

<b>Affiliate</b>	<input type="checkbox"/> Rhode Island Hospital	<input type="checkbox"/> VNA of Rhode Island
	<input type="checkbox"/> The Miriam Hospital	<input type="checkbox"/> Hospice Care of R.I.
	<input checked="" type="checkbox"/> Bradley Hospital	<input type="checkbox"/> 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  
(Parent Interviews of Adult Participants)

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

Your son or daughter has been 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 effects 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 are being asked to participate in this study because your son or daughter has agreed to be in the study. Your participation will only include an interview by a researcher in which you will be asked about your family's experience with alcohol and your psychological and medical history. This study is sponsored by the National Institute on Alcohol Abuse and Alcoholism.

2. Explanation of Procedures

You will be interviewed in the Bradley Hospital Sleep Research Laboratory or in a place of your convenience. If you live outside of the Providence area, you may be interviewed over the phone. During the interview you will be asked questions about medical and psychological health as well as questions about your experiences over your lifetime with alcohol and the experiences of your parents, your siblings, and your children. The interview will take about 45 minutes.

You receive \$10 for your time and effort.

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

3. Discomforts and Risks

The interview is a routine, standardized interview for psychology research and poses 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.

4. Benefits

You will receive no direct benefits from participating in this study. You may enjoy being a participant in scientific research. 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 \*\*\*\*\*

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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.