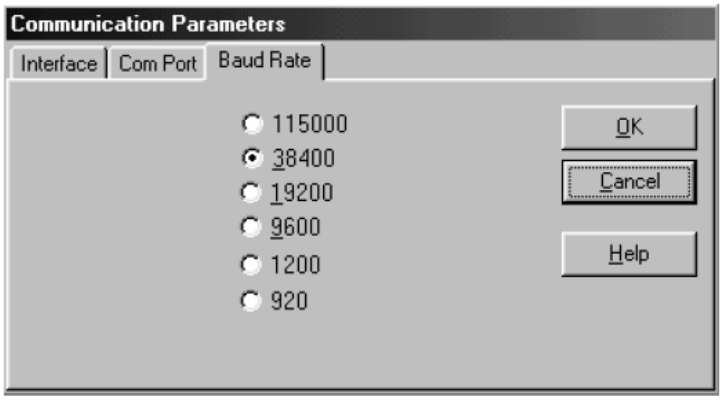
Notice the three tabs appearing at the top. These tabs permit one to select which configuration parameters need to be set. Choose the Interface type that matches existing hardware. All BASIC Motionloggers are supplied with an **Auto Switching Interface**.

Pressing the Com Port Tab shows this selection:



Here is the serial port selection. Choose the computer port that is (or will be) attached to the interface unit. Many computers and laptops sold these days have only one serial port available and it is **COM1**. So when in doubt choose this.

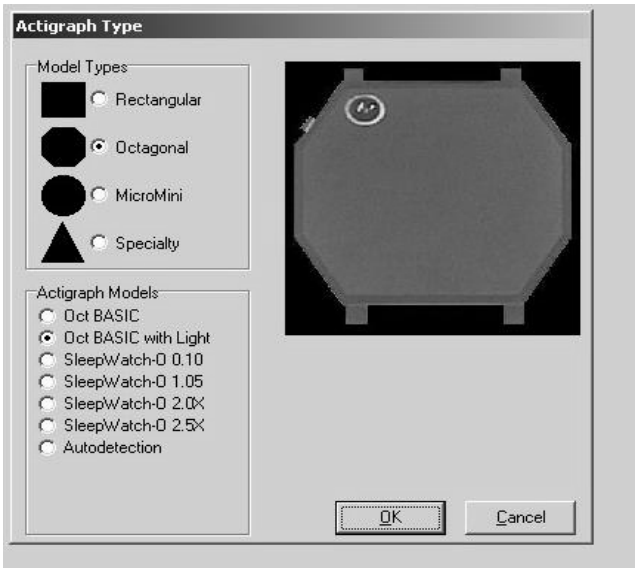
Selecting the Baud Rate Tab shows this screen:



Note that Octagonal BASIC Motionloggers require **38400 Baud**.

Configuring Actigraph Type

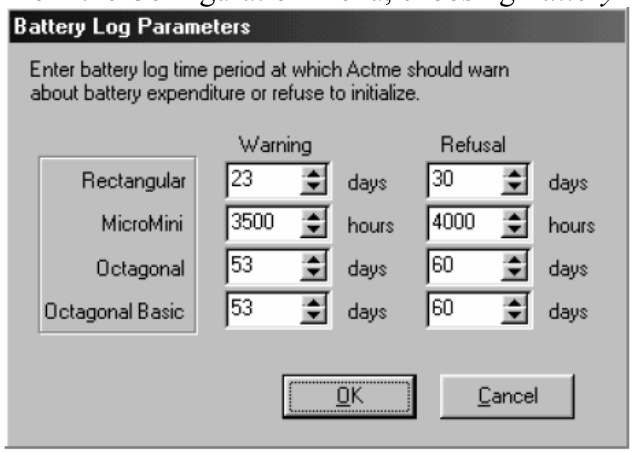
From the Configuration menu, choosing *Actigraph Type* causes this screen to be displayed:



Choose the actigraph type you are planning to use. Under *Model Type* choose **Octagonal**. Then choose **Oct BASIC with Light**.

Configuring Battery Life Warning and Refusal Levels

From the Configuration menu, choosing *Battery Logs* causes this screen to be displayed:



"Battery Log Parameters" allows one to customize a warning level and refusal level for battery life. During the initialization process, if the battery life has been exceeded then initialization will be refused until the devices battery has been changed or the refusal level has been increased. At the warning level one will be informed of the number of hours logged on the device's battery and remind the user about the approaching refusal level. For the Octagonal Basic indicates, enter a Warning of **53 days** so that an alert will be issued about battery life while still at least one week of battery life remains. For the Refusal, enter **60 days**.

After completing the configuration settings, make sure that the configuration is saved (Configuration:Save).

5.4 INSTALLING THE INTERFACE

The interface is dual powered. A 9 Volt battery can be used for field applications or an external power supply can be plugged into the main electrical supply. A 9 Volt battery should supply enough power for at least 100 hours of operation. The power indicator will glow green if the battery has sufficient capacity to communicate with actigraphs and *RED* if it does not. The external power supply for the interface is US 110V type. The external power supply has priority and bypasses the battery, so that the battery need not be removed when operating using the power supply. The AC plug should be inserted into an available outlet. The 9 Volt DC end should be placed into the labeled receptacle on the back panel of the interface. An LED indicator on the FIU indicates adequate power for communications. Always have a spare battery on hand to insure communications with the Motionlogger if you will not have access to an electrical supply. The serial cable provided is a 9-pin-male to 9-pin-female. The female end should be plugged into an unoccupied serial port of your PC. ACT Millennium supports serial ports COM1 through COM4. Adjust the setting in ACT Millennium from the "Com Port" Tab of the Configuration Menu.

.

Loop Testing – verifying proper serial communications

Loop testing is a way to make certain that your serial cable is connected to the communications port that has been configured in ACT Millennium. Octagonal Interfaces come with a built in loop test circuit that is activated by a button labeled "Loop Test."

Running a Loop Test with an Interface or a Loop Tester

1) Be sure that the software is properly configured for the hardware you are using. Go to the CONFIGURATION menu and choose "Edit" then choose the Com Port Tab. Make certain that the hardware port chosen is the one your RS232 cable is *physically* connected to. If you are not certain, you may have to run the Loop Test several times changing the configured port until successful.

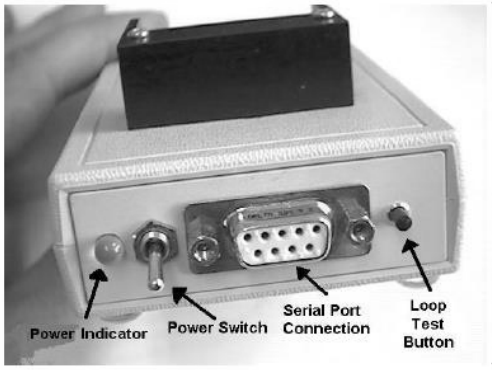
2) Go to the DIAGNOSTIC Menu and choose Loop Test. **Make sure that the power of the interface is switched ON.** The program will instruct you to "Insure that the Loop Reset Button is held throughout the test." If you are connected to a properly working serial port then a window will be presented indicating "Loop Test Successful."

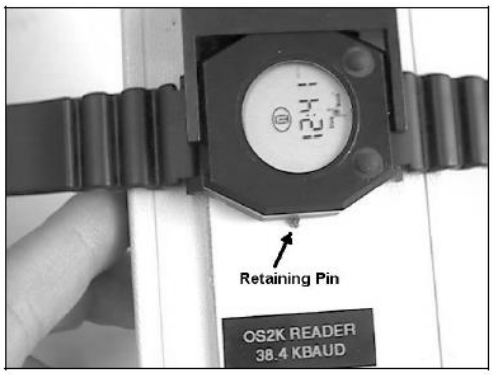
3) If the Loop Test is unsuccessful and you are certain that the COM Port chosen matches physical port to which the RS232 cable is connected, then try another Communications Port. If none of the Com Ports of your computer pass this test, it may be necessary for you to contact your computer professional.

Note – it is also of value to run a Loop Test without holding down the loop button (or attaching the loop tester device) and forcing the test to fail. This eliminates the possibility that the configured serial port is actually connected to some other serial device (i.e. a modem) that can also return a successful loop test signal.

5.4.1 Insertion into the Interface

This interface is powered by a single 9-volt battery that can be accessed by a sliding compartment door on the bottom. Thus powered the interface should supply approximately 100 hours of operation. When the interface battery needs changing the battery indicator will change from green to red, or not come on at all. Remember to keep a fresh 9-volt battery on hand for replacement. Insert the Motionlogger into the interface face-up by aligning the 4 gold contacts with the 4 gold pins of the interface. The Motionlogger is held in place by a retaining pin on the opposite side.





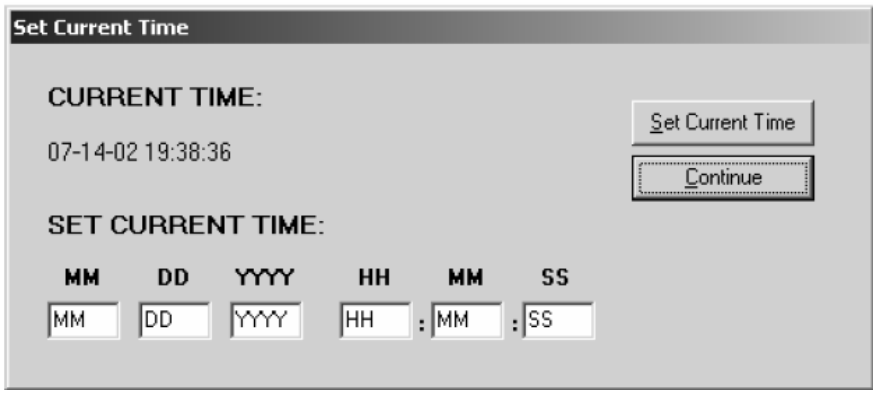
5.5 INITIALIZING THE ACTIGRAPH

This section describes what you will have to do before each participant wears a watch. The same steps need to be followed each time a watch is initialized.

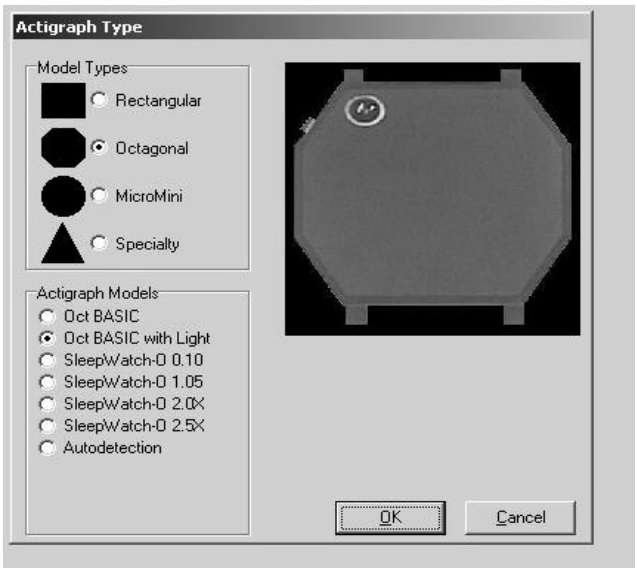
Turn the IU on and insert the SleepWatch into the IU so that it is secured in the holder. Put the watch in the IU so that the 4 gold pins on the side of the watch are touching the IU. Remember to clean any tape residue off of the pins using an alcohol swab before placing the watch in the IU.

Go to the “Actigraph” menu and select “Initialize” or use the initialize icon on the toolbar. Switch the toggle switch on (green light will appear). When the “Set Current Time” window appears, check that the time is correct. The program uses military time. The program sets its time according to the internal time on your computer so you need to make sure that the time setting on your computer is correct (AM/PM). If you need to change the time you can do so by filling in the boxes at the bottom of the pop-up window, be sure to use Military time(see table 1 in the appendix).

