IRB Approval:7/19/2013
IRB Accepted:7/19/2013
IRB Expiration:6/17/2014

Study Volunteer Initials

Affiliate	☐ Rhode Island Hospital	☐ The Miriam Hospital
	☒ Bradley Hospital	☐ Newport Hospital

Agreement to Participate in a Research Study And Authorization for Use and Disclosure of Information

4078-08
Committee #

Name of Study Volunteer

Study 1- Sleep and Mood in College Students (Phase 2)

You are being asked to take part in a research study. All research studies at Lifespan hospitals follow the rules of the state of Rhode Island, the United States government and Lifespan. Before you decide whether to be in the study, you and the researcher will engage in the "informed consent" process. During this process, the researcher will explain the purpose of the study, how it will be carried out, and what you will be expected to do if you participate. The researcher will also explain the possible risks and benefits of being in the study, and will provide other information. You should feel free to ask any questions you might have. The purpose of these discussions is for you to decide whether participating in the study is the best decision for you.

If you decide to be in the study, you will be asked to sign and date this form in front of the person who explained the study to you. This form summarizes the information you discussed. You will be given a copy of this form to keep.

1. Nature and Purpose of the Study

You are being asked to take part in a research project because of your participation in Phase 1 of the study. You are invited to participate in Phase 2 of this study on sleep and the daily biological rhythms that control many of the body's processes. In this study, we hope to learn how sleep and mood are affected by the transition into college. Phase 1 began after your acceptance into college (but before you enrolled) to measure what your sleep and mood were like before college. Phase 2 assesses how your sleep and mood are affected in the first 10 weeks of your first year in college. We will study approximately 1050 first year students in Phase 2. This study is sponsored by the National Institute of Mental Health.

2. Explanation of Procedures:

If you take part in Phase 2 of this study, you will complete an online sleep diary each day for approximately 10 weeks at the beginning of your first college year plus a short online form every two weeks. You will be offered the option of completing a brief additional survey on occasion.

You will also complete a set of questions that assess sleep habits, medical history, mood, alcohol and substance use, family history and psychological disorders. All of these surveys will be posted on a secure website for completion.

We will also collect a sample of skin cells from the inside of your cheek. You will be asked to do this by rubbing the inside of your cheek for 20 seconds with three sterile cotton-tipped wooden swabs and then rinsing out your mouth with water and adding it to the tube. These cells will be used to identify genes that may be associated with sleep and biological rhythms. You will need to sign a form when you give the skin cells. Your height and weight will also be measured. At the end of Phase 2, your height and weight will be measured again.

All participants are invited to provide blood samples. The blood samples will be collected through a small needle in an arm vein. Three 10 cc samples (2 teaspoons each) will be collected at your consent visit and again at the end of Phase 2 of this study. The blood samples will be sent to a laboratory for analysis of the genes associated with your daily sleep and circadian rhythms. If you choose to give blood samples, it is important to give at time 1 and time 2. You will need to sign a form when you give the blood samples.

After about 6 or 7 weeks, all participants will be invited to spend six hours one evening for saliva collection as part of Phase 2. This session ends about 30 minutes after your usual bedtime. Group sessions will be planned and announced for you to choose the best evening for your schedule. During this session, you will give saliva samples (less than one teaspoon each) at set intervals to measure the hormone melatonin. Each saliva sample is obtained by holding a small piece of cotton in your mouth for about one minute. Although the lights will be dim, you can bring homework, reading materials and/or a personal music player while undergoing the saliva collection. This procedure allows us to evaluate your body clock through the melatonin levels present in your saliva. You will return home after the saliva samples are collected and transportation will be provided.

You will be given $1 for each day you complete the online diary, with a $1 bonus each time you complete 3 consecutive days (resetting as the bonus is earned), and a $3 bonus each time you complete 7 consecutive days (resets as each bonus is earned). You will receive an additional $3 for each bi-weekly survey completed and $1 for each brief additional survey completed. You will receive $18 for completing questions pertaining to your sleep patterns, medical history, mood, alcohol and substance use, and family history of sleep and psychological disorders. You will also receive $7 for the cheek swab for genetic association assessments. If you come for the evening saliva samples you will receive an additional $50. If you agree to do the blood samples, you will be compensated $10 for the time 1 sample, and $20 for the time 2 sample.

