Study Volunteer Initials

Affiliate	☐ Rhode Island Hospital	☐ VNA of Rhode Island
	☐ The Miriam Hospital	☐ Hospice Care of R.I.
	☒ Bradley Hospital	☐ Newport Hospital

Agreement to Participate in a Research Study

Committee #

Name of Study Volunteer

Alcohol, Sleep, and Circadian Rhythms in Young Humans
Study 2—Effects of Evening Ingestion of Alcohol on Sleep, Circadian Phase, and Performance as a Function of Parental History of Alcohol Abuse/dependence

Your child is being asked to take part in a research study. All research studies carried out at Lifespan institutions are covered by the rules of the Federal Government as well as rules of the State and each institution. Under these rules, the researcher will first explain the study and then ask you to participate You will be asked to sign an agreement which states that the study has been explained, that your questions have been answered, and that you agree to have your child participate.

The researcher will explain the purpose of the study. He or she will explain how the study will be carried out and what your child will be expected to do. The researcher will also explain the possible risks and possible benefits of being in the study. You should ask the researcher any questions you have about any of these things before you decide whether you wish to allow your child to take part in the study. This process is called informed consent.

This form also explains the research study. Please read the form and talk to the researcher about any questions you may have. Then, if you decide to allow your child to be in the study, please sign this form in front of the person who explained the study to you.

Federal and Lifespan institution regulations require that if the child is 8 years or older, the "assent" (agreement) of your child be obtained by the researcher before your child may participate in this study. Your child must sign the consent form as well. You will be given a copy of the signed consent form to keep.

1. Nature and Purpose of the Project

   Your child is invited to participate in a study of the impact that a small or moderate dose of alcohol has on sleep, performance, sleepiness, and mood. In this study, we hope to learn how these may differ between adolescents and young adults and between individuals who have a parent with alcohol dependency or abuse and those who do not. Your child has been selected for this study because s/he reports good health and has some experience drinking alcohol. Your child may or may not have parent(s) who have had problems with alcohol. The study lasts a total of 4 weeks and includes 5 nights spent in the Sleep Research Laboratory. For the first 2 weeks your child is studied at home on a fixed sleep schedule. During the next 2 weeks your child is studied in the laboratory on 5 nights, not all of which are consecutive. In the laboratory, your child's sleep is monitored and s/he is asked to perform computerized and paper and pencil tests, take brief naps, and take a dose of alcohol mixed in tonic water. You and your child are asked to provide information about any family sleep, medical, substance abuse, or psychological disorder. In addition, your child has a medical and psychological evaluation. This study is sponsored by the National Institute on Alcohol Abuse and Alcoholism.

2. Explanation of Procedures

   In the pre study phase, we ask you and your child to complete a series of questionnaires and interviews that allow us to know more about you and your child's sleep patterns, alcohol and other substance use, medical history, and family history of sleep, psychological disorders, and alcohol dependence. We also interview your child's genetic mother and father to find out about their experiences with alcohol and their psychological and medical histories. Your child also has a medical examination to assure good health and a psychological interview to determine that s/he is able to take part in the study. A psychologist also interviews your child to determine the medical and mental health history of your family. If your child is a girl, she completes a Menstrual Status Form and Menstrual calendar. The forms and interviews take approximately 2 hours to complete.

   You and your child come to the sleep laboratory during an evening at the beginning of the study for an orientation meeting. At this meeting you and your child complete other forms, pick up materials for the at-home part of the study, and learn about the study procedures. We measure your child's height and weight in order to calculate his or her alcohol dose for the laboratory portion of the study. Your child also provides a blood sample (about 1 teaspoon) to screen for any liver problems that would be made worse by drinking alcohol and would keep him or her out of the study. If your child is female and capable of childbearing, her blood is also used for a pregnancy test. If we find she is pregnant, we will notify her and she will not be able to be in the study; we will otherwise keep the information confidential within the limits of the law.

During all 4 weeks of the study, your child keeps a strict schedule set by the study director that includes 10 hours of sleep every night, completes sleep diaries every morning and evening, telephones the sleep lab each evening and morning to report bedtimes and risetimes, and wears a small activity monitor, called an actigraph, on one wrist to measure the amount of movement s/he makes. The actigraph is very similar in size to a wristwatch and is not very noticeable. Your child wears the actigraph all the time except when it might get wet or subjected to physical shocks. A member of the sleep laboratory staff calls your child 1-3 times a week with a reminder to complete sleep diaries and to follow the sleep schedule. Your child also wears eye shades during the night every night, avoid napping during the day, and must not consume any caffeine (including chocolate) or other substances or medications.