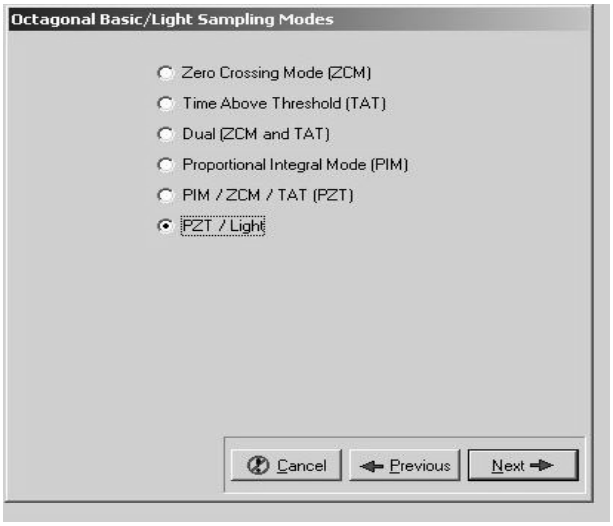
Hit “Continue” once the correct time appears under “Current Time:”



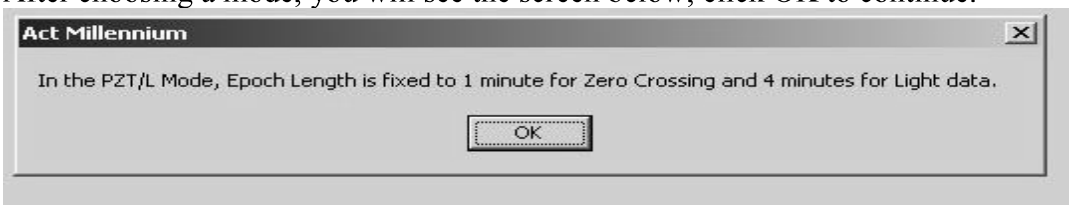
Now the Actigraph Type window is displayed as shown in the figure below. In the Model Types section, select the **Octagonal** and **Oct BASIC with Light** for the actigraph model. Click the OK button to proceed.



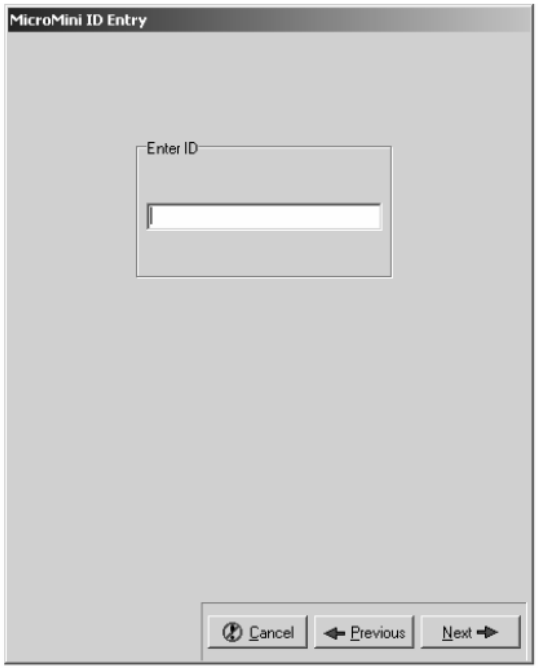
For the operational mode, select: **PZT/Light**



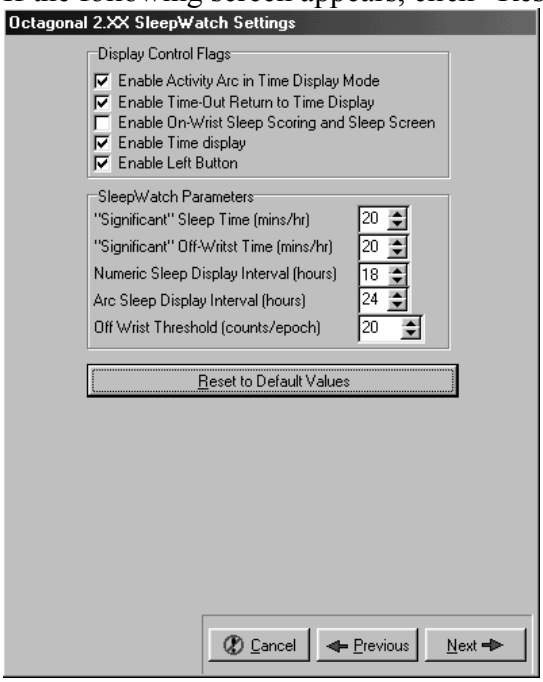
After choosing a mode, you will see the screen below; click OK to continue.



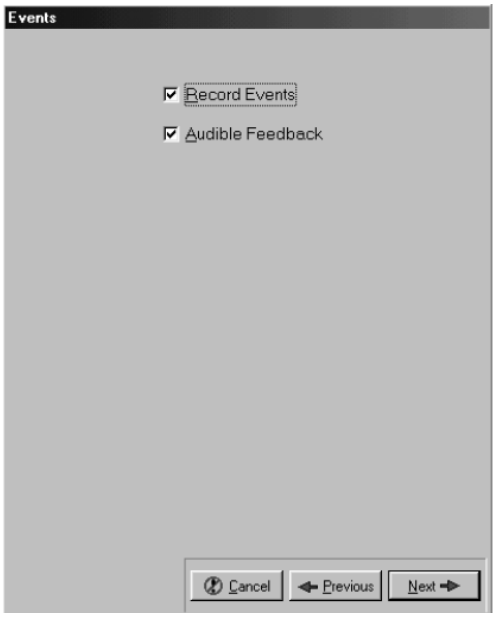
The next screen is for entering an ID. Enter the resident subject's 5 digit ROSTERS **ID** and **acrostic (ROSTERIDAcrostic)** for the data collection session. For example: **N1001ABCD**. Click Next to continue.



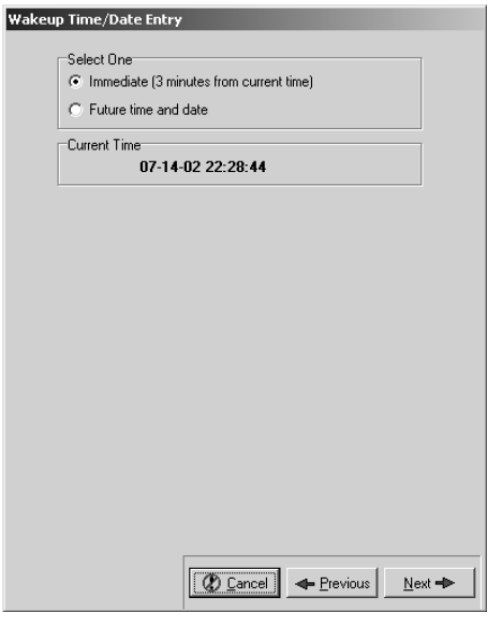
If the following screen appears, click “Reset to Default Values” and click Next.



Select **Record Events** and **Audible Feedback** and click Next.

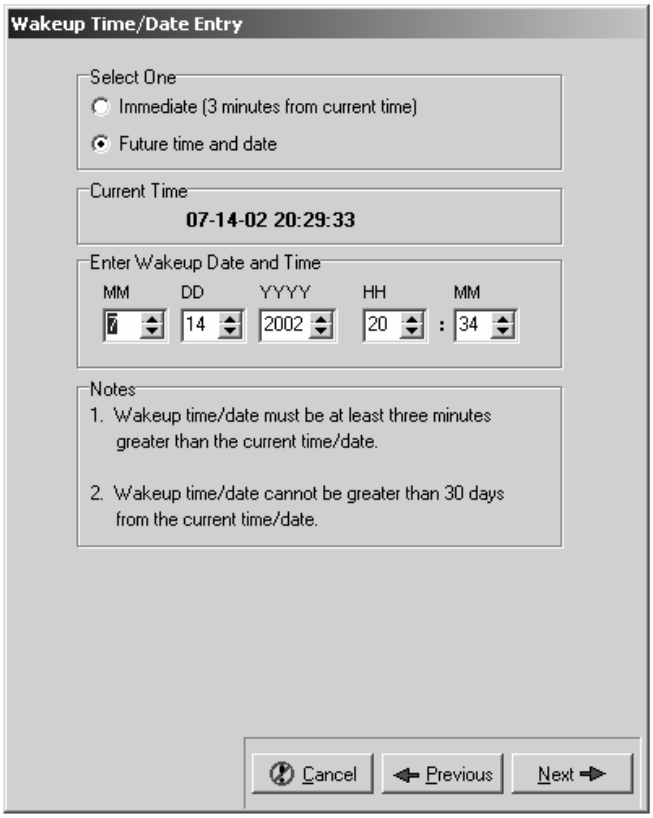


At this point it is necessary to decide whether the device will start immediately (within three minutes) or start at some future time. The Future startup feature is convenient when multiple devices are to be synchronized or if you will be distributing the actigraph to a resident subject prior to the start of his/her rotation. The figure below shows the dialog box that is used to make that decision. Click on the startup condition desired and then click the Next button to continue.

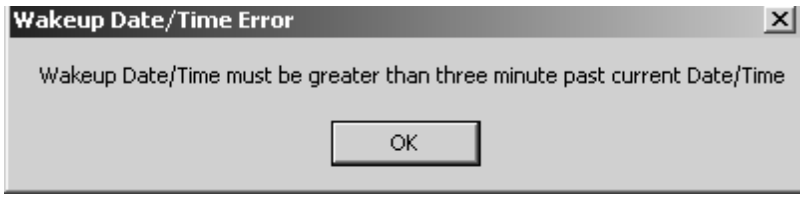


"Immediate' start ups automatically sets the startup time 3 minutes past the current time.

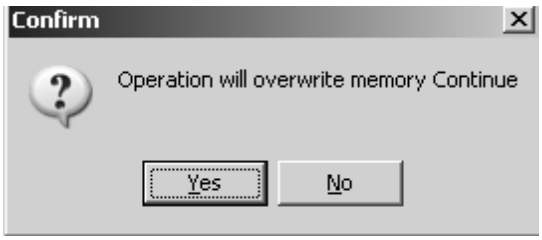
If a future start up condition is selected, one will be presented with the dialog box shown in the figure below. Enter in the month; day, year, hour and minute of the device should commence data collection. Time spent waiting for the startup time and date expend a very small amount of battery power that would be insignificant for delays of up to a week. Longer delays should be tested, particularly with rechargeable batteries, to make certain that a long delay does not impact recording time by shortening battery life.



The Wakeup Time/Date cannot be greater than **30 days** from the current Time/Date. If the Wakeup Time/Date is larger than 30 days from the current date the following message will be displayed as shown in the figure below. Clicking the OK button will take one back to the Wakeup Time/Date Entry form.

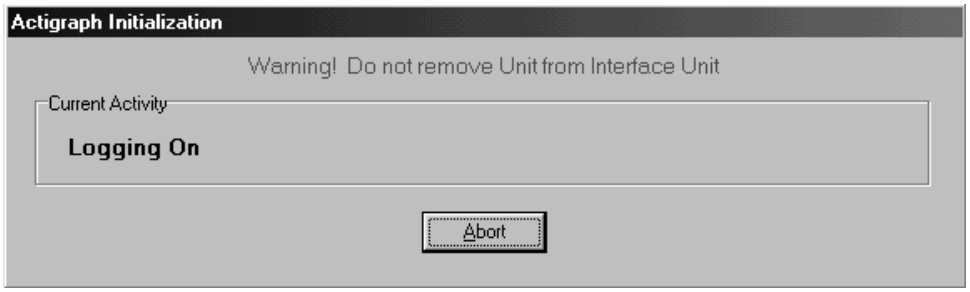


Since initialization erases any previous data, an Overwrite verification dialog box is displayed as shown in the figure below. If one are sure that one want to initialize the Motionlogger, click the YES button.



If one does not wish to initialize the device at this time click the NO button. The following message will be displayed as shown in the figure below.

If you wish to proceed with the initialization, make sure the Motionlogger has been placed correctly in the interface unit.



"Logging on" is replaced by "Detecting Actigraph Type," then "Sending Intialization Data" (this step is the longest in duration), followed finally by "Logging off."

If the actigraph is initialized successfully, then the dialog box shown in the figure below is displayed. One may now remove the Motionlogger and begin using it.

To eliminate the risk of a leakage current the pins on the side of the watch should be covered with a small piece of black electrical tape. When the patient returns the watch this tape will need to be removed before the data is downloaded from the watch. Clean the pins with alcohol swabs to ensure that there is no remaining residue. If the pins are not completely clean there may be a problem downloading the data from the watch.

Important Reminders:

- Each time you put the watch into the IU to initialize download a file, check the life of the battery. To do this, place the Motionlogger into the IU and after the download is completed, go to the File menu and select "Summary". "Battery Runtime Days" can be displayed. The battery life of the DL2430 or compatible Lithium Coincell battery used is approximately 60 days. Make sure you continually check the battery life when distributing watches and record the battery life on the sleep watch log in the clinic. Discard used batteries in an environmentally safe manner.

