Study Volunteer Initials

Lifespan Affiliate Site where research will be conducted

☐ Rhode Island Hospital
☒ Bradley Hospital
☐ The Miriam 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 expect to enroll 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 (bi-weekly survey). You will be offered the option of completing a brief additional survey on occasion. Toward the end of the study 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.
In addition, you will provide blood samples on 2 occasions. The blood samples will be collected through a small needle in an arm vein. Four 10 cc samples (~2 teaspoons each) will be collected today at your consent visit and again in November. If you are unable to provide a blood sample, you will provide a 2-milliliter (<teaspoon) saliva sample in a collection tube only one time (today). The samples will be sent to a laboratory for analysis of the genes associated with your daily sleep and circadian rhythms. Your height and weight will also be measured today and in November.

At the end of the study you will receive $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 $15 for completing questions pertaining to your sleep patterns, medical history, mood, alcohol and substance use, and family history of sleep and psychological disorders in November. You will receive $10 for the blood sample or $5 for the saliva sample today. If you agree to do the second blood sample in November, you will receive $20 at that time.

If your daily diary completion is infrequent, you may be dropped from the study and receive compensation only for what you’ve done.

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, or Janice Muratori in the Lifespan Office of Research Administration, at (401) 444-6246

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:

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- The researcher and their support staff;
- The study sponsor NIMH
- Doctors, nurses, laboratories and others who provide services to you or the sponsor 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; European Medicines Agency
- 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.
- Accrediting Organizations

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 effect 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. You may see and copy the information when the study is completed.

**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.

Participation in Specimen Banking
You are agreeing to participate in this research study by signing this form (the “Main Study”). Blood/body fluid/tissue samples will be collected from you, which will be referred to here as your ‘Specimen.’ In addition to being analyzed as part of the Main Study, your Specimen may be useful for future research purposes. You are being asked to agree to this optional component (the “Specimen Banking Component”) of the study if you are willing to allow your Specimen to be saved or ‘banked’ for use in future research studies. If you agree to this optional Specimen Banking Component, you give permission for your Specimen to be stored in a specimen bank. Along with the specimens, portions of your personal health information collected as part of the Main Study will also be stored. Your Specimen and personal health information may be stored and analyzed at Lifespan; or, they may be shared with researchers at other institutions or companies that may store them and use them for their own research. It is very unlikely that any future research performed using your Specimen would benefit you directly. However, the research may provide important medical knowledge that in the future could help other patients with your medical condition or other medical problems.

At this time, we do not know what future research studies may be done using your Specimen. Such research studies may include genetic tests that would analyze your DNA, RNA or other gene products, like proteins and metabolites. These genetic tests may be done by Lifespan, or they may be done by other researchers with whom your Specimen and data have been shared. Because any genetic testing of your Specimen would be for research purposes, the results would have no clear implications for your health or medical condition, or that of your family members. Any testing results would not be made available to you or to any insurance company, your employer, your family, or any physician who treats you in the future.

There is a very remote possibility that your Specimen and some associated data may become part of a process or product that ultimately has commercial value. For instance, the Specimen could be used to establish a cell line (a group of cells that are able to reproduce, sometimes indefinitely) that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.

If you agree to this Specimen Banking Component, your Specimen will be stored for an indefinite period of time, until it is no longer usable. The Specimen may also be used to create a cell line, which would also be stored for an indefinite period of time. If you decide at some time in the future that you no longer wish your stored Specimen to be used in future studies, you have the right to request that the Specimen be withdrawn from the specimen bank. However, withdrawal cannot be guaranteed and may be impossible. For example, it is possible that the Specimen might no longer be identifiable as belonging to you, or it may have been used up, or it may already have been shared with other institutions or companies for their own research. To request withdrawal of your Specimen, please write to: Mary A. Carskadon, Ph.D. at 300 Duncan Drive, Providence RI, 02906.

Refusal to participate in this optional Specimen Banking component will in no way affect your ability to receive any treatment or services offered as part of the Main Study, and will not have any effect on your other health care, the payment for your health care, or your health care benefits. If
you are willing to allow your Specimen to be banked for future research purposes, please indicate your consent by signing below.

___________________________________________
Signature of study volunteer/authorized representative

__________________________
Date

While unlikely, it is possible that a researcher using your Specimen and data in a future research study may want additional information about you or may want to collect from you additional samples of your blood or body tissue. In such a case, you would be contacted by a researcher to see if you are able and willing to provide the additional information or samples. Please indicate below if you are willing to be contacted for the purpose of obtaining additional information about you or additional samples of your blood or other body tissue.

I am willing to be contacted for the purpose of giving further information and/or samples of my blood or body tissue. _______ (initials)

I am NOT willing to be contacted for the purpose of giving further information and/or samples of my blood or body tissue. _______ (initials)

_______________________________________________________________________

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

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
Study Volunteer Initials

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 5/19/2015. 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

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.

___________________________________________

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)