

Study Description of the 7-8 day Research Study

PURPOSE OF STUDY:

The purpose of this study is to learn how light and behaviors like eating affect the body clock. The body clock controls your daily cycles of sleep, body temperature, hormones, and performance.

OVERVIEW OF WHAT YOU WILL DO FOR THE 7-8 DAYS

We are looking for healthy, non-smoking, females/males, ages 18-35 years old, not on medications (birth control okay), have no history of medical, psychiatric, visual or sleep disorders/conditions. You may read, do hobbies, listen to music or work on a personal project. However, be aware that your free time will be interrupted frequently with mandatory computer testing, and all activities study related will be scheduled for you. On 2 occasions, you are asked to remain awake for 20-70 hours lying in bed the entire time. This is called a Constant Routine. A technician will be there to entertain you, play games, and assist you in staying awake when you need it.

WHAT WE MONITOR BEFORE AND DURING STUDY

For several weeks prior to being studied in the laboratory, your sleeping patterns will be monitored several ways. This includes a wrist activity recorder (actiwatch), which measures your activity and movement during the day and night, as well as you keeping a log of your sleep/wake times (this requires call-ins every night and morning to a voice-mail system). Once you are admitted to the hospital, we will record your sleep patterns, take blood samples and urine samples. Throughout your stay here there are two video cameras in your room. They are used to help the technicians monitor your well being and to make sure that you are staying awake when you say you are. However, at no time are you being recorded on video or audiotape.

PRESTUDY SCREENING

In order for us to determine if you are eligible for the study you will need to go through a screening process. This consists of multiple (up to 5) visits to our office to:

Fill in paperwork

Have a physical, an EKG and lab work (a blood and urine sample)

Meet with our psychologist for a routine assessment

Meet with the Doctor that runs the study to discuss in-study procedures/rights of a volunteer

Pick up food that we will provide for you to eat for the 3 days before you come into the lab

After these are completed (or while you are working on them) we will need you to keep a regulated 8-hour sleeping schedule for 3 weeks immediately prior to you starting the study. You will be able to pick your own 8-hours but they must stay the same over the 3 weeks. You keep track by calling into a voice-mail system every night and every morning at the times you go to sleep and the times you wake up. As the 3rd week is starting, you will be given the wrist activity recorder mentioned in the paragraph above. Your admission to the study is directly related to how well you maintain (or try to maintain) this schedule. We will also ask you to record all the food and drinks that you consume for up to 11 days before your study using a mobile phone application where you take pictures of what you eat and drink.

There are no other options to these steps, except to not do the study.

PROHIBITED SUBSTANCES DURING SCREENING

The following substances are prohibited throughout the course of the study, from the time of the screening evaluation until the completion of the 7-8-day inpatient/lab stay.

- Alcohol

- Caffeine (frequently found in coffee, tea, soft drinks, dark and white chocolate, etc.)
- Nicotine (tobacco products of any kind)
- Prescription or non-prescription (over-the-counter) drugs
- Recreation/street drugs
- Other foreign substances

**If in doubt about a particular substance, ask before taking.

STUDY CONDITIONS AND DATA BEING COLLECTED

Blood Drawings: During your stay in the lab, you will have an IV catheter that will draw small amounts of blood at various times. This is for hormonal analysis. The total blood lost over the entire length of the study is 2 pints. A very small amount of Heparin (an anti coagulant derived from porcine intestinal mucosa) will run through the IV to prevent clotting in the tube.

Urine Samples: Throughout the entire study, urine will be collected.

Cognitive performance battery: During the study, you will perform several performance tests. The tests are presented on a computer. You respond to these tests by using a trackball, the keys on the computer keyboard, or a two-button response pad. The performance tests are of several types, testing for reaction time, memory, hand-eye coordination, math and your mood at that time. Most people are surprised at the frequency and the repetition of computer testing, so please realize that this will take up a lot of your time.