- Always use fresh batteries. Whenever you replace a battery, the software reads it as a new (fresh) battery and begins battery life at "0" days. Reusing batteries will give inaccurate battery life readings.

- The first time you initialize a watch or the first time you initialize a watch after putting a new battery into the watch, hit the reset button (black button) on the back of the IU before starting the initialization process.

5.6 THE RESIDENT SUBJECT AND THE ACTIGRAPH

The actigraphs will be distributed to the residents prior to or at the start of their rotation in the unit. The resident will receive:

- BASIC Motionlogger-L
- Information Sheet
- Instructions for completing the sleep/work diary
- Schedule for weekly data downloads

The procedure for wearing the watch, downloading the data and completing the sleep/work diary should be explained to the resident subjects when they receive the actigraph. Instructions include:

1) Wearing the watch - the watch should be worn on the non-dominant wrist and should be securely fastened around the wrist (but not tight). It should be worn just as a wrist watch would be worn and it should be treated as you would an expensive watch. A wrist or sweatband may be worn under the watch if it's more comfortable and to ensure a secure fit. The watch should not dangle from the wrist or slide around.

2) Removing the watch - the watch should only be removed when it will be submerged in water, as when swimming or taking a bath. It is ok to keep the watch on while showering and washing dishes.

3) When to wear the watch - the watch should be worn night and day throughout the resident subject's month-long rotation in the unit.

4) Completing sleep/work diary - the sleep/work diary should be explained to the resident, emphasizing that a diary entry must be completed every day. If the resident misses a day, there will be a short window within which s/he may go back and complete the information. Let the resident know that the study will be monitoring the completion of the diary and may contact the resident if there are missing entries.

5) Downloading the data – provide the resident with a schedule of his/her weekly downloads. On the appointed day (at the end of Week 1, Week 2, Week 3 and at the close of their rotation, when they return the actigraph), the resident will need to give his/her actigraph to the research assistant to download the data and check the battery life. This should only take a few minutes, after which the resident should resume wearing the actigraph.

6) A summary of the above information with critical points should be provided to the resident. An example of an information sheet is appended to this chapter and can be found on the ROSTERS website. The sheet will provide them with contact information (phone number, email) for the research assistant, in case there are any questions.

The actigraph should already be set to start collecting data when the resident puts it on at the start of their rotation. The participant will start completing the sleep/work diary the following morning.

5.6.1 Actigraphy Checklist and Actigraph Log

Go to the study website to complete the **Actigraphy Checklist** for each resident when they receive the actigraph. To complete the checklist, you will need the serial number of the watch, as well as the resident's ID, acrostic, and date they received the actigraph.

The **Actigraph Log** is another way to keep track of the individual actigraphs at your site. Actigraph Log worksheets can be found in the Device Log Excel Workbook. Logs may be printed or maintained electronically. On each log, you will record the dates each actigraph was initialized; data downloaded; battery life; and voltage.

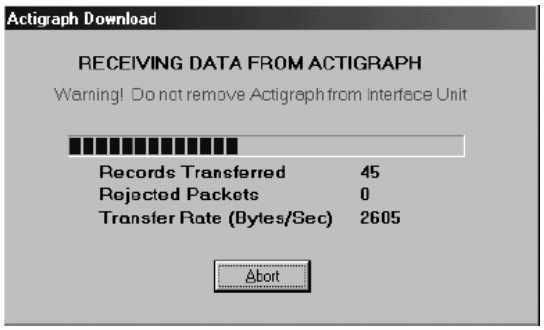
5.7 DOWNLOADING DATA FROM THE ACTIGRAPH

At weekly intervals (end of Week 1, Week 2, Week 3 and Week 4 (end of rotation)), the actigraph data needs to be downloaded from the Motionlogger to the study PC. The data then needs to be sent as an .ami file to the DCC for review and analysis (the data will default to being

a .dat file so you need to change this by using the drop down menu in the Save As window and select "AMI File Without Application Area").

a) Open ACTMe on the computer. Place the Motionlogger in the IU and make sure that the toggle switch is ON.

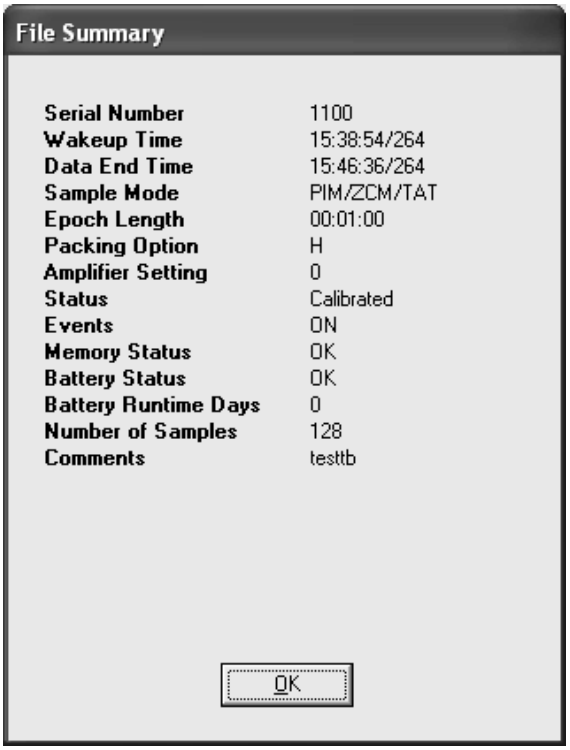
b) Press the  button or select "Actigraph" and then "Download." At this point the downloading process will commence displaying a progress bar as shown below. The user has the option of stopping the transfer by clicking the Abort Button.

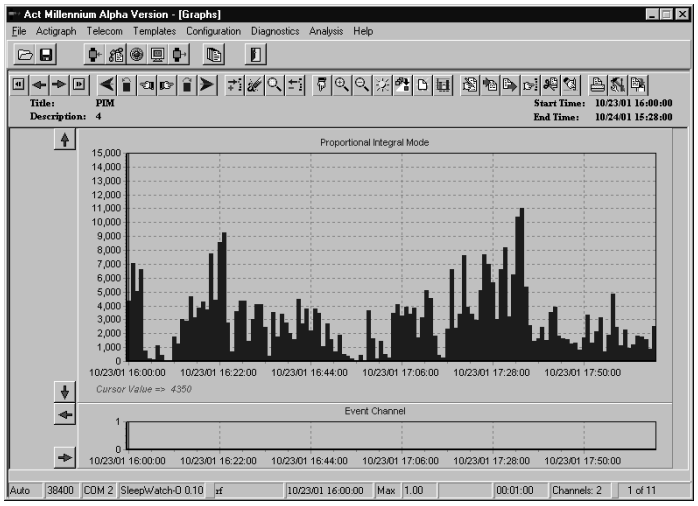


Your IU battery may be low if the downloading freezes up. Check the light at the back of the IU. If red, replace battery and try downloading again. Another problem may be too much electrical tape residue on the watch's 4 pins. This results in inaccurate downloading and loss of full information. Clean pins completely with alcohol swabs before putting watch in the IU.

If you get a message that says the download was aborted remove the SleepWatch from the IU and run a loop test to ensure that the correct COM PORT is still selected. Then begin the download process again after replacing the watch in the IU. If you are told that the download occurred but there were rejected packets try to download again after adjusting the watch to make sure it is secure in the IU.

When download completes, you will see this file summary screen. Click "OK".





Once download is completed successfully you will be prompted to save the file. Click on "Yes" and save the file as "ROSTERSIDAcrostic" (using the ID and Acrostic of the resident who most recently wore the watch, e.g. N1001ABCD). You must save the file as an "AMI file without application area", you can do this by using the pull down box next to the file type box.

Before you close the file, go under "File", then "Summary" to list "Battery Run Days". Record that number on the **Actigraphy Log** for that watch. Also, look at the file itself to see if there were any watch or wearing problems (see Potential Watch Problems in the

appendix). You can view the file by "DAYS" by clicking on the "SUN" icon in the menu bar. Each view is a 24-hour period. It will be easier to tell the difference between daytime and nighttime activity and to see if the watch was off for a long period of time. Close the program. Make sure that the ROSTERS ID on the watch file matches the ID of the person that wore the watch.

Remove the watch from the IU and turn the IU off.

5.8 SENDING DATA TO THE DATA COORDINATING CENTER

When you save the data (remember to save it as an '.ami' file without application area) it will be saved as 'ROSTERSIDAcrostic_Date.ami' (ex. N1001ABCD_15NOV2013.ami) in C:\Program Files\AMI\ActMillenium\ (unless you installed the program in a different directory). This file, specific for the resident, needs to be sent electronically to the DCC.

Transfer of data will occur via the DCC's secure website. Secure remote access to the website is provided by the Juniper Networks Instant Virtual Extranet (IVE) appliance which sits behind our network firewall.

Authorized users will be given a login id and password

- Log onto our secure website (website) (see picture below)
- Click on the "Actigraphy" folder. Choose "Upload file"
- Browse for the file you wish to upload and then click "Upload"

Retain a copy of the file on the study computer hard drive until you receive notification from the DCC that it is ok to delete the file. Record the date the data was downloaded from the actigraph and uploaded to the DCC in the Actigraph Log.

5.9 MOTIONLOGGER AND IU MAINTENANCE

See Attached Motionlogger User's Guide for further instruction and detail. Setting the time that is displayed on the watch and installation of batteries are described in the User's guide.

Maintaining an Actigraph Log

A log should be maintained at the clinic so that the location of the actigraphs is known at all times. An example log is included in the Appendix, it can be modified as individual clinics see necessary. A serial number (ex. S/N 2284) for each watch can be found on a sticker on the back or side of the watch. This should be used as the Watch ID.

5.10 QUALITY ASSURANCE FOR THE ACTIGRAPH

Each staff 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 watch's two visual functions, battery life and voltage readings, use of interface unit, and cautions related to the watch's sensitive inner workings. Only personnel who meet these standards will be certified and approved to handle the watches and instruct the participants.

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

1. Overview of Actigraphy Manual - including detailed use of the Actigraph, the software and the Interface Unit.

2. Hands-on training for initializing, wearing of the watch and downloading/saving of files. Transfer of Actigraphy file to DCC will also be shown but may not be required for each personnel (this requires a secure web site with limited access.) Each personnel involved with Actigraphy, will be required to wear an Actigraph for one over-night period. They will be required to download/save the file and print out the visual tri-mode activity report, and discuss results. There will be a discussion of some common questions from participants, watch problems, battery problems, and other situations that may occur. Monthly Actigraphy conference calls are suggested.

3. Overview of AMI's Motionlogger User's Guide

Certification

Besides completing the requirements in the Actigraph Traning Checklist, each personnel needs to successfully complete 3 initializations, downloading, file checking and the saving to the assigned folder.

Actigraphy Measurement Reliability Studies

At the beginning and ending of the study, each actigraph will be calibrated using equipment developed by Ambulatory Monitoring, Inc., to ensure that accurate measurements are being obtained. Watches generating differences that exceed acceptable limits (to be determined) will be returned to the manufacturer for evaluation and repair, if necessary.

5.10 QUALITY ASSURANCE FOR THE SLEEP/WORK DIARIES

The sleep/work diary software has been designed to help minimize data entry errors, by providing calendar views to assist in the entry of dates, and displays of total sleep time, so that the resident may determine if the times they entered are accurate. Subquestions will only appear as needed based on responses to parent questions to avoid the risk of skip pattern errors. In addition to built-in edit checks, the DCC will review the sleep/work diaries on an ongoing basis to ensure that the resident subjects are imputing data correctly.

Participant Instruction on How to Complete the Diaries
Trained and certified study staff will instruct each participant on how to fill in the Sleep/Work Diary by using the instructions on the **Actigraphy Information Sheet**. Examples of these are in the Appendix.

