

Affiliate	<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

Adolescent Assent to Participate in a Research Study

Committee #

Name of Study volunteer

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

In this study we are trying to find out whether there are differences in the effects of small or moderate doses of alcohol on sleep, performance, sleepiness, and mood between teenagers with parents who have had difficulties with alcohol and teenagers with parents who haven't. We are also interested in differences between teenagers and adults. This study lasts four weeks and includes five sleepovers spent in the Sleep Research Laboratory.

Before the study begins you and your parents fill out some forms and answer some questions about sleep, alcohol and drug use, and medical history. You also are examined by a doctor to make sure you are healthy.

When the study begins, you and your parents come to the sleep laboratory to learn more about what you will do in the study. You and your parents complete some forms and you get your activity monitor and diary and learn how to use them. The activity monitor is a device that records your activity levels. It is very similar in size to a wristwatch and is not very noticeable. You also give a blood sample (about 1 teaspoon) for some tests of your liver. If you are a girl, we also test this blood to make sure you aren't pregnant. If we find you are pregnant, we will tell you and you will not be able to be in the study. We will not tell your parents unless you give us permission to do so. This meeting lasts about 45 minutes.

During the next four weeks you go to bed at a time we tell you every night and get out of bed at a time we tell you every morning, wear the actigraph all the time (except when it might get wet or hit against something). You must not use any nicotine products (like cigarettes or tobacco), illegal drugs, alcohol, or eat or drink anything containing caffeine (including chocolate). You must call the sleep lab before you take any medicine (even aspirin or antihistamines) and you cannot take naps. You fill in your diary every morning

just after you wake up and every evening just before going to bed. You wear eye shades during the night every night. You telephone the sleep lab every morning and evening to report your bedtime and risetime.

At the end of the first week you come to the sleep lab during the daytime so we can check your actigraph and diary.

At the end of the second week, you come to the sleep lab and stay there overnight. You will have a meal and then have sensors called electrodes attached to your head, face, and other places on your body so that we can record the signals coming from your brain and body while you sleep. The electrodes are attached to your head with a sticky solution called collodion and dried with compressed air. Other electrodes are taped on your face, shoulders, side, and legs. It does not hurt much to have electrodes attached or removed. You also wear a rectal temperature sensor overnight. We will give you one of these sensors to take home and practice inserting at the beginning of the study so that you are comfortable putting it in when you are in the laboratory. You place the sensor about 4 inches into your rectum. If you have trouble inserting it, someone can help you. The sensor does not hurt you, and after it is in a short time you will probably not notice it is there. Small pieces of tape will hold it in place and we will ask you to check that it is in place several times during the evening. You also complete some forms, give saliva samples, and take some short tests. Some of the tests are paper and pencil tests, some are on the computer, and some are driving simulation tests. You give about 14 saliva samples during the evening by chewing on small pieces of cotton for about one minute at a time. You also give a urine sample that we will test for drugs. If we find signs of drugs in your urine we will tell you but will not tell your parents unless you give us permission. You sleep overnight in the sleep lab and leave in the morning after breakfast and after the electrodes are removed.

The next two nights you return to the sleep lab for overnight sessions that are about the same as the first night. On these nights you also drink 3 glasses of tonic water while you are sitting alone in your bedroom. These drinks contain either a small or moderate dose of alcohol. On one night you get a small dose and on another you will get a moderate dose but you will not know which dose you are getting. Before and after drinking the drinks you rinse your mouth with mouthwash. You also breathe into a small machine called a breathalyzer several times during the evening.

About a week after the first three laboratory nights, you come back for 2 more overnight sessions. These nights are very similar to your other overnight stays with the saliva samples and tests. You will also be given drinks containing alcohol on these 2 nights. You stay up a little later on these two nights, and you may be a little sleepy on the days after these nights.

You must remain in the laboratory after consuming any alcohol until we can tell that your alcohol level is back to normal. It may take up to 6 hours for this to happen. If you absolutely have to leave the laboratory before this time we will call your parent to pick

you up. You will not be allowed to drive yourself to or from the laboratory on nights you receive alcohol. If you cannot get a ride, we will provide you with transportation by cab.

At the end of the study you have a interview session with a psychologist about alcohol.

You receive compensation for your time and effort in completing the study. Successful completion means that you wore the actigraph, completed the daily diary, followed the sleep schedule and rules about what you couldn't eat, drink or take, and finished the parts of the study in the laboratory. For completing the study you receive \$10 for the 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 whole study. The total amount you receive for completing all the study is \$630.

If you have questions about study procedures you may call Mary Carskadon, Ph.D. at
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This is not a treatment study. Participation in this study will not affect any treatment that you are currently receiving.

Alcohol is a toxin and it is possible that you may have some stomach discomfort and may vomit, but this risk is very slight. Alcohol may also be harmful to an unborn fetus. That is why you cannot be in this study if you are pregnant. If you are sexually active, you must use a form of contraception that we will approve. If you become pregnant during the 4 weeks the study lasts, you must let us know immediately.

The blood test may cause some slight pain and you may have a bruise where the blood is drawn. Some of the questions we ask may make you uncomfortable. You do not have to answer any questions you don't want to and if something makes you very uncomfortable we will get someone to help you. You may be sleepy on some days after your overnight lab sessions. You should be extra careful on those days.

The research team may talk about this study with your parents or guardian, but not with anyone else unless your parents, your guardian, or you say it is OK. You need to know, however, that if you tell us that you are going to harm yourself or someone else, we have to by law tell your parent or guardian and/or the authorities in order to keep people safe.

Your mom, dad, and/or guardian know about this study and think that it is OK for you to be in the study. If you want to be in the study, you can tell the researcher and sign on your parent's form. If you don't want to be in the study, it is OK to say no. No one will be upset with you. Also, if you agree to participate now, you can decide to stop being in the study any time you want, and nobody will be upset with you.

If you have any complaints about being in this project, you can call Kathy Handshaw in the Office of Research Administration, at (401) 444-6246