In the event that any material you provide is lost or damaged, we may ask you to provide it again.

Contact Information:
If you have questions about study procedures you may contact Mary A. Carskadon, Ph.D. at (401) 421-9440.

3. Discomforts and Risks

The questions you will be asked are from standard questionnaires used in sleep and psychology research. Certain questions may be mildly upsetting as they may probe sensitive psychological areas and others inquire about family history of medical and psychological illness. Additionally, certain questions ask about your use of drugs and alcohol. If you provide blood samples there is a risk that minor bruising or infection may occur at the site of the blood draw. You will be instructed to look for these minor bruises and infection following the procedure. Universal precautions including the use of gloves and disposable needles will be used. A risk of this study is that this information could be disclosed in the event that a legal authority subpoenas our records. If this were to happen, we would do all that we reasonably could to protect the records against release, including consulting with our legal representatives. No subpoenas have ever been issued to our lab in over 20 years of research at Lifespan

4. Benefits

You may not experience any direct benefit as a result of participating in this study; however, we hope to benefit society as a whole by gaining knowledge of how changes in sleep patterns and circadian rhythms across the first year of college may affect mood and whether these changes are affected by genes.

5. Alternative Therapies

This is not a study of experimental therapies, thus there are no alternative therapies.

6. Refusal/Withdrawal

It is up to you whether you want to be in the study. You are not required to enroll or participate. If you decide to participate, you can always change your mind and quit at any time. If you decide not to be in the study, or if you quit later, you will still be able to get the health care services you normally get. If you join, but later on the researcher or your doctor feels being in the study is no longer good for you, they may choose to take you out of the study before it is over. If new information becomes available that might change your mind about whether you want to stay in the study the researcher will share this information with you as soon as possible.

7. Medical Treatment/Payment in Case of Injury

A research injury is any physical or mental injury or illness caused by being in the study. If you are injured by a medical treatment or procedure you would have received even if you were not in the study that is not a research injury. To help avoid research injury and added medical expenses, it is very important to follow all study directions carefully. If you do experience a research injury, Lifespan or the study doctor can arrange medical treatment for you. Such treatment will be paid for as described below.

If you have insurance and have a research injury that is not covered by the study, it is possible that some or all of the cost of treating you could be billed to your insurer. If your health insurance will not cover such costs, it is possible you would have to pay out of pocket. In some cases, Lifespan might be able to help you pay if you qualify for free care under Lifespan policy.

However, Lifespan has no policy to cover payment for such things as lost wages, expenses other than medical care, or pain and suffering.

8. Rights and Complaints

Signing this form does not take away any of your lawful rights. If you have any complaints about this study, or would like more facts about the rules for research studies, or the rights of people who take part in research studies you may contact Patricia E. Houser, in the Lifespan Office of Research Administration, at (401) 444-6246.

9. Confidentiality and Research Authorization for Use and Disclosure of Your Health Care Information.

Your research records will be treated as private health care records and will be protected according to Lifespan privacy practices and policies that are based on state and federal law. In particular, federal law requires us to get your permission to use or disclose (release your information to someone outside of Lifespan) your health information for research purposes. If you sign this form you agree to be in this research study and you permit the use and disclosure of your health information for the purpose of conducting the research, providing treatment, collecting payment and running the business of the hospital. This permission has no expiration date. You may withdraw from the study at any time. However, if you do not want the researchers to use or disclose any further information in this study you must cancel permission in writing and may do so at any time. If you cancel your permission, you will stop taking part in the study and no new information will be collected about you. However, if you cancel your permission, it will not apply to actions already taken or information already collected about you by the hospital or the researchers before you canceled your permission.

Generally, the entire research record and any medical records held by the hospital may be used and released for research purposes. The following people or businesses/companies/ might use, release, or receive such information:

- The researcher and their support staff;
- The study sponsor ____NIMH_____
- Doctors, nurses, laboratories and others who provide services to you in connection with this study;
- The company or section of the U.S. government that is paying for the study and others they hire to oversee, administer, or conduct the research;
- The United States Food and Drug Administration, the Department of Health and Human Services, the Office of Inspector General, and the Office of Civil Rights;
- People who volunteer to be patient advocates or research volunteer protectors;
- Members of the hospital's administrative staff responsible for reviewing, approving and administering clinical trials and other healthcare or research activities.