5.11 APPENDICES

Include all of the following:

1. Actigraph Watch Log Sheet
2. Actigraphy Checklist
3. Motionlogger Information Sheet
4. Actigraphy Training and Certification
5. Sleep/Work Diary
6. Potential Watch Problems
7. Military Time Table

Actigraph Log for Watch ____________

ID (NNNNN)	Acrostic (ABCD)	Date Initialized	Voltage Initialize	Battery Days	Week 1: Download Date	Week 2: Download Date	Week 3: Download Date	Week 4: Download Date	Voltage final download	Battery days final download	NOTES

ROSTERS Resident Actigraphy Checklist

Study ID #	Acrostic	Date Form Completed	Staff ID #
		/ /	

1. Did the Resident receive an actigraph?
    a. Yes
        i. actigraph serial number: NNNNNNN (alpha-numeric)
        ii. Which arm was the actigraph worn on (should be worn on the non-dominant arm if possible)
            1. Left, non-dominant
            2. Left, dominant
            3. Right, non-dominant
            4. Right, dominant
    b. No
        i. Why not?
            1. Refused
            2. Physical/medical problem
            3. No watch available
            4. Other_____

2. Date watch given to Resident: MMDDYYYY

Actigraphy Motionlogger Information Sheet

Thank you for agreeing to participate in the ROSTERS Study.

You will be wearing the actigraph for the duration of your month-long residency in the PICU in order for us to monitor sleep quality and your activity.

Things to Remember About Wearing the Motionlogger:

- The watch measures motion. It will tell us when you are sleeping quietly or restlessly and how active you are during the day. The Sleep/Work Diary is used to interpret this information correctly.
- Appearance of the watch: The watch displays the time-of-day, allowing you to keep track of time without needing to wear another watch. The watch buttons on the side may get bumped, changing the time display. Do not worry if the display is altered, we are still getting the motion information that we need and at the time it occurs. Continue to record the times for your diary using any clock and call a staff person to help you correct the display.
- Wearing the watch: The watch should be worn at **all** times, except when it may be submerged in water, as when swimming or taking a bath. You may shower with the Miotionlogger. It should be worn on the non-dominant wrist and should fit snuggly enough so that it doesn't slide around. (You may wear a wrist/sweat band under the watch band if you experience any discomfort.)
- You will wear the watch day and night starting at the beginning of your rotation and complete your first Sleep/Work Diary entry the following morning.
- If you are sitting for a long period of time watching TV or reading, make sure to jiggle your wrist every few minutes to show you are not napping.
- You should treat it as you would an expensive watch and do not subject the Motionlogger to excessive impact.
- Complete the Sleep/Work Diary to describe <u>your last 24 hours</u>. It should be completed each morning. The first half of the diary contains questions about your sleep and the latter half about the times you were working. Questions 1-5 describe your "main" sleep in bed and Question 6 is for listing any additional sleep (naps). If you remove your actigraph, please annotate that in the space following question 6. For the work portion of the diary, if one or more work shifts have ENDED in the past 24 hours and you have NOT recorded them on previous entries of the diary, please record the time and date that the shift started (which may not have been in the past 24 hours) and the time and date that the shift ended. If you did not work in the past 24 hours or if your shift has not yet ended, please check the appropriate box.

- You will receive a schedule of when you'll need to meet with the research assistant to perform your weekly data downloads. You will need to do this three times prior to returning the actigraph at the end of your rotation.
- On the last day of your rotation, return the actigraph to the research assistant.
- **Contact Information:** If you have questions about wearing the watch or about filling out the diary, please call:

  _____

- **IMPORTANT:** The device does leak a very small amount of current through the four pins on the watch. To avoid any potential exposure, we have covered these pins with insulating tape. Before wearing the watch, please ensure that the tape is securely covering the pins and add more tape, if necessary.

Weekly Download Schedule:

Week	Date	Day	Time (approx)
Week 1			
Week 2			
Week 3			
Week 4			

ROSTERS

ACTIGRAPHY TRAINING CHECKLIST

PICU name:

Staff member name: _____ Staff ID #: _____

CHECKLIST

- ❑ Read and study Operations Manual Chapter 5: Actigraphy
- ❑ Attend training session on techniques (or observe administration by experienced examiner)
- ❑ Configure the Motionlogger® software (Act Millenium)
- ❑ Initialize Motionlogger® in the interface unit (IU)
- ❑ Use correct settings for:
  - ❑ Current time (military time), actigraph type, octagonal mode, epoch, ROSTERS ID, startup conditions. Place tape over 4 pins. After 3 minutes, observe that arc is moving.
- ❑ Correctly keep track of actigraph, battery life (days) and data downloads using worksheets in the Device Log
- ❑ Explain the procedures for wearing the **Motionlogger ®** the participant
- ❑ Complete Actigraphy Checklist on ROSTERS website to record distribution of actigraph to Resident
- ❑ Download data from Motionlogger®, recording battery life, and saving file correctly
- ❑ Log in DCC IVE site and upload file.

Trainer Name: _____ Date:_____

Trainer Signature: _____

ROSTERS Sleep/Work Diary

Please complete in the morning and describe the last 24 hours
Please describe your main sleep in bed in Q1-5
If you have not slept in the past 24 hours, answer Q1-5 '0'

Today's Date: (mm/dd/yy)_____ **Time:_____hr_____min am / pm**

1. What time did you try to fall asleep? _____hr _____min am / pm

2. How long did it take you to fall asleep? _____hr _____min

3. What time did you finally wake up? _____hr _____min am / pm

4. How many times did you awaken? _____

5. List each: when you woke and for how long? [put extra awakenings under 'Comments']

When? _____hr _____min am / pm For how long? _____hr _____min
When? _____hr _____min am / pm For how long? _____hr _____min
When? _____hr _____min am / pm For how long? _____hr _____min
When? _____hr _____min am / pm For how long? _____hr _____min

6. Did you nap yesterday? [Yes / No] How many?_____

List each: when the nap started and when it ended [put extra naps under 'Comments']

Nap start _____hr _____min am / pm Nap end _____hr _____min am / pm
Nap start _____hr _____min am / pm Nap end _____hr _____min am / pm

Actiwatch removed at:____hr_____min am/pm Put back on at:____hr _____min am/pm

Comments:

Please complete in the morning and describe your work shifts over the last 24 hours

If one or more work shifts have ENDED in the past 24 hours and you have NOT recorded them on previous diary entries, please record below the time and date that the shift started (which may not have been in the past 24 hours) and the time and date that the shift ended. Monthly calendar and example are shown below.

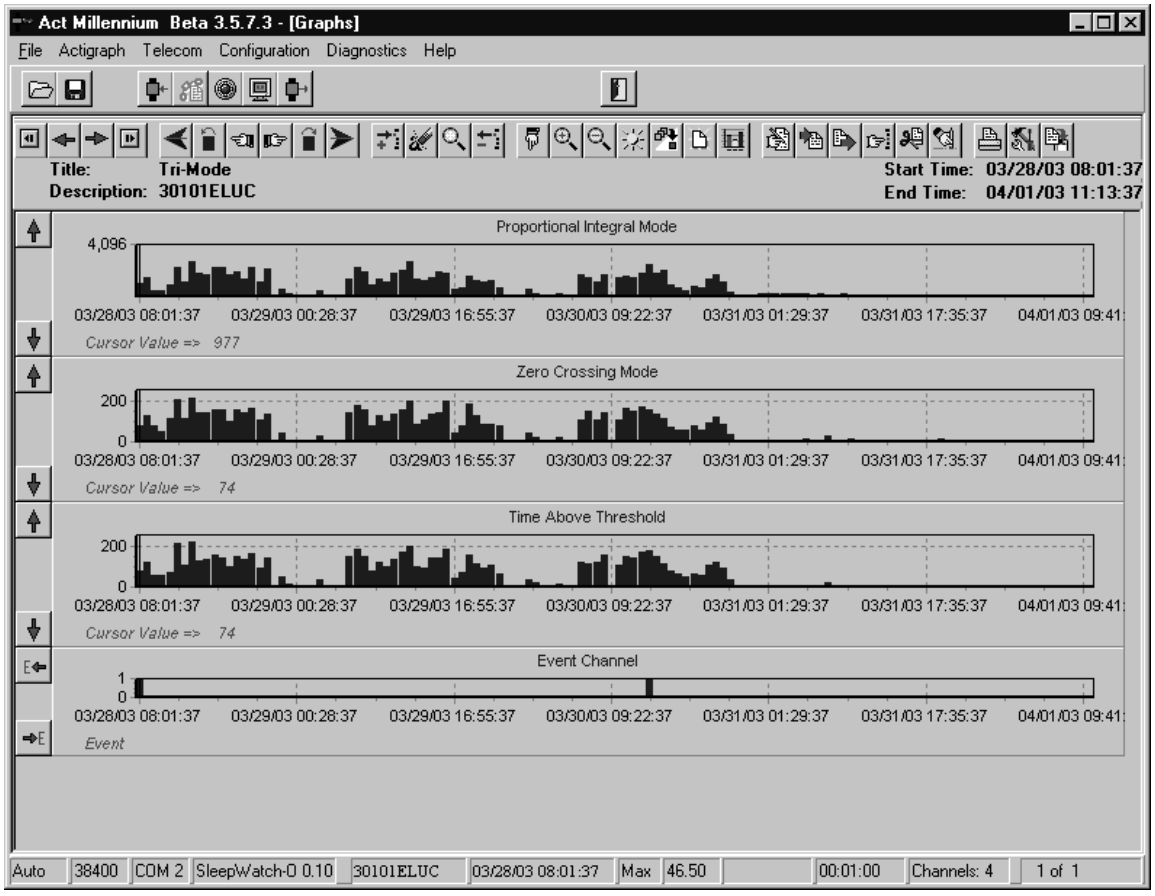
If you did not work in the past 24 hours, please check here: ☐

If your shift has not yet ended and you are still working, please check here: ☐

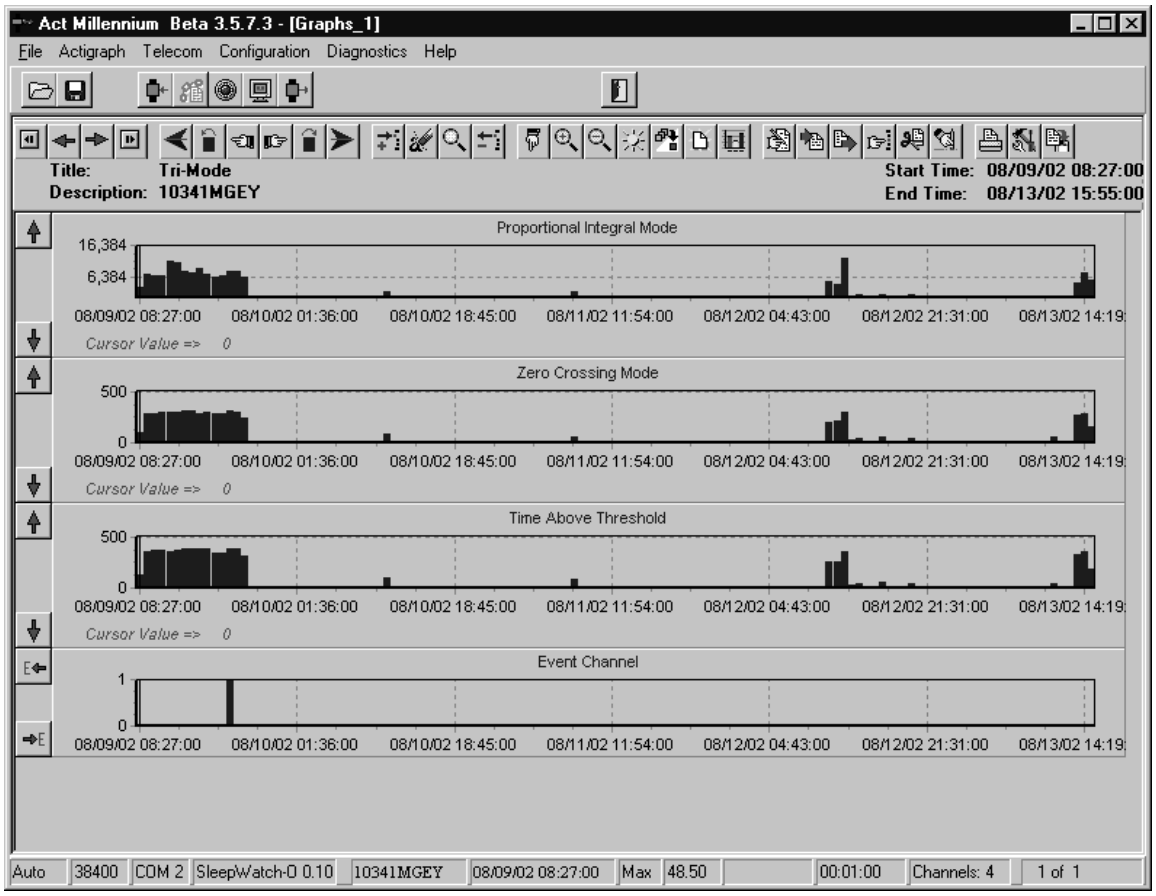
WORK	Shift 1	Shift 2
Shift Began: (Hour and Date) Please note AM or PM	M T W T F S S	M T W T F S S
Shift Ended: (Hour and Date) Please note AM or PM	M T W T F S S	M T W T F S S

Potential Watch Problems:

This is an example of a watch with “fading” problems. Notice after around 09:22 on 3/30/03 the data activity levels get very low and fade out.