Your child comes to the laboratory during the daytime at the end of the first week. We test your child's actigraph to make sure it is working and go over his or her diary with him/her. At the end of the second week, your child comes to the sleep lab on the campus of Butler Hospital in the morning to drop off the actigraph and diary, then returns in the late afternoon according to the schedule provided by the laboratory for the first laboratory night. On this first laboratory night, your child is given a standard meal and then he or she has sensors and electrodes attached for sleep and body temperature monitoring (described below). Your child gives saliva samples (less than one teaspoon each) at set intervals during the evening until about one-hour past his or her usual bedtime (14 samples total). Each saliva sample is obtained by asking you to hold a small piece of cotton in your mouth for about one minute. These samples allow us to measure levels of the hormone, melatonin, which is related to the body's biological clock and can be found in saliva. Your child also performs brief (15-30 minutes) testing at intervals during the evening with computerized and paper and pencil performance and driving simulation tests, and fills out rating scales of sleepiness and mood. Your child also provides a urine sample, which will undergo toxicology screening. If we find a positive drug test, we will notify your child; we will otherwise keep the information confidential within the limits of the law. In the morning your child eats breakfast, the electrodes and sensors are removed, and she or he leaves the laboratory for the day.

Your child returns to the laboratory for 4 other overnight sessions. Nights 2 and 3 directly follow lab night 1, night 4 is about a week later, and night 5 is about a week after night 4. Your child keeps the fixed sleep schedule this entire time. For all of these overnight sessions, your child comes to the laboratory in the morning to drop off the actigraph and diary, then returns in the late afternoon according to the schedule provided by the laboratory. Your child is given a meal, provides a urine sample for toxicology testing, and is prepared for sleep and body temperature recording. During the evenings your child does performance testing and is asked to drink 3 glasses of tonic water and ice over a timed interval while s/he is seated alone in his or her bedroom. These drinks contain either a small or moderate dose of alcohol; on some nights your child will get a small dose and on other nights a moderate dose of alcohol. For comparison, the highest dose is calculated by your child's weight to equal about 3 so-called standard drinks for a 150-pound male, and

slightly less than 2 standard drinks for a 100-pound female. (A standard drink is a cocktail containing 1.5 ounces of liquor or a 5-ounce glass of wine or a 12-ounce bottle of beer.) Before drinking the alcohol dose your child is asked to rinse his or her mouth with mouthwash and after consuming the alcohol dose, s/he remains seated and provides breath samples from a breathalyzer at 30-minute intervals. Your child will not be informed of the results of the breath tests until after the end of the study.

On nights 2 and 3, your child goes to bed and gets up in the morning at the usual time as set by his or her schedule. On nights 4 and 5 your child stays up longer, seated in bed, to continue performance and driving simulation testing, provides saliva samples, and takes a series of small naps. Because your child stays up late on nights 4 and 5 s/he will lose some sleep and may be a bit sleepy the next day**.**

On all nights your child is not in the laboratory, s/he follows the sleep schedule assigned to him or her. Your child is required to refrain from ingesting caffeine or chocolate, drinking any alcohol or using nicotine products or illicit substances during the entire study, except for the alcohol dose that is given to him or her during the laboratory portion of the study. Your child must call the sleep laboratory before taking any medication (for example, aspirin, antihistamines, and so forth).

When your child is in the sleep laboratory, sleep and daytime functioning are monitored using standard sleep laboratory procedures. Small electrode sensors are attached to him or her to monitor sleep. The sensors are taped to the forehead, beside the eyes, behind the ears, under the chin, on one shoulder, and on one side. These sensors allow us to measure eye movements, muscle activity, and heart rate. Four additional sensors are attached to the surface of the scalp using small gauze patches that are soaked in a sticky solution [collodion] and dried with compressed air. These scalp sensors permit us to measure brain waves. All of these measures are required to evaluate sleep. Your child's sleep is continuously monitored and continuously observed by a technologist throughout the nights in the Sleep Research Laboratory. In addition, body temperature is measured continuously with a portable monitor attached to a rectal thermometer sensor that is pliable, flexible, and harmless to a normal person. Your child places the thermometer sensor approximately 4 inches into the rectum, and it is held in place with a single piece of tape on the lower back. Your child is asked to check the probe by feel at intervals to determine that it remains in place. The monitoring system is portable so your child will be able to move around while it is in place. This technique is well-tolerated by most participants and is a standard procedure in human studies of this type.

