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

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

The researcher will explain the purpose of the study. He or she will explain how the study will be carried out and what you 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 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 be in the study, please sign and date this form in front of the person who explained the study to you. You will be given a copy of this form to keep.

1. Nature and Purpose of the Project

You are 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. You have been selected for this study because you report good health and have some experience drinking alcohol. You 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 you are studied at home on a fixed sleep schedule. During the next 2 weeks you are studied in the laboratory on 5 nights, not all of which are consecutive. In the laboratory, your sleep is monitored and you are asked to perform computerized and paper and pencil tests, take brief naps, and take a dose of alcohol mixed in tonic water. You are asked to provide information about any family sleep, medical, substance abuse, or psychological disorder. In addition, you have 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 to complete a series of questionnaires and interviews that allow us to know more about your sleep patterns, alcohol and other substance use, medical history, and family history of sleep, psychological disorders, and alcohol dependence. We also interview your genetic mother and father to find out about their experiences with alcohol and their psychological and medical histories. You also have a medical examination to assure good health and a psychological interview to determine that you are able to take part in the study. A psychologist also interviews you to determine the medical and mental health history of your family. If you are female, you complete a Menstrual Status Form and Menstrual calendar. The forms and interviews take approximately 2 hours to complete.

You come to the sleep laboratory during an evening at the beginning of the study for an orientation meeting. At this meeting you complete other forms, pick up materials for the at-home part of the study, and learn about the study procedures. We measure your height and weight in order to calculate your alcohol dose for the laboratory portion of the study. You also provide a blood sample (about 1 teaspoon) to screen for any liver problems that would be made worse by drinking alcohol and would keep you out of the study. If you are female and capable of childbearing, your blood is also used for a pregnancy test. If we find you are pregnant, we will notify you and you 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, you keep a strict schedule set by the study director that includes 8.5 to 9 hours of sleep every night, complete sleep diaries every morning and evening, telephone the sleep lab each evening and morning to report bedtimes and risetimes, and wear 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. You wear the actigraph all the time except when it might get wet or subjected to physical shocks. A member of the sleep laboratory staff calls you 1-3

times a week with a reminder to complete sleep diaries and to follow the sleep schedule. You also wear 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.

You come to the laboratory during the daytime at the end of the first week. We test your actigraph to make sure it is working and go over your diary with you. At the end of the second week, you come to the sleep lab on the campus of Butler Hospital in the morning to drop off the actigraph and diary, then return in the late afternoon according to the schedule provided by the laboratory for the first laboratory night. On this first laboratory night, you are given a standard meal and then you have sensors and electrodes attached for sleep and body temperature monitoring (described below). You give saliva samples (less than one teaspoon each) at set intervals during the evening until about one-hour past your 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. You also perform brief (15-30 minutes) testing at intervals during the evening with computerized and paper and pencil performance and driving simulation tests, and fill out rating scales of sleepiness and mood. You also provide a urine sample, which will undergo toxicology screening. If we find a positive drug test, we will notify you; we will otherwise keep the information confidential within the limits of the law. In the morning you eat breakfast, the electrodes and sensors are removed, and you leave the laboratory for the day.

You return 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. You keep the fixed sleep schedule this entire time. For all of these overnight sessions, you come to the laboratory in the morning to drop off the actigraph and diary, then return in the late afternoon according to the schedule provided by the laboratory. You are given a meal, provide a urine sample for toxicology testing, and are prepared for sleep and body temperature recording. During the evenings you undergo performance testing and are asked to drink 3 glasses of tonic water and ice over a timed interval while you are seated alone your bedroom. These drinks contain either a small or moderate dose of alcohol; on some nights you will get a small dose and on other nights a moderate dose of alcohol. For comparison, the highest dose is calculated by your 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 you are asked to rinse your mouth with mouthwash and after consuming the alcohol dose, you remain seated and provide breath samples from a breathalyzer at 30-minute intervals. You will not be informed of the results of the breath tests until after the end of the study.

On nights 2 and 3, you go to bed and get up in the morning at the usual time as set by your schedule. On nights 4 and 5 you stay up longer, seated in bed, to continue performance and driving simulation testing, provide saliva samples, and take a series of small naps.

Because you stay up late on nights 4 and 5 you will lose some sleep and may be a bit sleepy the next day**.**

On all nights you are not in the laboratory, you follow the sleep schedule assigned to you. You are 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 you during the laboratory portion of the study. You must call the sleep laboratory before taking any medication (for example, aspirin, antihistamines, and so forth).

When you are in the sleep laboratory, sleep and daytime functioning are monitored using standard sleep laboratory procedures. Small electrode sensors are attached to you 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 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. You place 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. You are asked to check the probe by feel at intervals to determine that it remains in place. The monitoring system is portable so you 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 chest and abdomen to measure breathing movements and beside your nose and mouth to measure breathing airflow. Another sensor is taped on one finger to measure the amount of oxygen in your blood. [No blood is taken for any of these measures.] These latter measures allow us to evaluate your 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 face, scalp, shoulder and side remain on for the entire study, except when you are bathing.

At the end of the study, you participate in an interview session with a psychologist to provide you with information about alcohol and its use and abuse.

Your safety requires that you remain 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 breath alcohol level to be close to zero. If it is necessary that you leave the laboratory at any time before the breath alcohol level is close to zero, we ask that you remain until you see the study director (Dr. Carskadon) or the medical consultant. If it is necessary that you leave the laboratory at any time before the breath alcohol level is close to zero, a staff member will accompany you (usually by taxi) until you are in a safe environment. On any

night you will be receiving a dose of alcohol, you are not permitted to drive yourself to the laboratory. If you cannot get a ride, the laboratory will provide transportation by cab.

You receive $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 have questions about study procedures you may contact Mary A. Carskadon, Ph.D. at ********.

3. Discomforts and Risks

Because you have told us that you have 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 you may experience some stomach discomfort and may vomit. We do not know whether the alcohol consumed in this study increases the risk for future alcohol abuse or 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 you become pregnant during the at-home portion of the study, you must inform the study director. You will not be able to continue in the study.

Your behavior is observed and monitored carefully while in the sleep laboratory, and you are not permitted to do any activities that might be harmful.

Before you do 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.

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 give us about illegal substance use 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 you to be irritable and sleepy the next day. Your behavior will be observed while in the lab, and you will not be permitted to do any activities that might be harmful to a sleepy person.

4. Benefits

You have a physical examination, and an evaluation of your sleep is performed as part of the project; you are fully informed if any abnormalities appear. You may learn about sleep and scientific research. You may enjoy being a participant in scientific research. You are given information about alcohol and its use and abuse. Otherwise, we cannot promise that you 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 records from this study will be treated as confidential medical records. The records will be safeguarded according to the policy of the Lifespan institution. 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 name and the fact that you were in the study will be kept confidential.

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

7. Refusal/Withdrawal

The decision whether to be in this study is entirely up to you. Participation is voluntary. Also, if you decide now 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 participate, or if you withdraw from the study. If the researcher or your doctor feels it is in your best interest, they may choose to end your participation in this study at any time prior to the 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 participation in this study, Lifespan will provide you with what it considers fair and appropriate treatment for that injury, without charge to you. Lifespan will not however, provide any money or other payment if this happens. 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 have any complaints about your 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 AGREE TO PARTICIPATE IN THIS RESEARCH STUDY.

Signature of study volunteer/authorized representative* Date

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

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

I CERTIFY THAT I HAVE EXPLAINED FULLY TO THE ABOVE 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 study volunteer, please explain below.