This is an example of a watch that was worn for part of the first day and, then removed. You can see there is no activity until the watch is picked up by the clinic staff a few days later.



Military Time Table

1:00AM	0100	1:00PM	1300
2:00AM	0200	2:00PM	1400
3:00AM	0300	3:00PM	1500
4:00AM	0400	4:00PM	1600
5:00AM	0500	5:00PM	1700
6:00AM	0600	6:00PM	1800
7:00AM	0700	7:00PM	1900
8:00AM	0800	8:00PM	2000
9:00AM	0900	9:00PM	2100
10:00AM	1000	10:00PM	2200
11:00AM	1100	11:00PM	2300
12:00PM	1200	12:00AM	2400

CHAPTER 6: OPTALERT

The optalert is a drowsiness monitoring system. The collection of this data was discontinued early on in the study.

CHAPTER 7: PSYCHOMOTOR VIGILANCE TASK (PVT) TESTING

7.1 OVERVIEW

This chapter reviews all aspects of the implementation of the PVT.

7.2 Background

The PVT is an established metric of vigilance that is sensitive to sleep deprivation and circadian misalignment. The task requires the participant to look at a computer monitor that is blank except for a small, central, white rectangular box. Periodically numbers will begin to count up in the box. On detection of the numbers, the participant presses a button on a custom controller, the box then once again becomes blank. This repeats for multiple trials over the course of each test. The test to be used in this study will be 10 minutes in duration.

7.3 PVT SCHEDULE

Each participant will engage in PVT testing during one of their scheduled shifts per week. The participant will take the test at the beginning and end of the shift and every 5 hours in between, for a total of 4-7 tests per shift. If possible, tests should be administered as close as possible to 7 days after the previous week's test. If your site is currently running the intervention schedule, tests should be administered on alternating shifts each week (Day, Night, Day, Night). If your site is currently running the traditional schedule, tests should be administered once a week as normal, but ONLY on call shifts.

7.4 PVT Testing Station

The PVT test will be completed on a customized laptop computer situated close to the PICU. While taking the test, the participant will be in a controlled environment, void of all possible distractions (eg. ringing phones). A research assistant will be present but out of view during the test. The research assistant will record any events that occur during testing that could have affected the participant's vigilance on a **PVT Checklist** that will be completed for every test. On arrival at the testing station, the research assistant will enter the subjects ID and acrostic (for example, IDACROSTIC or 91001ABCD). The subject will then be guided through a calibration screen that first tests that the PVT response box is functioning correctly and then asks the participant to specify there dominant hand, as this is the hand that has to be used throughout the test. On future tests, the research assistant will select the study ID from a list of stored ID's. (See Appendix A for detailed test administration and checklist instructions)

If the test crashes before completion, the test will be re generated and completed again. Likewise, if there is an interruption and the participant can no longer continue with the test, the test will be cancelled and re generated. However, if the participant has already

completed more than 80% of the test, as deemed by the technician who gathered the start time, the test does not need to be repeated. All of the above events will be thoroughly documented in the PVT checklist.

7.5 PVT Data Management

Several PVT test files are saved automatically to your C: Drive under the resident subject ID. The files are cumulative and therefore will contain all completed PVT tests for a given resident when his/her rotation comes to an end. The following four complete files should be uploaded to the DCC at the end of each rotation:

NNNNN.KSSEXT (Scales for subject to rate their performance)
NNNNN.VPVTONE (Raw file; includes each trial within a session)
NNNNN.VPVTALL (Summary file)
NNNNN.VPVTLog (Program issues log)

To upload the files, go to to the DCC's secure portal: WEBSITE

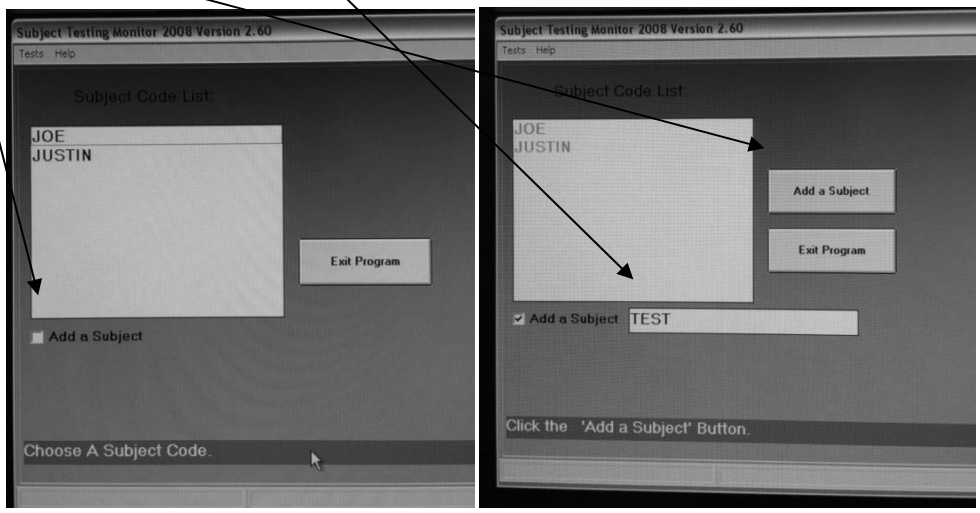
Login with the same user name and password used to access the main study website. Upload the files to the "PVT" folder.

At the end of each participant's rotation, the DCC will use information gathered from the PVT checklist forms to clean the database files that contain the full data set for each test. Tests will be disregarded if the participant used their dominant hand in response to >10% of the trials in a given test. Tests will also be disregarded if they were cancelled or crashed with less than 80% (8 minutes) of data collected. Individual trials will be disregarded if the response is deemed to be coincidental (i.e. the response was faster than a human is able to respond to a stimulus). Each trial will "time out" after 30 seconds if there is no response. Trials that time out will not be included in any calculations.

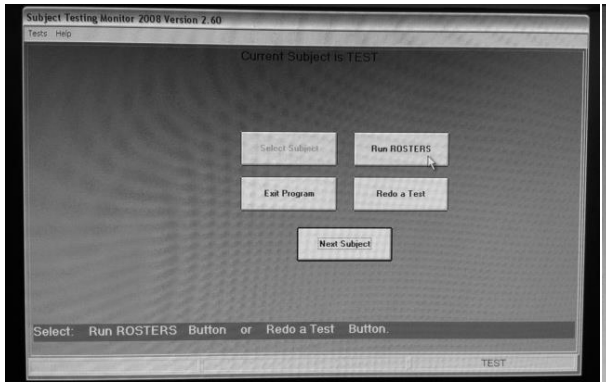
APPENDIX A: PVT Test Administration Instructions

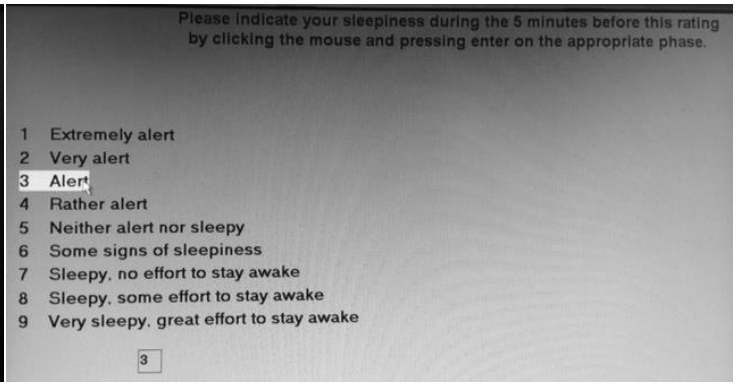
Logging in: Login to PVT Test on the dedicated ROSTERS computer. Enter your username and password. The PVT test software will automatically boot up.

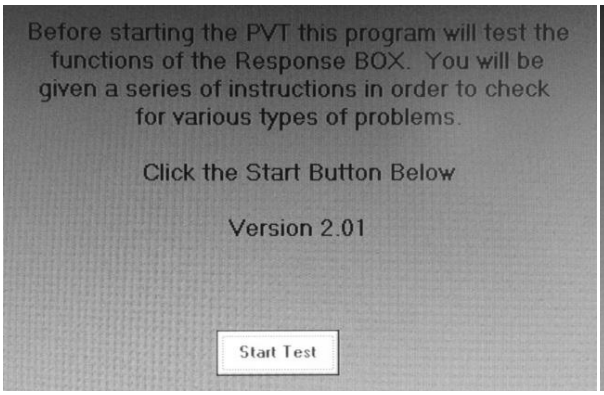
Adding New Subject: The following screen will appear after the software opens. If a new subject needs to be added click the "Add a Subject" box. Enter the resident subject ID and acrostic (for example, IDACROSTIC – or – 91001ABCD)in the test box to the right of the "Add a Subject" text. Once entered click the "Add a Subject" box to the right of the Subject Code List field.

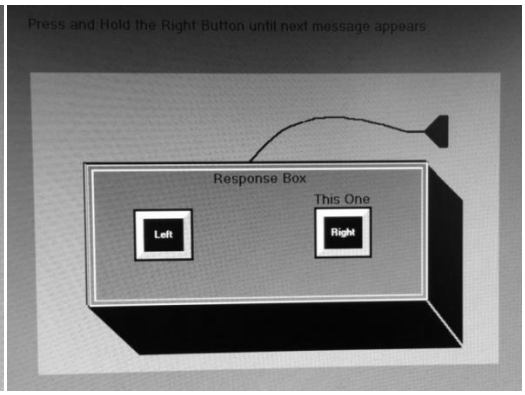


Starting a new Test: You will be directed to a screen with four selectable boxes. Confirm that the current subject, listed at the top of the screen, is the subject being administered the test. You can now turn over control to the subject. Have subject click the "Run ROSTERS" box to begin the test. The subject will first be prompted to answer the following question; "Please indicate your sleepiness during the 5 minutes before this rating by clicking the mouse and pressing enter on the appropriate phase". The subject will select an answer whose key will appear in the text box at the bottom of the screen. The subject will then press enter to proceed to the next screen. The next screen will inform you that the PVT response box functionality will be tested, additionally at the end of this test the subject will be asked to select their dominant hand. You will first be asked to test both the right and left button by holding them down with your thumbs when prompted and releasing them when prompted. If any errors occur the software will inform you that one or both of the tests have failed. If the test fails, check the connectivity of the device. The same screen will then prompt the subject to press and hold the button with the same designation as their dominant hand; this will be the button the subject should press during the test. The opposite button will work however and the results will be logged as an inappropriate button pressed. Once completed the test landing page will appear. Double check that the instructions here match the subject's handedness. When subject is ready and the room cleared of distractions, have subject press the space bar to begin the test.

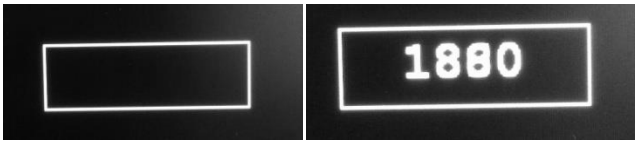








Test Responses: An empty white rectangle will be present in the center of the testing screen. Subjects should press the appropriate button when the counter appears in the middle of the rectangle. This will record the subject's response time in milliseconds. If the button is pressed prematurely the word "Anticipation" will appear in the center of the rectangle. The test will last for 10 minutes with varying lengths of time between responses. If for any reason a disturbance occurs, see "PVT CHECKLIST" below, the test must be allowed to run out and can then be retaken by clicking the "Redo a Test" box on the test start page. The test cannot be exited during administration.