Only on the first night of sleep in the laboratory, sensors are also placed on your child's chest and abdomen to measure breathing movements and beside his or her nose and mouth to measure breathing airflow. Another sensor is taped on one finger to measure the amount of oxygen in your child's blood. [No blood is taken for any of these measures.] These latter measures allow us to evaluate your child's breathing function during sleep. Electrodes are taped on each leg to measure leg movement activity—again only on the first

night. The electrodes on your child's face, scalp, shoulder and side remain on for the entire study, except when he or she is bathing.

At the end of the study, your child participates in an interview session with a psychologist to provide him or her with information about alcohol and its use and abuse.

Your child's safety requires that s/he remains in the laboratory after consuming any alcohol until alcohol levels are no longer detectable by the breath test. It may take up to 6 hours for your child's breath alcohol level to be close to zero. If it is necessary that s/he leave the laboratory at any time before the breath alcohol level is close to zero, we ask that s/he remain until you see the study director (Dr. Carskadon) or the medical consultant. Your child is not permitted to leave the laboratory until a parent or guardian arrives to transport him/her home. On any night your child will be receiving a dose of alcohol, s/he is not permitted to drive him or herself to the laboratory. If s/he cannot get a ride, the laboratory will provide transportation by cab.

You receive $10 each (total $20) for the screening interview.

Your child receives $10 for the screening interview, $50 for the first 2-week at-home monitoring, $25 each for the third and fourth week of at-home monitoring, $350 for the overnight laboratory sessions (night 1=$60, night 2=$65, night 3=$70, night 4=$75, night 5=$80), and a $170 bonus for completing the study. The total amount you receive for completing all of the study is $630.

If you or your child have questions about study procedures you may contact Mary A. Carskadon, Ph.D. at ********.

3. Discomforts and Risks

Because you and your child have told us that your child has taken alcohol in the past with no harmful effects, the risks of drinking the doses of alcohol provided in this experiment are minimal. Alcohol is a toxin, however, and it is possible that your child may experience some stomach discomfort and may vomit, although this risk is very slight. We do not know whether the alcohol consumed in this study increases the risk for future alcohol abuse of dependence for individuals whose parents have a history of alcohol abuse.

Alcohol may be harmful to an unborn fetus. Therefore, females are asked to provide a blood sample for pregnancy testing at the beginning of the study and must use a barrier form of contraception throughout the study if sexually active. If your child becomes pregnant during the at-home portion of the study, your child must inform the study director. She will not be able to continue in the study.

Your child's behavior is observed and monitored carefully while in the sleep laboratory, and s/he is not permitted to do any activities that might be harmful.

Before your child does the study, we need to draw blood to check for any liver problems that might be made worse by ingesting alcohol and for pregnancy testing for women. This procedure may involve some mild pain and discomfort, and bruising may occur at the site that the sample is taken from.

It is illegal in Rhode Island to serve alcohol to anyone under 21 years of age; however, we have received a waiver of prosecution from the Rhode Island Attorney General that allows us to provide doses of prescribed alcohol to participants in this study who are under 21. According to the waiver agreement, we provide names of study participants under age 21 to the office of the Attorney General.

The interviews and forms are routine, standardized forms for sleep research and psychology research. They pose no known risks, although certain questions may be mildly upsetting because they may probe sensitive psychological areas and others inquire about family history of medical and psychological illness or alcohol and substance use. We have a federal certificate of confidentiality so that any information you or your child give us about illegal substance use by you or your child is protected from use in potential prosecution. Appropriate referrals are offered if areas of concern arise in the course of collecting this information.

There is no known risk to wearing the wrist actigraphs. The sleep tests involve standard sleep laboratory procedures with low risk and very little discomfort. A minor skin rash may develop from sleep sensors, but this risk is very slight. We have had participants in the laboratory wearing electrodes for as long as 20 days and nights with minimal skin irritation. The rectal thermometer may cause minor discomfort at first, but is not harmful. The restricted sleep that you experience on laboratory nights may cause your child to be irritable and sleepy the next day. Your child's behavior will be observed while in the lab, and s/he will not be permitted to do any activities that might be harmful to a sleepy person.