Constant routines: The constant routine is considered by some to be the most difficult part of the study. During this time we will ask you to remain awake while sitting in bed for anywhere between 20-70 hours. We realize that this is a very long time to be awake, so we give you a person to talk with, play games with and do anything they can do to help you through it. Also note that we give you this range " 20-70" hours because your constant routine may be ANYWHERE in that range. During this time your brain waves are monitored (using encephalographic monitoring), along with frequent blood drawings. Periodically you will participate in short computer testing. You will be fed small frequent snacks throughout the constant routine, so your daily overall daily caloric intake will be equal to the amount of food you would receive in three meals and a snack. Since you are not allowed out of bed, you would have to use a bed pan or urinal during this time. This occurs two separate times throughout the study.

Light treatment: For most of the study, the lighting may seem rather dim during the time you are awake. Because the lights are at the dim level, you would not be allowed to watch movies as the TV monitor throws off more light levels than needed. It is perfectly reasonable to read in this light without straining your eyes. When it is time for you to go to bed, the lights will be turned out, and it will be complete darkness until the scheduled time for you to wake up.

On 1-3 occasions you may be exposed to a bright indoor light that would last for up to 16 hours. If you receive this bright light exposure you may be asked to look at a specific point marked out for you in order to ensure that you are getting the maximum exposure of light. You will be given mini-breaks during these sessions, but will not know how long you have done it for or how long you have left to finish.

Meals: On some days of the study you will receive a typical meal schedule consisting of a breakfast, lunch, dinner and snack. During constant routines you will be given your normal amount of food in

frequent snacks. During the study you may also be exposed to a restricted eating schedule. This means that we will ask you to eat the same number of calories you would in a normal day in a short window of time and you will not be allowed to eat outside of that window. We will ask that you eat and drink all of each meal you are given during the study.

STUDY CONDITIONS AND TIME-FREE ENVIRONMENT

Again, this study involves spending up to 8 days and 7 nights living in a lab. That means you cannot leave the room. You will not know what time of day it is. This is so that your knowledge of what time of day it is does not affect how you are feeling at any particular time. For example, if we ask you if you are sleepy and you know that it is 11pm, you are more likely to say that you are sleepy than if we asked you at 11am. As there are no time cues allowed during the study, there are no windows in the suites. In addition, no watch, clocks, TVs, radios, visits or phone calls are allowed in order to maintain a time free environment.

PAYMENT

Payment begins once you have completed the paperwork and begun your regular sleep-wake schedule. Please know that at any time you may be screened out. If this happens, then you will be paid for what you have completed. Payment is broken down as such:

Medical Screening:	\$25
8-h sleep schedule:	\$25 / week (includes Call-ins / Sleep log)
Wrist actigraphy:	\$25
Return actiwatch:	\$25
Food tracking:	\$25
Food pickup:	\$25
Screening bonus:	\$300 (completing all screening and admitting to the hospital for the inpatient stay)
Inpatient study:	\$250 / day
Completion bonus:	\$1,000 or \$1,250 depending on randomization

Therefore, if you complete the entire study, you will receive a total of \$3,500.

Payment is in the form of one check about 4-6 weeks after the study. If the entire study is not completed for any reason, you will be paid for your participation up through your last day in the study. Also, there is no monetary compensation paid to any person whose blood and/or urine tests indicate use of drugs, alcohol, caffeine, nicotine, nonapproved prescription or over the counter drugs, recreation/street drugs, illicit drugs or any other foreign substances.

OTHER BENEFITS

There will be no direct benefit to you from participating in this study. There is the chance that the pre-study screening may reveal some medical abnormality. This information will be conveyed to you at once, together with a recommendation to a local clinic or physician.

There are no lingering effects of this study, although it may take your body a day or two to adjust to its normal schedule after having been awake (as if you had jet lag).

QUESTIONS?

Please contact us to arrange a time to speak with a study representative:

Ph. 617-525-8464

Version date: 2/28/2024

Email sleep_PRC@partners.org