Test Competition: After the test is completed (More than 80% done "8 minutes", with no disturbances) the subject will be prompted to again respond to the question "Please indicate your sleepiness during the 5 minutes before this rating by clicking the mouse and pressing enter on the appropriate phrase". Once a response has been entered, the Test is complete.

PVT Checklist Instructions

A checklist list should be completed each time the resident completes a PVT test. Each resident should complete tests during one of their scheduled shifts per week. Tests should be taken at the beginning and end of the shift, as well as every 5 hours in between, for a total of 4-7 tests per shift. If possible, tests should be administered as close as possible to 7 days after the previous week's test. If your site is currently running the intervention schedule, tests should be administered on alternating shifts each week (Day, Night, Day, Night). If your site is currently running the traditional schedule, tests should be administered once a week as normal, but ONLY on call shifts.

Checklists may be accessed through "**Expected Forms**" for each enrolled resident. Click on the form for the appropriate week and test number for a specific resident and those fields will be prefilled on the checklist.

If you are accessing the PVT Checklist through "**Documents & Forms**," you will need to fill in the ID, acrostic, week number and PVT test number.

Study ID: Enter the 5 digit participant ID number that you have assigned to this resident on your internal Resident Subject Log (located in your site Rosters Folder).
Acrostic: Enter the four character acrostic you have assigned this resident from the Resident Subject Log.
Staff ID: Enter your four digit assigned ID.

Residency Week Number: From the drop-down menu, select which week of the rotation the Resident is currently in. For example:

Week 1 = Day 1 through 7 of rotation
Week 2 = Day 8 through 14 of rotation
Week 3 = Day 15 through 21 of rotation
Week 4 = Day 22 through 28 of rotation9
Week 5 = Day 29 through 35 of rotation

PVT Test Number: Enter the number of the PVT test for the week. For example, during the PVT test day during the Resident's first week, the first test of the shift would be "1", the second test would be "2" etc. At the subsequent weeks, the numbering should restart. For example:

Week 1: PVT Test #1, PVT Test #2, PVT Test #3 and PVT Test #4
Week 2: PVT Test #1, PVT Test #2 and PVT Test #3

Date Resident completed the PVT test: Select the date from the calendar or enter a date in (or MM/DD/YY) format.
Time resident completed the PVT test: Select both the hour (0 – 24, military time) and the minute from the drop-down menus.
Was the resident able to complete the entire PVT test: Indicate Yes or No; If the resident has completed at least 80% (8 minutes) of the test, select "Yes"; otherwise, select "No."

NOTE: If the resident completed more than 80% of the test (or 8 minutes), as determined by the study staff who noted the test start time, the resident does not need to re-do the test. If it is less that 80% complete, please have the resident restart the test. Please note if the resident was holding the device correctly. If not all responses will be logged as given by the wrong hand.

Were there any disturbances during the test?: Indicate Yes or No.
If **Yes,** the following subquestions, detailing types of disturbances, will appear. Select Yes or No for each question:

- o Staff entered the room during testing
- o Staff attempted to speak with the resident during testing
- o Phone/pager rang (hospital's or resident's)
- o Code alert or alarm sounded during testing
- o Participant was frequently adjusting posture

o Participant was not looking at monitor
o Other: please describe

Please use the below space to document any other events that you fee may have impacted the integrity of the testing data: If applicable, use this space to describe any events, issues or circumstances that may have impacted the test. This question will appear whether you have indicated there were specific disturbances or not.

Saving and Uploading PVT Data Files

Location:
Computer Login "optalert" password: "2optalert4"
My Computer\C:\Online\
Each Participant will have a folder (ID Number)

PVT Testing Data is presented in four file types:

- Vpvt1 (Raw File, each trial within a session 90-120 trials)
- Vpvtlog (Program issues log)
- Vpvtall (Summary file containing some summary statistics)
- Kss(Scales used to ask subjects to rate their performance)

All files should be uploaded to the DCC following the residents' rotation. Authorized users may upload files to the "PVT" folder using the following link: WEBSITE

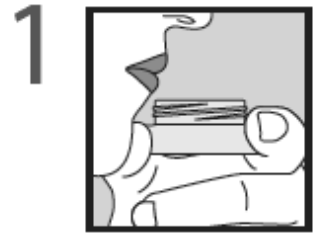
CHAPTER 8: COLLECTING SALIVARY SAMPLES

8.1 Overview

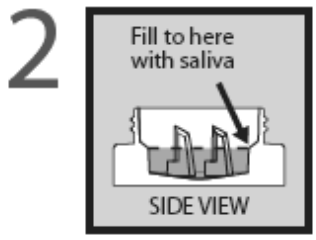
Each participant will be asked to provide a single saliva sample during the course of the study. This sample will be used to extract DNA for use in future studies of the relationship between circadian genotypes and fatigue phenotypes. The participant may choose not to provide the saliva sample. No explanation will be required and this will not affect the participant's eligibility to participate in the rest of the study.

8.2 Protocol

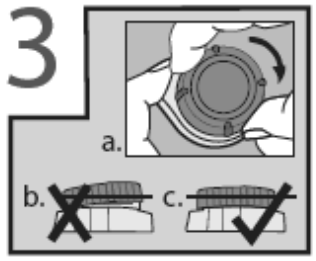
An OGR-250^{tm} DNA collection/storage kit manufactured by DNA Genotek ^{tm} will be used for saliva sample collection. Below are the instructions to the participant provided by DNA Genotek^{tm}. The sample will be kept indefinitely for future analysis.



The participant opens the collection vessel and begins to spit in the bottom portion.



Participant spits into the vessel until it is filled to the marked line with saliva



Carefully screw the cap back onto the base (now containing saliva).

Shake the now sealed container to mix the saliva and the preservative chemicals (now released from the cap).

CHAPTER 9: COLLECTING AND REPORTING SERIOUS ADVERSE EVENTS

9.1 OVERVIEW

All serious adverse events (SAEs) will be collected and reported for the resident subjects enrolled in the trial. SAEs will not be collected for patient subjects on study data collection forms, as all adverse events will be documented in their medical records.

9.2 DEFINITION OF A SERIOUS ADVERSE EVENT

A Serious Adverse Event (SAE) is any untoward medical occurrence that results in death; is life threatening; requires or prolongs hospitalization; causes persistent or significant disability/incapacity/permanent damage; requires medical, surgical, or other intervention to prevent permanent impairment or damage; a cancer diagnosis; congenital anomaly or birth defect; or other serious medically important event.

9.3 COLLECTING SAES

When enrolling resident subjects, study staff should explain to the residents that they will be collecting information on any events that constitute an SAE. Staff should provide the definition of an SAE and let the residents know that they should report any events that might qualify to study staff. Staff should also note that they may check in with the residents during the course of the study to determine if any events have occurred that require reporting.

9.4 REPORTING SAES

Complete a separate **SAE Report Form** (Appendix A) for each SAE within 24 hours of learning of the event. Please review all information with the Site PI before submitting the form.

9.4.1 Completing the SAE Report Form.

Guidance on completing certain sections of the form are provided below.

- SAE Report number: SAEs should be numbered consecutively for each subject. For example, if two SAEs are reported for a subject, the first one should be labeled “01” and the second one should be labeled “02”. If you are unsure if a previous SAE has been reported for a subject, go to “Data Inventory” on the study website, enter the ID number, and select “SAE Report Form” from the drop-down menu of forms.

- SAE Dates: The form asks for several dates; clarification is provided below.
    - Date notified of SAE: This is the date the study staff learned about the SAE.
    - Date of onset: This is the date the subject identifies as the start of the event and/or the date the subject presented to the hospital or other medical provider, if unclear when the date of onset occurred.

- Date of diagnosis: This is the date a diagnosis was made by a medical provider. If unclear from the subject or medical records, this may also be the date the subject was admitted to the hospital or sought medical attention.
- Date stopped: This is the date the medical issue was resolved, if applicable. This may be the date the subject was discharged from the hospital. If the issue has not been resolved and/or the subject is still in the hospital, you may mark "Continuing."

- Classification of SAE: Using the categories provided, please classify the SAE, marking all options that apply.

- Diagnosis and History: Provide a summary of the diagnosis and any relevant medical history or related events.

- Outcomes: Determine the outcome at the time of the report and mark one of the following: (1) recovered completely; (2) recovered with residual effects; (3) continuing; or (4) death.

- Related to study participation: The Site PI should make this determination. Based on his/her judgment, please indicate if the event was: (1) not related; (2) unlikely to be related; (3) possibly related; (4) probably related; or (5) definitely related.

9.4.2 Supporting Documentation

For all events that are possibly, probably or definitely related to study participation, please ask the resident if s/he is willing to provide supporting documentation (discharge summary, autopsy report, lab or other test results, pathology report, radiology report) so the SAE may be independently evaluated. If the resident agrees, please mail it to the address below, send via secure email or upload the file to the secure file transfer site.

NAME
ADDRESS

If you have any questions, please contact NAME at PHONE NUMBER or EMAIL

9.5 Additional Safety Monitoring and Reporting Requirements

Safety Alerts

As part of this study, we will ask resident subjects questions about depression, including questions about suicidal thoughts and plans, motor vehicle incidents, drowsy driving, including falling asleep at the wheel, and occupational exposures. The Data Coordinating Center for the study reviews survey responses, and if responses indicate suicidality, 3 or more occupational exposure reports, and/or motor vehicle crashes in which the damage was >$1000 and/or drowsiness was reported as a factor, the study principle investigator will be asked to follow up with the resident subject. Near misses will not be followed up on. Additionally, initial reports of falling asleep at the wheel will trigger a follow up with

by each site's research study coordinator; 3 or more responses of falling asleep while driving will trigger a follow up by each site's principle investigator. Specifically in regards to questions concerning suicide, if resident subjects respond to the question "Over the past two weeks, how often have you thought about or wanted to commit suicide?" with "Some of the time," "Most of the time," or "All of the time," regardless of whether they respond "Yes" or "No" to "Do you have a plan?", the following message will appear on the form: "Your response to the previous questions causes us to be concerned for your welfare. All reports of suicide ideation will be reported to your site PI, who should in turn contact the Residency Program Director. The site will then follow their protocols for timely intervention and action, in compliance with their organizational rules and standards." These criteria were discussed and decided on by the Clinical Coordinating Center, Steering Committee, and voted on and approved by the Data Safety Monitoring Board for this protocol.

Incidental Health/Mental Health Findings
In addition to SAEs and alerts from the DCC, study staff should be alert to any significant health or mental health issues resident subjects may be experiencing. Examples could include a resident exhibiting signs of depression or narcolepsy. Site staff should report any finding or awareness to the site PI to determine how to handle the situation. These occurrences should be reported to the DCC, who will keep track of all communications and report findings to the DSMB.

Unanticipated Problems
The study staff and investigators should also be alert to any unanticipated problems that occur during the course of the study. Clinical site staff and investigators will be queried on monthly teleconferences regarding any problems and will be encouraged to notify staff of the CCC or DCC between calls as issues arise. The DCC will keep track of these issues and report any unanticipated problems to the DSMB and NHLBI.

9.6 IRB REPORTING REQUIREMENTS

Please follow your site IRB guidelines for the internal reporting of SAEs, unanticipated problems and incidental findings for the study. Furthermore, please notify the DCC as soon as you have submitted a report to the IRB for any study-related event as the DCC is required to report these instances to the DSMB and NHLBI.

APPENDIX A

ROSTERS Resident SAE Report Form

Study ID #	Acrostic	Date Form Completed	Staff ID #
		/ /	

A Serious Adverse Event (SAE) is any untoward medical occurrence that results in death; is life threatening; requires or prolongs hospitalization; causes persistent or significant disability/incapacity/permanent damage; requires medical, surgical, or other intervention to prevent permanent impairment or damage; a cancer diagnosis; congenital anomaly or birth defect; or other serious medically important event.

