CONSENT TO PARTICIPATE IN RESEARCH
Brown University

TITLE:	Alcohol Effects on Brain and Immune Function
PROJECT DIRECTORS:	Mollie Monnig, Ph.D. Peter Monti, Ph.D.
PHONE #:	Dr. Monnig: 401-863-3491; Dr. Monti: 401-863-6661

You are being asked to take part in a research study at Brown University. This study is covered by the rules and regulations of Brown University. The investigators are receiving a grant from Brown's COBRE Center for Central Nervous System Function to support this research.

The first step of participating in a research study is informed consent. First, the researcher will explain the study and answer any questions you have. Next, you will be asked if you will participate.

Please read this form carefully. This form explains:

- How the project is carried out;
- What you will be asked to do;
- The possible risks and benefits to you.

It is important for you to understand this information before agreeing to participate.

If you decide to participate in this study, please sign this form in front of the researcher. Signing this document means that you understand the information it contains and that you agree to participate.

1. What is this study about?
This study investigates how alcohol affects the brain and the immune system. We will examine whether changes in immune function and the brain occur after drinking alcohol.

2. What will be done?

TODAY: SCREENING (up to 4 hours)

The purpose of today's session is to determine if you are eligible for the study. It will take up to 4 hours.

- Today's session will take up to 4 hours. You will be paid up to $60 for your time and effort. If you are not eligible to complete all of today's session, you will receive a pro-rated payment of $15/hour.
- You will be asked questions about your alcohol use, drug use, medical history, and mental health.
- You will be given tests of mental abilities, such as memory and reaction time.
- Your height, weight, pulse, and blood pressure will be measured.

- A urine sample will be taken for drug testing. For females, the urine sample will be tested for pregnancy hormones.
- You will be asked to breathe into a tube that measures the amount of alcohol on your breath. If there is alcohol on your breath today, we may need to re-schedule your appointment.
- If you are eligible for the rest of the study and decide to participate, we will schedule a time for you to return.

SECOND VISIT: THE LAB STUDY (up to 8 hours)

If you are eligible for the rest of the study, there will be one more session ("lab study") that will last up to 8 hours. Please agree to participate ONLY if you are willing and able to return for the lab study. That session will be scheduled within the next 4 weeks on a day that is convenient for you.

Before your lab study:

- You will be asked **to not use alcohol, drugs, and some over-the-counter medications for two days** before the lab study. Exceptions are made for **some medications such as birth control, which you should continue to use as prescribed**.
- You will be asked **to not eat or drink anything except water for TWO HOURS** before your appointment time.
- We will arrange for a taxicab to pick you up and take you home. For safety reasons, **you must not drive**. The study will pay for all taxi fares.
- If you do not follow these instructions, your appointment may need to be rescheduled.

During your lab study:

- The visit will last all day (up to 8 hours). You will be paid $120 for completing it.
- First, you will receive an MRI scan on the Brown University campus. You will be asked to lie still for about one hour in the MRI scanner. MRI uses a powerful magnetic field to take an image of your brain. MRI and associated risks are described in the attached document titled "MRI Research Facility Informed Consent Addendum."
- After the MRI scan, you will come to the lab. You will be asked to drink a beverage. The beverage may or may not contain alcohol.
    - The researcher will NOT be able to tell you whether or how much alcohol is in the beverage.
    - You may feel mildly or moderately intoxicated, or you may feel no different.
- **Up to 6 blood samples** will be drawn by a needle from your arm.
    - An IV catheter will be used for the blood draw. This device can help to reduce discomfort by avoiding multiple needle-sticks. An IV catheter is a small, flexible tube that will be inserted into your arm vein. It will remain in your arm for approximately 4 hours to allow access to your vein for blood draws. If there are technical difficulties with the IV catheter, or if it makes

you uncomfortable, a different blood draw device such as a winged infusion set ("butterfly needle") may be used.
    - The total amount of blood taken is up to 100 ml (3.4 oz, or 7 tablespoons). As a comparison, the volume of a standard blood donation is about 450 ml (15 oz).
- You will be asked to complete some **questionnaires on paper and by computer**. You will be asked whether you are having various sensations, for example, "sleepy" or "excited."
- You will be given **tests of mental abilities**, such as memory and reaction time.
- Your basic vital functions may be monitored periodically for safety.
- After about four hours of this procedure, you will be given food and non-alcoholic drinks.
    - A list of food ingredients will be provided. Please review the list carefully if you have any food allergies.
- Next, you will be taken to receive a second MRI scan.
- After the second MRI scan, the lab study will be complete. You will receive payment at this time. In addition, the researcher will provide further explanations about the study. This process is called "debriefing." You will have the opportunity to ask questions and provide feedback during the debriefing.

3. What are the risks involved with being in this study?

- Risks of MRI scan. The researcher will provide you with the document titled "MRI Research Facility Informed Consent Addendum." That document explains risks associated with MRI scanning in this study.
- There is some risk to your privacy. The research team takes many precautions to protect the privacy of your information. However, no system of protection is 100% guaranteed.
    - Minimizing risk*:* The information you give us will be stored on secure and encrypted computer networks. Your information will be stored with a code instead of your name.
- Drinking alcohol has risks. You may be given alcohol in the lab study. The risks of drinking alcohol include: dizziness; confusion; loss of coordination; nausea and/or vomiting; injury due to slips or falls; adverse interactions between alcohol and other drugs you are taking; worsening of medical problems (e.g., liver or heart disease, ulcers); worsening of pre-existing alcohol problems; embarrassment due to disinhibited behavior.
    - Minimizing risk*:* The researcher will review your medical history and medication use with you. **It is very important to tell the researcher every medication you are taking.** You will be asked to sign a form to acknowledge that the potential for medication interactions has been discussed with you.
    - Minimizing risk: You will be seated in a comfortable and private area. The researcher will monitor your breath alcohol content and possibly your vital signs as a safety precaution. The researcher will escort you during any activity that involves significant amounts of walking (e.g., trip to the

restroom). You must have two breath alcohol readings ≤ .02% before leaving the laboratory.

