Informed Consent Form

NCT03449095

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- ***Experimental Session Consent Friends***

University of Illinois at Urbana –Champaign
Information and Consent for Participation in Research

TITLE: ***Alcohol's Effects on Cognition, Language, and Mood***

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What is informed consent?

Federal regulations require that you are informed about research studies. The following information explains the objective, procedures, risks, benefits, restrictions, and requirements of this research study. Signing this form will indicate that this study has been explained to you, and that you agree to participate in it. The process of reading and signing this form is known as *informed consent.*

Why is this research study being done?

The purpose of this research study is to gain a better understanding of the effects that alcohol has in social drinkers and to examine how certain factors such as drinking patterns, gender, personality, and age may be related to aspects of drinking in social drinkers. Knowledge of how these factors may influence alcohol's effects in social drinkers may contribute to a more comprehensive understanding of factors that contribute to drug addiction and its treatment. In addition, the results of this research will be used to validate transdermal technology for the measurement of alcohol consumption, which may ultimately be useful for the treatment of problematic drinking. Importantly, all information collected from you will be assigned a unique coded number. No data collected will contain your name or other personal information.

Who is being asked to take part in this study?

You are being asked to participate because you are a social alcohol drinker. People invited into this study are males and females, between 21-30 years of age, and fluent English speakers. The study is being performed on a total of 2,000 individuals.

What procedures will be performed for research purposes?

If you agree to participate in this study, you will take part in one laboratory session, during which you will be administered either an alcoholic or a control beverage. You will need to refrain from alcohol for 12 hours and other drugs for 24 hours before your session, and refrain from eating for 4 hours. Further, all members of your friendship group who were scheduled for the experimental session will need to attend, or the session will need to be rescheduled. During this session, you will wear the Secure Remote Alcohol Monitoring System (SCRAM). The SCRAM is a lightweight device that is worn discretely around the ankle and monitors your Blood Alcohol Content (BAC) at regular intervals through your skin. Your BAC will not be displayed on these devices at any time but is stored securely in a monitoring facility, separate from any of your identifying data. Depending on your condition and your rate of alcohol absorption, this session will last approximately 6-9 hours.

1. When you arrive for the session, a breathalyzer test, which takes approximately 2 minutes, will be used to ensure that your BAC is 0. If your BAC is greater than 0 when you arrive you will not be allowed to take part in this study. If you are female, you will be asked to take a urine pregnancy test.

2. Next, you will be fitted with the SCRAM transdermal sensors. While these sensors establish baseline readings, you will complete a series of questionnaires about your background, your current and past drinking patterns, your mood, and your thoughts and attitudes about drinking alcohol and other non-alcohol factors.

4. If you are assigned to the alcohol condition, we will then provide you with a dose of alcohol designed to produce a BAC of .075%, which is just under the legal limit for driving a car. The drink is one part 100 proof vodka and 3 parts juice/soda. We will monitor your BAC throughout the study using breathalyzer tests, and you will be asked to report how intoxicated you feel. On non-alcohol (control) sessions, you will drink an equivalent volume of juice or soda. The beverage administration phase will last approximately 40 minutes.

5. After the beverage phase, you will complete some tasks and activities relevant to your thoughts, attitudes, and social experience. Also, your brainwaves will be recorded while you view or listen to stimuli and perform tasks. The electrical responses of the brain can be seen in the electroencephalogram (brain waves) recorded from electrodes that make contact with your scalp, face, and neck. The brain waves are measured with standard polygraph machines which are designed to make this procedure harmless. Some of the electrodes will be embedded in an elastic cap that you will wear, and others will be attached individually with sticky electrode collars. Your skin will be cleaned beneath each electrode and gently scraped using a blunt needle or sack in order to remove any dry skin. A gel (similar to hair gel) will then be applied, which allows, the electrode to make contact with your skin. The gel will be wiped off of your skin and hair after the experiment, and any residual gel will wash out with soap and water. The elastic cap varies in how comfortable it is for different people, we will make every effort to make the cap as comfortable as possible for you. If you find it too uncomfortable at any time during the experiment, let us know and we will adjust it.

6. You will be told about the study and be permitted to leave. If assigned to the alcohol condition, you will need to remain in the laboratory until your BAC drops below a value of at least .03% and your transdermal alcohol levels begin to descend. This means that you'll have to stay in the lab for several hours after alcohol-administration (for example, until 7pm-8pm, depending on how long it takes your BAC to descend). Following alcohol sessions, you will not be permitted to drive or to operate any machinery following the experiment. If you do not walk, you will receive paid public transportation to and from the experiment.

After your participation in this study is completed, we may contact you with opportunities to participate in follow-up interviews and/or additional research activities, involving separate informed consent procedures. We may use a variety of means to contact you, including email, text, phone, social media, secondary contacts (friends or names provided by you), physical mailings, or in-person visits. If you prefer not to participate in follow-up assessments and wish not to receive more communications from our lab, you can notify us at any time.

Monitoring/Follow-up Procedures:

Procedures performed to evaluate the effectiveness and safety of the experimental procedures are called "monitoring" or "follow-up" procedures. For this research study, the monitoring/follow-up procedures include:

Immediately following completion of the experimental procedure, an experimenter will repeat the rationale for this study and will give you the opportunity to ask questions regarding the procedures in this study and/or express any concerns you may have.

What are the possible risks, side effects, and discomforts of this study?