*Complete a separate form for each SAE reported for a resident. Please complete and submit this form within **24 hours** of learning of the event. Please review all information with the Site PI before submitting the form. Follow your site IRB guidelines for the internal reporting of SAEs for the study.*

1. SAE Report Number # (SAEs should be numbered by participant, starting with #1): NN
2. Date notified of SAE: MM/DD/YYYY
3. Date of onset: MM/DD/YYYY
4. Date of diagnosis: MM/DD/YYYY
5. Date stopped: MM/DD/YYYY
    a. Continuing
6. Date of death (if applicable): MM/DD/YYYY

7. Classification of SAE (Mark all that apply):
    a. Death
    b. Life threatening
    c. Hospitalization
    d. Persistent or significant disability, incapacity, or permanent damage
    e. Required medical, surgical, or other intervention to prevent permanent impairment or damage
    f. Cancer
    g. Congenital anomaly / birth defect
    h. Other serious medically important event

8. Diagnosis: [text box]

9. Describe event, event chronology, symptoms, and treatment: [text box]

10. Does the participant have a history of this type or a similar SAE? Yes/No/Don't Know
    b. If yes, please describe: [text box]

11. Does the participant have other relevant history, including pre-existing conditions? Yes/No/Don't Know
    c. If yes, please describe: [text box]

12. Outcome (at time of this report):
    d. Recovered completely
    e. Recovered with residual effects
    f. Continuing
    g. Death

13. Was the SAE related to study intervention/participation?
    h. Not related
    i. Unlikely to be related
    j. Possibly related
    k. Probably related
    l. Definitely related

NOTE: If the SAE was *Possibly, Probably or Definitely Related*, please send any supporting documentation (e.g., discharge summary, autopsy report, lab or other test results, pathology report, radiology report) to the Data Coordinating Center.

Resident SAE Report Form

Please complete the survey below.

Thank you!

A Serious Adverse Event (SAE) is any untoward medical occurrence that results in death; is life threatening; requires or prolongs hospitalization; causes persistent or significant disability/incapacity/permanent damage; requires medical, surgical, or other intervention to prevent permanent impairment or damage; a cancer diagnosis; congenital anomaly or birth defect; or other serious medically important event.

Complete a separate form for each SAE reported for a resident. Please complete and submit this form within 24 hours of learning of the event. Please review all information with the Site PI before submitting the form. Follow your site IRB guidelines for the internal reporting of SAEs for the study.

Study ID:

_____

Acrostic:

_____
(Please enter four letters)

Staff ID:

_____

SAE Report Number (SAEs should be numbered by participant, starting with #1):

_____

Date notified of SAE:

_____

Date of onset:

_____

Date of diagnosis:

_____

Is the SAE continuing?

☐ Yes
☐ No

Date stopped:

_____

Classification of SAE:

Death

☐ Yes
☐ No

Life threatening

☐ Yes
☐ No

Hospitalization

☐ Yes
☐ No

Persistent or significant disability, incapacity, or permanent damage

☐ Yes
☐ No

Required medical, surgical, or other intervention to prevent permanent impairment or damage

☐ Yes
☐ No

Cancer

☐ Yes
☐ No

Congenital anomaly / birth defect

☐ Yes
☐ No

Other serious medically important event

☐ Yes
☐ No

Date of death:

_____

Diagnosis:

_____

Describe event, event chronology, symptoms, and treatment:

_____

Does the participant have a history of this type or a similar SAE?

☐ Yes
☐ No
☐ Don't know

Please describe:

_____

Does the participant have other relevant history, including pre-existing conditions?

☐ Yes
☐ No
☐ Don't know

Please describe:

_____

Outcome (at time of this report):

☐ Recovered completely
☐ Recovered with residual effects
☐ Continuing
☐ Death

Was the SAE related to study intervention/participation?

☐ Not related
☐ Unlikely to be related
☐ Possibly related
☐ Probably related
☐ Definitely related

NOTE: If the SAE was Possibly, Probably or Definitely Related, please send any supporting documentation (e.g., discharge summary, autopsy report, lab or other test results, pathology report, radiology report) to the Data Coordinating Center.

CHAPTER 10 DATA MANAGEMENT AND QUALITY ASSURANCE

10.1 OVERVIEW

The overall goal of our data management and quality assurance system is to provide high quality and timely data to the study investigators and to provide study management tools for the Steering Committee. Electronic data entry and internet technology are utilized to provide real-time data access.

The ROSTERS study website and data system are designed and managed by the Data Coordinating Center (DCC) based at the San Francisco Coordinating Center (a collaboration between the California Pacific Medical Center Research Institute and the UCSF). Your main point of contact at the DCC is the Project Director, NAME (EMAIL).

Study data will be collected and submitted electronically using online data collection instruments. These online instruments may be accessed via a tablet, laptop/PC or smart phone. The data collection forms will be designed to prevent missing data, skip pattern errors, and inconsistent and out of range responses. Once data is submitted, it is viewable on the study website by authorized study personnel. Study data will be subject to further daily error-checking programs following submission, results of which are posted to the study website. Select research staff will have permissions to resolve edits and update data as necessary via the website.

Clinical site personnel should check the website daily to confirm that the DCC has received all submitted forms and to address any posted data queries.

10.1.1 Equipment

The following equipment will be needed to perform the data management tasks outlined in this chapter:

1) Computer with internet access* and Adobe Acrobat Reader
2) Tablet with internet access

** Please note that the website works optimally when used with Microsoft Internet Explorer version 5.5 or later.*

10.2 ROSTERS STUDY WEBSITE

A password-protected website will be the study's data collection hub. Log-in access to the study website will be provided to all clinical Site investigators and staff. Computers at the clinical Sites will access a secure and private DCC web server that provides continually updated data summary reports. All reports available on the website will be generated on demand from current study data.

We have developed a number of levels of data security. Users will need a unique password to access the study website. Passwords allow access only to the areas relevant to the specific user. For example, users at one clinical Site will only be able to access and change data for their site.

10.2.1 Obtaining Log-In Access

Prior to study start-up, the DCC will create accounts for all site staff and investigators who will be accessing the ROSTERS study website. Account information (user name and temporary password) will be sent to staff and investigators, along with instructions on how to change your password upon first long-in. Requests for password resets may be sent to the DCC Project Director, NAME (EMAIL) or the DCC Data Manager, NAME (EMAIL).

10.2.2 Termination of Log-In Access

If new staff are hired or study staff leave, the DCC must be informed immediately, so log-in access may be added or terminated as appropriate, which will secure the integrity of the study data.

10.2.3 Logging-In

To access the site, a user must:

1) Go to the following website*: WEBSITE
2) Click on the "ROSTERS" logo
3) You will see a pop up box. Log in using the individual's user name and password.

Your user ID will probably be composed of the first initial of your first name followed by your last name (do not include any spaces between your initial and your last name). A password will be assigned to you by the DCC. Please note that the password is case sensitive.

10.2.4 Changing your Password: First Time Log In

To start, each clinical site staff person will be assigned a temporary password. To create a permanent password, follow these steps:

- Log on to the website
- You will be automatically directed to the Password Changing web-page
- Type in your account name.
- **Be sure that your Caps Lock is OFF.** Type in your old password, your new password (which you choose yourself), and then confirm your new password by re-typing it. Hit the OK button.
- You should then get a message saying that your password was successfully changed.
- **If you are not successful changing your password, try again.** If it does not work the second time, contact the CC. **Do NOT try a third time** as a third error may get you locked out of the system.

10.2.5 Logging Out

In order to ensure the security of the study website, you must close Internet Explorer when you have finished using the website. If you are going to use the web for other purposes after accessing the study website, close your browser and then re-open it to browse the web.

10.2.6 Website Features

Examples of features and items available on the study website include:

- Study Directory
- Calendar of meetings/calls
- Q & A (section where you can ask study-related questions and view a log of previously asked questions and answers)
- Documents & Forms (downloadable)
  - Protocol
  - Operations Manual
  - CRFs
    - Links to electronic RedCAP forms
    - PDF versions
  - Study memos
  - Training materials
  - Meeting materials
- Reports
  - Enrollment and Patient Days reports and plots in aggregate and by site
  - Suspected Event Form Save and Return Report (for Physician Observers and Research Nurses)
  - Suspected Event Adjudication Report (for Physician Reviewers)
  - Resident Portal Password Tracking Report
- Data Management Features
  - Data inventory
  - Expected forms, rejected forms
  - Resolve queries, post queries
  - Audit trail

10.3 STUDY CODES

Each site will be sent an Excel Workbook prior to enrollment with ID logs for Staff IDs, Resident Subject IDs, Patient Subject IDs, Incident IDs and Screening IDs. The logs will include the allowable range of IDs for each site and instructions on assigning IDs. Sites should store these logs (electronic or printed versions) in a secure location (eg, password protected folder, locked office and/or file cabinet, etc) and only allow access to authorized users.

10.3.1 Clinical Site

Each clinical site will be assigned a 1 digit site code at the start of the study, which will be used as the prefix for all study IDs (see below).

Clinical Site # Example: 9

10.3.2 Staff ID

Each staff member at the clinical site will be assigned an individual Staff ID# to be used throughout the length of study. The ID# will be comprised of the 1 digit site code and a unique 3 digit number.

Staff ID# Examples:	9001
	9002
	Etc.

Sites were sent a log prior to study enrollment to assign staff IDs. The log contains a range of staff IDs for your site with fields to record the staff member's first name, last name and role in the study. Sites should maintain this log and not send copies to the Coordinating Center. If any staff leave during the study and new staff are hired, a new ID# should be assigned. Do NOT re-use previously assigned numbers.

10.3.3 Participant Study ID # and Acrostic: Residents and Patients

RESIDENT STUDY ID: At enrollment, each resident subject will be assigned an individual Study ID# to be used throughout the length of their participation. The Study ID# will be comprised of the 1 digit site code + **1** + a unique 3 digit participant number. The range of resident IDs is N1001-N1998; N1999 is reserved for non-subject residents (and may be used on the Suspected Event Form).

Resident Study ID# Examples:	91001
	91002
	Etc.

Sites will be sent a log prior to study enrollment to assign participant IDs. The log contains a range of participant IDs for your site with fields to record the participants' acrostic (see below), first and last names. Sites should maintain this log and not send copies to the Coordinating Center. If a resident subject consents to participate and later changes his/her mind, his/her Study ID # should NOT be re-used. Assign a new Study ID# for subsequent enrollees. Do NOT re-use previously assigned numbers.

RESIDENT ACROSTIC: Each participant will also be assigned a second data identifier in this study. A participant's acrostic is a random four letter code which the resident may choose or the study staff may assign. Do not include any symbols (e.g., dashes, etc.).

Acrostic Examples:	ABCD
	BALL
	DADA

PATIENT STUDY ID: All patients who's information will be included in the study will be assigned a an individual Study ID# to be used throughout the length of their stay in the PICU. The Study ID# will be comprised of the 1 digit of the site code + 2 + a unique 3 digit participant number. The range of patient IDs is N2001-N2999. If additional patient IDs are needed, please use your 1 digit site code + 9 + a unique 3 digit number. The additional range of IDs is N9001-N9999.

Patient Study ID# Examples: 92001
92002
Etc.

Sites will record these IDs in the Patient Days Log, which contains a range of participant IDs for your site with fields to record the participants' acrostic, first and last names, and MRN (optional) The Log also contains the following required fields: admission date, discharge date, observed PICU length of stay, age and gender. Once a patient has been discharged from the hospital, the site staff are required to enter the ID, acrostic and required fields listed above into an electronic Patient Days Form, which can be accessed on the study website. Site should NOT re-use previously assigned numbers for new patients; however, if a patient returns to the unit, the same study ID should be used. Staff may insert a row in the log, rather than assigning the next available ID.

PATIENT ACROSTIC: Patients will also be assigned a second data identifier in this study. The acrostic is a random four letter code which the study staff will assign and record in the Patient Days Log and on the Suspected Event Form, as applicable. Do not include any symbols (e.g., dashes, etc.).

Acrostic Examples: ABBA
BEEP
DCBA

10.3.4 Incident ID

Each incident reported on a Suspected Event Form will be assigned a five digit incident ID. The incident ID is comprised of the site code + **3001** through **8999**, which should be assigned consecutively by site. The range of IDs is N3001 – N8999.

Incident ID Examples: 93001
93002
Etc

10.3.5 Screening ID#

Each resident who is screened, but not enrolled should complete a paper Screening Form. This data (reason for not enrolling, basic demographic info) will then be entered into an electronic version of the form and assigned a screening ID. The ID is comprised of the site code + **9** + a unique 2 digit number. The range of IDs is N901-N999.

Screening ID Examples: 9901
9902
Etc.

10.4 DATE FIELDS

All date fields in this study will use the following format: MONTH/DAY/YEAR.

