

# **10-Day Sleep Research Study Description**

## **PURPOSE OF STUDY**

The study is being conducted to help people better understand the impact of different sleep patterns on your health, cognitive performance, mood, circadian rhythms, sleep, and related body functions and aviation safety, including how you feel and perform on tests and how chemicals in your body change.

## **OVERVIEW OF WHAT YOU WILL DO FOR THE STUDY**

There are two parts to the study: (1) approximately 3-4 weeks of outpatient, when you will live at your home and (2) 10 days of inpatient when you will live in our specialized suites at the Brigham and Women's Hospital (BWH). During the inpatient portion, all of your time will be spent in your suite. You will not leave the suite until the end of the 10 day period unless you decide to withdraw from the study. You will not have access to your phone, computer or the internet. You will not be allowed to have visitors. You will not know what time or day it is during the study.

During some times within the inpatient study, you will have free time. 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 performance testing and other study-related events, and that all study-related activities will be scheduled for you. A technician and other study staff will be there to visit with you, play games, and assist you in staying awake if you need. Your sleep and wake schedule during the study may be different than what you do at home; on some study days you may get more sleep than usual and on other study days you may get less sleep than usual. You may also have an extended period of time (up to 72 hours) when we ask you not to sleep. We will discuss this with you in more detail before you start the study.

## **WHAT WE MONITOR BEFORE AND DURING STUDY**

For several weeks prior to entering the inpatient portion of the study at the BWH, your sleeping patterns will be monitored. (i) One or more wrist activity recorders (actiwatches), which measure your activity and movement during the day and night, and (ii) a paper log of your sleep/wake times and other sleep-related information, and (iii) call-ins every time you go to sleep and every time you wake up to an automated voice-mail system.

## **SCREENING PROCEDURES**

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 visits that may include a combination of virtual visits with our study staff and visits to Brigham & Women's to:

- Complete questionnaires (takes three to four hours)
- Have a physical, an ECG and lab work (a blood and urine sample)
- Give us permission to contact your regular doctor to obtain any medical records of treatments/non-routine visits.
- Meet with our psychologist
- Have an at-home sleep test to determine if you have a sleep disorder
- Meet with the project leader that runs the study to discuss in-study procedures and your rights as a volunteer

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

## **PROHIBITED SUBSTANCES**

The following substances are prohibited from the time you enroll in this study until the completion of the inpatient stay.

- Prescription medications
- Women who are currently using a non-barrier form of birth control (e.g., pills, IUD, implant) for at least 3 months must remain on this form of birth control until the end of the study. If you are not currently using one of these birth control methods but plan to in the near-future, please let us know; we may need to delay your study start or exclude you from the study.
- Alcohol
- Caffeine (frequently found in coffee, tea, soft drinks, dark and white chocolate, etc.)
- Nicotine (tobacco products of any kind)
- Non-prescription (over-the-counter) drugs
- Recreation/street drugs
- Other foreign substances

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

## **WHAT THE RESEARCHERS MONITOR DURING THE INPATIENT PORTION AT THE BWH**

During the inpatient part of the study at the BWH, we will record your sleep patterns, take blood, urine, saliva and fecal samples, and ask you to complete performance and alertness tests.

There are two video cameras in your suite that are used to help the technicians monitor your well-being and to ensure that you are staying awake at the required times. However, at no time are you being recorded on video or audiotape.

### ***INPATIENT-STUDY CONDITIONS***

\*COVID-19 testing: You may be tested for COVID-19 at least once during your 10-day inpatient stay. If you test positive for COVID-19, you will need to leave the study.

\*PSG (Polysomnography): During some nights and days your sleep and wake will be monitored. Just before you go to sleep, you will be asked to wash your face with special soap and cleanse your skin with an alcohol swab. Small electrodes will be placed on the skin of the scalp, face and chin. Some electrodes are held in place with special glue that will shampoo out.

\*Blood Draws: During the study, you will have an IV catheter that will draw small amounts of blood at various times. The total blood lost over the entire length of the study is less than 2 cups. A very small amount of heparin (an anti-coagulant) may be run through the IV to prevent clotting in the tube.

\*Urine Samples: Your urine may be collected throughout the inpatient portion of the study.

\*Saliva Samples: During some parts of the study, saliva may be collected by asking you to spit in a small test tube.

\*Fecal Samples: We may take a sample of your feces when you have a bowel movement up to 3 times during the study.

This study involves spending 10 days and 9 nights living in a specialized hospital suite. During the inpatient portion of the study, you will not leave the suite unless you want to end the study.

### ***PERFORMANCE TESTING***

During the study, you will complete multiple performance tests. These tests are presented on a computer or on paper. You will respond to these tests by using a trackball, the keys on the computer keyboard, a response pad, or by hand writing a response. There are a variety of performance tests, including testing for reaction time, memory, hand-eye coordination, math and mood.

## **PAYMENT**

Compensation begins accumulating once you have completed the paperwork and initiate your regular sleep-wake schedule. You will be paid \$25.00/ week for call-ins, keeping a paper log and a regular schedule. This increases to \$50.00/ week when you receive the actiwatch. Please know that at any time you or we may decide to not continue with the outpatient or inpatient portion of the study; if this happens, then you will be paid for the portions of the study that you have completed.

Payment is composed of

- Sleep and wake time call-ins: \$25 per week
- Completion of PE visit: \$25
- Completion of psychologist visit: \$25
- Sleep and wake time call-ins with actigraphy: \$25 per week
- Payment for at home sleep test: \$25
- Daily pay during in-patient stay at BWH suite: \$300 per day
- Bonus: \$700, payable only if inpatient study is completed
- Return wrist actigraphy device(s): \$25
- Some parking and transportation reimbursement

The total payment will be mailed in the form of a single check about 4 weeks after completing the study. If the entire study is not completed for any reason, subjects are paid for their participation up through their last day, but none of the Bonus is included. Also, there is no monetary compensation paid to any person whose blood and/or urine tests indicate use of drugs, alcohol, caffeine, nicotine, non-approved prescription or over the counter drugs, recreation/street drugs, illicit drugs or any other foreign substances.

## **OTHER BENEFITS**

There may be no direct benefit to you from participating in this study. There is the chance that the pre-study screening or various blood and urine samples taken during the study may reveal a medical condition. This information will be conveyed to you at once, together with a recommendation to a local clinic or physician.

There are no expected long-term effects of this study, although it may take your body a day or two to adjust to its normal schedule, as if you had jet lag.