4. Benefits

Your child has a physical examination, and an evaluation of your child's sleep is performed as part of the project; your child is fully informed if any abnormalities appear. Your child may learn about sleep and scientific research. S/he may enjoy being a participant in scientific research in a project that involves such close one-on-one participation with the research staff. Your child is given information about alcohol and its use and abuse. Otherwise, we cannot promise that your child will receive any direct benefits from this study. In terms of the benefits to society as a whole, we hope to be able to learn more about how the effects of alcohol may differ between adolescents and young adults, and between individuals with and without a parent with alcohol dependency or abuse. The data from this study may begin to provide some understanding of how impairment from alcohol varies depending on age and family history.

5. Alternative Therapies
Because this is not a treatment study, no alternatives are offered.

6 Confidentiality
All of your child's records from this study will be treated as confidential medical records. The records will be safeguarded according to Lifespan institution policy. This policy is based on Rhode Island law, which promotes protection of confidential health care information. State law requires health care providers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF). State law also requires health care providers to report abuse or neglect of persons age 60 and older to the Department of Elderly Affairs.

While the results of the research study will probably be shared with other people and may be published in scientific reports, your child's name and the fact that your child was in the study will be kept confidential.

In addition, we will obtain a federal certificate of confidentiality to ensure that your and your child's responses to our questions are kept private.

Information about alcohol or other substance use that your child gives us will not be shared with you unless your child gives his or her permission for us to do so.

7. Refusal/Withdrawal
The decision whether to allow your child to be in this study is entirely up to you and your child. Participation is voluntary. Also, if you decide now to allow your child to participate, you will be able to change your mind later and withdraw from the study.

There will be no penalty or loss of health care benefits if you decide not to allow your child to be in the study or withdraw from the study later. If the researcher or your doctor feels it is in your child's best interest, they may choose to end your child's participation in this study at any time prior to completion of the study

The researcher will provide you with additional information as it becomes available, that may affect your decision to continue in the research study.

In addition, the sponsor may choose to end the study at any time, for reasons unrelated to health care.

8. Medical Treatment/Payment in Case of Injury
We do not expect any unusual risk in this research study. If an unexpected injury occurs as a result of your child's participation in this study, Lifespan will provide your child with what it considers fair and appropriate treatment for that injury,

Study Volunteer Initials

without charge to you. Lifespan will not, however, provide any money or other payment for this injury. Signing this consent does not reduce or revoke any of your legal rights. For more information regarding this provision, please contact *********in the Office of Research Administration at *********.

.

9. Rights and Complaints

If you or your child have any complaints about your child's participation in this study, or would like more information about the rules for research studies, or the rights of people who take part in those studies, you may contact *********, anonymously if you wish, in the Lifespan Office of Research Administration, telephone number *********

Study Volunteer Initials

I ACKNOWLEDGE THAT I HAVE READ THE ABOVE EXPLANATION OF THIS STUDY, THAT ALL OF MY QUESTIONS HAVE BEEN SATISFACTORILY ANSWERED, AND I GIVE PERMISSION FOR MY CHILD TO PARTICIPATE IN THIS RESEARCH STUDY.

Signature of parent/guardian Date

Signature of parent/guardian Date

I AGREE TO PARTICIPATE IN THIS STUDY

Signature of study volunteer (child) Date

Age of study volunteer (child)

IF STUDY VOLUNTEER IS UNABLE TO SIGN OR EXCEPTION TO ASSENT IS SOUGHT, PLEASE EXPLAIN:

I ACKNOWLEDGE THE PROCESS AND/OR SIGNATURE OR STATEMENT SET FORTH ABOVE

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

Study Volunteer Initials

I CERTIFY THAT I HAVE EXPLAINED FULLY TO THE ABOVE PARENTS AND PATIENT THE NATURE AND PURPOSE, PROCEDURES AND THE POSSIBLE RISK AND POTENTIAL BENEFITS OF THIS RESEARCH STUDY.

Signature of researcher or designate Date

Consent form copy: study volunteer medical record researcher other(specify)

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