Example: December 1, 2010 = 12 / 01 / 2010

10.5 CASE REPORT FORMS

There are a few different categories of Case Report Forms (CRFs) in this study:

- Site Coordinator Forms
  - Enrollment Form
  - Actigraphy Checklist
  - PVT Checklist
  - Resident SAE Form
  - Resident Withdrawal Form
  - Missed Observation Shift Form
  - Protocol Deviation Form

- Resident Subject Forms
  - Baseline Survey
  - End-of-rotation SurveySleep/Work Diary

- Physician Observer and Research Nurse Forms
  - Suspected Event Form
  - Patient Days Log
  - Observer Shift Summary (Physician Observers Only)
- Physician Reviewer Forms
  - Event Classification Form

All forms will be completed electronically, which paper copies available as a back-up, which may be data entered following data collection.

10.5.1 Site Coordinator Forms

The Site Coordinator is responsible for submitting the Enrollment form for newly enrolled residents, following their consent. The Enrollment form is the "gold standard" form and must be received in the data system prior to all other resident-related forms. The Site Coordinator will also submit other resident-related forms, such as the Actigraphy Checklist, Resident SAE Form, and Resident Withdrawal Form. The Site Coordinator or the Physician Observer may submit the PVT Checklists for the residents' PVT tests. Lastly, the Site Coordinator is responsible for reporting Protocol Deviations, should they arise, and documenting missed observation shifts.

10.5.2 Resident Subject Forms

Resident subjects will be required to complete a Baseline Survey at the start of their rotation, daily Sleep & Work Diaries and twice daily Drive Diaries (if they drive to/from work) throughout their rotation, and finally an End-of-Rotation Survey.

10.5.2.1 Baseline and End-of-rotation Surveys

Resident subjects will access their forms through a ROSTERS Resident Portal website: http://rds.sfcc-cpmc.net/

The resident will need to know a common user name and password (the shared username will be unique to the clinical site and the shared password will be changed with each rotation of residents). The usernames and passwords will be available in the Resident Portal Password Tracking Report on the main ROSTERS Keeptrack website.

Once on the website, the residents will need to know their unique 5 digit ID and 4 letter acrostic in order to complete the forms.

10.5.2.2 Sleep & Work and Drive Diary

The diary will all be made available on a dedicated website (WEBSITE), where the data may be entered electronically and securely submitted to the DCC. The residents will be required to know their 5 digit study ID number and 4 letter acrostic in order to complete these forms. The electronic diary will require a response to all main questions; sub-questions will only appear (and be required) based on the response to a main (parent) question, to avoid skip pattern errors. The forms will also be designed to prevent inconsistent responses and flag out-of-range data. Residents may log into the website and complete forms on a computer (desktop/laptop), tablet or smart phone. Forms must be completed in their entirety before they may be submitted.

Residents who drive to work will be required to complete a Drive Diary entry after each drive to and from work. After logging in to the diary website (WEBSITE) with their ID and acrostic, the Resident may select “Drive Diary” rather than “Sleep & Work Diary” to complete these entries.

10.5.3 Physician Observer and Research Nurse Forms

The main form for collecting the data on potential events is the Suspected Event Form. Staff will be able to access this form by logging into the main study website. The Physician Observers will have tablets to access and initiate this form while observing residents. They will complete as much of the form as possible and save the partially completed form. The Research Nurse will then be able to log into the study website, access the form through the Save & Return report and enter any remaining details for the event. Once complete, the Research Nurse will submit the complete form. The Physician Observers are also responsible for completing an Observer Shift Summary for each of their shifts.

10.5.4 Physician Reviewers Forms

The Physician Reviewers will review the suspected events via the Suspected Event Adjudication report link on the website and complete an online Event Classification Form. Each event will be reviewed by two reviewers and discrepant cases will be assigned to a third reviewer. Reviewers will not have access to the classifications of the other reviewer(s).

10.6 DATA MANAGEMENT

10.6.1 Data Inventory, Rejected, and Expected Forms

During the daily website checks, clinical sites should check the following sections on the study website:

1. Data Inventory (for each participant (resident or patient))
   - to ensure that all of their forms have been accepted by the data system.

2. Rejected Forms
   - Even when a CRF is successfully submitted to the system, it may not be added to the database.
   - This report will show the reason why the form was rejected by the system. There are three reasons why a form may be rejected:

     1) Participant ID does not match Gold Standard ID
        Explanation: This means that the Study ID # on a CRF is not "valid". E.g, there is no randomized participant on record with this Study ID #.
        Action: If the ID # on the rejected form is incorrect, contact the ROSTERS HelpDesk to fix it.

     2) Acrostic does not match
        Explanation: Acrostic is not filled out or is incorrectly filled out.
        Action: Contact the ROSTERS HelpDesk to fix it

     3) Duplicate
        Explanation: A form with the identical ID #, acrostic and other unique information (e.g., date) is already in the database.
        Action: Contact the ROSTERS Helpdesk to determine if the duplicate form contains the same information as the one in Data Inventory. If so, the rejected form will be "hidden"; if not, the data from the two forms may need to be reconciled.

   -

3. Expected Forms
   - This report will list CRFs which are expected but have not been received.
   - E.g., if a resident subject has not completed a PVT test for a particular week.

10.6.2 Queries

The CC runs a query-generator program regularly each day. Clinical sites will edit the data from the CRFs on the website. As part of the data editing system, the website will also include pages that closely resemble the CRFs. Clinical sites will access their data via these pages and address edit queries. Access to these pages will be restricted to authorized personnel.

- Go to the **Resolve Queries** section of the study website.
- When you check your clinical Site's queries, it is recommended that you choose to view all and address all queries on a daily basis.
- These queries attempt to support the logic of the form:
  - "Stem" questions are considered to be "required," so if any of them have no data, the query generator will create a "missing" query.
  - Questions that should or shouldn't be answered depending on the answer to some other question or questions will be noted as "missing" if the earlier question requires that they be answered or "inconsistent" if the response to the earlier question indicates that the secondary question should not be answered.
  - More complex queries will have their own unique description.
  - The three primary types of errors are described below:

Error type	Description
Missing	The question should be answered, but there is no data. The correct answer to the question should be filled in.
Out of range	The value for the data is not within the allowable range. For instance, a date of 06/15/2031 would be noted as out of range. The correct value should be inputted.
Inconsistent	The question has been answered, but should not be or is incorrect, based on a response to an earlier question. Answering this question is logically inconsistent with the answer to an earlier question. Either the answer to this question should be deleted/changed, or the answer to the earlier question should be changed.

10.6.2.1 Addressing Queries

NOTE: you must address queries via the website. You can NOT make a change by re-submitting an updated version of the CRF, as the form will be rejected as a duplicate.

To address a query by changing the answer to a question (on a CRF after it has been submitted):

- Begin by clicking the red "fix" box next to the listed query. This will bring you to the page containing the data that needs fixing.
- The question with a potential error will be highlighted in yellow.
- Fields consist of drop-down lists that allow the user to choose from a list of allowable answers. However, some must be filled in directly. With these fields, it is possible to type in something that is inappropriate for the respective field. If an inappropriate entry is made, it will not be saved to the database. A message will state that the change was not saved.
- Any field on the screen can be changed.
- In order to save the changes, you must click on the "Save Change" button above the first question on the page.

- "Inconsistent" errors will be displayed with both of the related questions highlighted in yellow. Make the desired changes and click on the "Save changes" button at the top of the page.
- Note that the query listed in the Edit Report disappears immediately upon saving the changes. This does not stop the query report from testing this data again the next time it runs to make sure that it is still not breaking any of the "rules" set forth for this data.
- NOTE: It will not always be the highlighted field that will need to be changed. Indeed, any field on the screen can be changed. No changes are saved until the "Save changes" button at the top of the page is clicked.

10.6.2.2 Making "Comments" to Address a Query

Comments should be used only when a query cannot be addressed with the correct data. They will cause the query to be removed from the edit report. There are currently three possible choices for the comment field:

Not an error
Irretrievable
Other

If, for example, a query is erroneous, you should choose the comment "Not an error" from the list of comments on the same line as the query. For these specific comments, the CC will review the edit system and make appropriate changes.

If data is indeed missing, but there is no way to retrieve the information, you should choose the comment "irretrievable." For "missing" queries that reflect questions intentionally not answered because a participant was found to be ineligible, the comment "participant ineligible" should be chosen.

When the query-generator runs it inspects the entire database. If a query has been addressed properly, it will not be re-generated by the program, i.e., it will disappear from the edit report the next day and will no longer be subject to the "rules" set forth for this data. Therefore, **do not** enter a "comment" if a query can be addressed.

10.6.2.3 Posting a Query & Updating Data

The majority of queries will be identified by the CC using the "rules" set forth in the data query system about required fields, skip patterns and ranges for numbers such as height. However, in some cases, clinical Sites may want to generate their own queries, via the **Post Query** selection. Queries should only be generated if data on a form has been changed since it was submitted to the CC. The process of originating a query is as follows:

- Go to 'Post Query' on the study website
- Enter the selection criteria for the participant for which you want to address a query. In this case, you cannot select all, you must list a specific participant and form.
- Click on the red "fix" bubble listed next to the form desired.
- Type in the problem or concern in the 'problem box.'
- Click on 'post query.' It will show you the field you want to make a change on, as well as other fields that are related. In the following example you see that the "How many times" is related somehow to "Are you taking…" This is because the "how many times" question is not supposed to be answered unless the previous question is yes. So, if you were to put something in that "How many times" box, you would generate an "inconsistent" edit when the edits run again.
- Make the necessary changes to the data.
- Click on 'save change' and the edit to the database will be saved.

10.7 REVIEWING AND UPDATING RESIDENT DIARIES

Site Coordinators will be responsible for reviewing the sleep/work diaries on a daily basis (Monday – Friday) to ensure that residents are completing the diaries accurately. The DCC will check all resident diaries on a weekly basis to ensure that sites are keeping up with diary reviews.

10.8 TRANSMITTING DEVICE DATA

As described in the earlier related chapters, actigraphyand PVT data will be transferred to the DCC on a periodic basis. All files will be labeled with the resident subjects' study ID and acrostic and date data was downloaded (eg, 91001ABCD_15NOV2013). The file extension will indicate which type of data it is.

Transfer of device data files will occur via the DCC's secure website. Secure remote access to the website is provided by the Juniper Networks Instant Virtual Extranet (IVE) appliance which sits behind our network firewall.

Authorized users will be given a login id and password:

- Log onto our secure website (see below): WEBSITE
- Click on the appropriate folder (Actigraphy, Optalert or PVT).
- Choose "Upload file"
- Browse for the file you wish to upload and then click "Upload"

The DCC will track the receipt of files and notify the sites if expected files are missing or if there is a problem with the file. These data will also be subject to periodic QA reviews to determine if data is being collected accurately and appropriately. The DCC will be in contact with the sites to discuss any findings.

10.9 DATA CLEANING THE DEVICE DATA

10.9.1 Form Data

In addition to the edit checks programmed into the forms and data system, study statisticians will write additional cleaning code prior to the start of data collection to be run on a daily basis against the study data. DCC staff will follow-up with clinical sites on any additional data edits that need to be addressed, based on the output of these programs.

10.9.2 Device Data

The DCC will develop internal procedures detailing the protocol for cleaning the actigraph and PVT data. In general, the DCC will monitor and track the receipt of data files on a regular basis and conduct a preliminary check of the files as they arrive to determine if there were any collection or transmission issues. The device data will then be systematically cleaned once the DCC has received all data files for a given participant (eg, at the end of his/her rotation).

10.10 AUDIT TRAIL

All changes made to the database are tracked and recorded in an "Audit Trail" for your review. The audit trail includes the user ID of the person who made the change, the date and time, a description of the item changed, the old value, the new value, and the reason the change was made (name of the query). This report is primarily of interest to any auditors of the study.

10.11 QUALITY ASSURANCE (QA) REPORTS AND CALLS

Monthly QA calls will be held with site research assistants as well as DCC and CCC staff to discuss protocol and data issues. Sites may compare strategies for ensuring complete and accurate data collection and report on any issues they are having. The DCC and CCC will similarly use the calls to communicate study issues that have come to their attention. Site PIs and other staff are welcome to attend the calls and additional calls with the sites research nurses will be scheduled as needed. The following reports will be shared on these QA calls, as well as on Steering Committee and Executive Committee calls:

- Time to Submission Monthly Reports:
  - Observer Shift Summary
  - Patient Days Logs
  - Missed Shifts
  - Suspected Events
- Shift Coverage Summary (by week, run monthly)
- PVT and Actigraphy Quarterly Reports