There are times when the law might require or permit Lifespan to release your health information without your permission. For example, Rhode Island law requires researchers and

health care workers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF) and to report abuse or neglect of people age 60 and older to the Department of Elderly Affairs.

All researchers and health care providers are required to protect the privacy of your health care information. Other people and businesses/organizations that are not health care providers are not required by law to do that so it is possible they might re-release your information.

You have the right to refuse to sign this form and not participate in the research. Your refusal would have no affect on your treatment, charges billed to you, or benefits at any Lifespan health care site. If you do not sign, you will not be able to enroll in the research study and will not receive treatment as a study participant.

If you decide to quit the study after signing this form (as described in Section 6) no new information will be collected about you unless you gave us permission to do so. However, the hospital or the researchers may continue to use information that was collected before you quit the study to complete analysis and reports of this research.

You will not be allowed to see or copy the information described in this form as long as the research study is open.

GINA STATEMENT

This study involves 'genetic testing' as defined by the Genetic Information Nondiscrimination Act of 2008 (GINA). GINA generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. There are some limitations to GINA's protections (it does not apply to all insurers or employers, nor does it apply to all genetic information, such as information related to a genetic disease that you already have). In addition to GINA's protections regarding the ultimate use to which your genetic information is put, Lifespan's privacy policies generally protect the privacy of such information and restrict its release outside of Lifespan, unless you specifically authorize its disclosure or unless disclosure without your authorization is permitted under applicable privacy laws.

For more detail about your privacy rights see the Lifespan Joint Privacy Notice which has or will be given to you.

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Study Volunteer Initials

Our research team often has other studies for which you may be eligible. If you would like to be kept informed about other opportunities for participation, please indicate your wish by checking the correct statement below. You are under no obligation to participate in any future research study offered to you. You may withdraw this permission at any time by contacting us at 401-421-9440.

____ *I give my permission/____ I do not give my permission for you to contact me about other studies in the Bradley Sleep Research Lab.*

You may also decide if we can release your contact information (name, address, telephone number) to a professional locating agency to help us find you for future studies that you may be eligible for.

____ *I give my permission/____ I do not give my permission for you to release my contact information to a professional locating agency to help find me for future studies in the Bradley Sleep Research Lab.*

SIGNATURE

I have read this informed consent and authorization form. ALL OF MY QUESTIONS HAVE BEEN ANSWERED, AND I WANT TO TAKE PART IN THIS RESEARCH STUDY.

By signing below, I give my permission to participate in this research study and for the described uses and releases of information. *I also confirm that I have been now or previously given a copy of the Lifespan Privacy Notice*

This informed consent document expires on 6/17/2014 **.**
DO NOT sign this document after this expiration date

_____ _____ _____
Signature of study volunteer/authorized representative* Date and Time when signed

I WAS PRESENT DURING THE CONSENT PROCESS AND SIGNING OF THIS AGREEMENT BY THE STUDY VOLUNTEER OR AUTHORIZED REPRESENTATIVE

_____ _____
Signature of witness (required if consent is presented orally or at the request of the IRB) Date

_____
Study Volunteer Initials

I HAVE FULLY EXPLAINED TO THE ABOVE STUDY VOLUNTEER/AUTHORIZED REPRESENTATIVE, THE NATURE AND PURPOSE, PROCEDURES, AND THE POSSIBLE RISKS/BENEFITS OF THIS RESEARCH STUDY.

_____ _____ _____
Signature of researcher or designate Date and Time when signed

* If signed by agent other than study volunteer, please explain below.

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_____

Documentation that a copy of this Informed Consent was given to the research participant is a Federal requirement. Prior to making a copy of the signed and dated Informed Consent please check appropriate box(es) as applicable to indicate copy provided to:

☐ Study Volunteer ☐ Medical Record ☐ Researcher ☐ Other (Specify)