There are risks for persons who choose to participate in this experiment. This is because the use of any drug, including alcohol, carries risk. In this case there is a slight risk that our dose of alcohol, while targeted to be approximately equal to the legal limit for driving a car, could lead you to feel unwell (e.g., nausea). The prevalence of individuals feeling unwell using the drinking procedures in this laboratory is rare, occurring in less than 1% of people (less than 1 out of 100 people). A number of steps are taken to reduce what risk remains. First, we do not allow especially light drinkers or persons taking medication that could interact with alcohol, who are most likely to experience adverse reactions to alcohol, to participate in this study. Also, you will consume your drink over a 30-min period, rather than the 20-min period often used in similar studies. If you become ill, or if the experimenter judges you to be experiencing nausea, the experiment can immediately terminate. You still will remain in the lab until your BAC reaches a minimum of .03%, and be escorted to a nearby hospital (Carle Foundation Hospital, 611 W Park St, Urbana, IL), if necessary. Note that the exact same alcohol administration procedures have been used with over 1,000 participants at other institutions, and medical attention has never been necessary. The University of Illinois does not provide medical or hospitalization insurance coverage for participants in this research study nor will the University of Illinois provide compensation for any injury sustained as a result of participation in this research study, except as required by law.

Another potential risk is that you may drive an automobile in an impaired condition due to alcohol consumption. To minimize this risk, you will be asked not to drive to or from the experimental session, and you will not be able to leave the laboratory until your BAC is below a minimum of .03%, a level that is half of the level at which it is illegal to drive an automobile in the state of Illinois. You will also be instructed to drink no alcohol, and to use no other drugs, after returning home at the end of the experiment, and not to drive a car or operate heavy machinery until the morning after you participate.

If you are assigned to receive the electroencephalogram, the tape, gel and scraping procedures used to attach the electrodes may irritate some people's skin slightly, but any residual skin irritation will subside within a day or two.

The risks from the experimental procedures are no greater than those ordinarily encountered in everyday life.

What are possible benefits from taking part in this study?

This project will benefit scientific knowledge. In particular, the results of this study will help us understand why people consume alcohol and who might be at risk for developing a problem with alcohol. There will be no direct benefits to you as a result of participating in this study.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?

You will be promptly notified if any new information develops during the conduct of this research study, which may cause you to change your mind about continuing to participate.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?

Neither you, nor your insurance provider, will be charged for the costs of any of the procedures performed for the purpose of this research study (i.e., the Screening Procedures or the Experimental Procedures).

Will I be paid if I take part in this research study?

You will be paid a total of $80 if you and your friends complete this study. You will also receive a $20 no-cancel bonus if you don't cancel or reschedule the initial appointment you made with our lab.

How will you protect my privacy and the confidentiality of my data?

All records related to your involvement in this research study will be stored in a locked file cabinet and a password protected computer. Your identity on these records will be indicated by a case number rather than by your name, and the information linking these case numbers with your identity will be kept separate from the research records. Your de-identified data may be

made publicly available without requesting additional consent. Only the researcher listed on the first page of this form and her staff will have access to your research records.

In general, the research team will not tell anyone any information about you. When this research is discussed or published, no one but the research team will know that you were in the study. However, laws and university rules might require us to allow one or more of the following people or groups to see or copy information about you, including your signed consent form – a) The university committee and office that reviews and approves research studies, the Institutional Review Board (IRB) and Office for Protection of Research Subjects, and b) University auditors and other personnel responsible for oversight of research; and c) State auditors.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information. The fact that you are participating in a research study and that you are undergoing certain research procedures (but not the results of the procedures) may also be made known to individuals involved in insurance billing and/or other administrative activities associated with the conduct of the study.

Is my participation in this study voluntary?

Yes! Your participation in this study is completely voluntary. You may refuse to participate in this study, or you may stop participating at any time, even after signing this form, and this decision will not affect you or how you are treated. If you choose to withdraw after you've been administered alcohol, we do not recommend that you leave the laboratory before your BAC drops below .03%—a threshold which has been set with your safety in mind. You may also skip questions on measures if you do not feel comfortable responding to them, although, depending on the measure, the decision to skip questions may impact your eligibility

for study participation.

May I withdraw, at a future date, my consent for participation in this research study?

You may withdraw, at any time, your consent for participation in this research study. Any identifiable research information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent will continue to be used and disclosed by the investigators for the purposes described above. You may also be removed from the study by the investigators in the event that you no longer meet the eligibility criteria. The decision to participate, decline, or withdraw from participation will have no effect on your grades at, status at, or future relations with the University of Illinois.

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

If I agree to take part in this study, can I be removed from the study without my consent?

It is possible that you may be removed from the research study by the researchers if, for example, you do not follow the instructions given to you by the investigator, or if they learn that you have provided inaccurate information concerning your current level of alcohol use or the status of your physical health, or that you fall outside of the specified age-range of 21 to 30 years.

How can I get more information about this study?

If you have any further questions about this research study, you may contact the Principal Investigator, Dr. Catharine Fairbairn, at (217) 265-6767.

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VOLUNTARY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researcher listed on the first page of this form.

If you feel you have not been treated according to the descriptions in this form, or if you have any questions about your rights as a research subject, including questions, concerns, complaints, or to offer input, you may call the Office for the Protection of Research Subjects (OPRS) at 217-333-2670 or e-mail OPRS at irb@illinois.edu

I certify that I am at least 21 years of age and that I have read and understand the above consent form and voluntarily agree to participate in this study. A copy of this consent form will be given to me.

Participant's Signature	Date
Participant's Printed Name	
Person Obtaining Consent Signature	Date
Person Obtaining Consent Printed Name	