- You will be asked to share personal, private information. The study asks questions about sensitive subjects, such as alcohol use, drug use, medical problems, and psychiatric symptoms. You may feel uncomfortable or embarrassed.
    - Minimizing risk*:* You are free to not answer any question you do not wish to answer.
- There are physical risks from standard blood draw procedures. Risks include infection, pain or discomfort, hematoma (i.e., collection of blood under the skin), excessive bleeding, nerve damage, and vasovagal reaction or fainting.
    - Minimizing risk*:* This study follows best practices for blood draw procedures. The research staff will use an IV catheter set to avoid multiple needle-sticks. Sterile instruments, disinfecting agents, and non-latex materials will be used. **Individuals who are very sensitive to the sight or thought of blood, needles, or related items should not participate in this study.**
- Alcohol causes harm to an unborn fetus. If you are female and engage in unprotected intercourse, there is a chance of becoming pregnant. Although you will be given a urine pregnancy test before starting the study, there is a small chance that you could be pregnant but still have a negative test.
    - Minimizing risk*:* It is extremely important for women to use effective birth control if engaging in sexual intercourse with a man. **Women who are unwilling or unable to comply with this condition are not eligible for this study.**

Study termination: You have the right to stop participating in this study at any time. During the lab study, you can decline to drink the beverage provided to you. If you decide to terminate participation, you will be paid for your participation up to that point. If you have positive breath alcohol, you will be asked to wait in a comfortable area until your breath alcohol is less than .02% before leaving. You will be provided with a taxicab home at the study's expense, even if you decide not to complete the study.

4. What are the benefits of being in this study?
We cannot and do not guarantee or promise that you will receive any benefits from this study. The outcome of this study may increase scientific knowledge and help people in the future.

5. Will I be paid for participating?
The total amount for completing both study visits is $180.

Screening (Session 1): You will be paid $60 for completing this session. If you are found to be ineligible before the end of the session, you will receive payment pro-rated at $15/hour.

Lab Study (Session 2): You will be paid $120 for completing the 8-hour lab study.

Transportation: The study will pay for a taxicab to transport you to and from the next session (i.e., the lab study).

6. What happens if I am injured while participating in this study?
We do not expect that you will be injured as a result of participating in this study. If injury occurs, research staff are trained to help you obtain appropriate medical treatment. Emergency services (i.e., 911) may be called. If emergency services are called, you have the right to refuse treatment. If you become injured or ill as a result of participating in this study, you will be responsible for all related costs of care. Reimbursement will be sought first from your insurer, managed care plan, or other benefits program. You will be responsible for any associated co-payment or deductible as required by your insurance. If costs of care related to such an injury are not covered by your insurer, managed care plan, or other benefits program, you may be responsible for these costs.

7. Confidentiality
Your participation and the information obtained during this study are confidential. This information will not be disclosed outside of the research team except under circumstances described below. The research staff will identify themselves as "Brown University" during any communications, such as telephone calls. When we publish or present the results of the study, no names or other identifying information will be used. We will keep your name and other identifying information in a locked location that is separate from your questionnaires and biological data. Data will be identified with a unique code that does not identify you. Only the research team will have access to the key that connects the code to your identifying information.

There are a few important limits on confidentiality. These limits are:
1) Abuse or neglect of a child or elderly person;
2) Imminent risk of harm to yourself or others.

In these instances, reports will be made to the appropriate authorities. In addition, the Institutional Review Board (IRB) at Brown University, which oversees all research with human participants, may review records for quality assurance purposes.

8. What happens if I decide not to participate?
The decision to participate is entirely up to you. There are no negative consequences for not participating. You will experience no penalty or loss of benefits to which you are otherwise entitled. The research team has no alternatives to offer you at this time.

9. What if I start the study but change my mind about participating?
If you decide to participate but change your mind later, you can withdraw from the study at any time. You will be paid for your participation up to that point. Refusing to participate or discontinuing participation will involve no penalty or loss of benefits to which you are otherwise entitled.

10. What if I have questions about the study later?

Questions about this study should be directed to Dr. Mollie Monnig at (401)-863-3491 or the Research Assistant at (401)-863-6640.

If you have questions regarding your rights as a research participant or you have concerns or general questions about the research or about your privacy and the use of your personal health information, contact the Brown University Human Research Protection Program at 1-866-309-2095. You may also call this number if you cannot reach the research team or would like to talk to someone else.

11. Specimen banking

In addition to the main study described here, the researchers (Dr. Monnig and Dr. Monti) are asking for your permission to keep your blood samples in a specimen bank. The purpose is to preserve the blood samples for use in studies that may be done in the future. If you provide consent for this additional part of the study, your samples will be stored in a facility in the United States for an indefinite period, or until they are all used up. The samples will be identified using a code that is not associated with your identity or personal identifying information. The samples may be used in the future for DNA testing or for studies of major diseases or health conditions. The samples may be shared with other qualified researchers, who will not be given access to your personal identifying information. Tests on these samples would be done for research purposes only. Results of the tests would not be made available to you, your family, your employer, your insurance company, or your healthcare provider. Inventions or discoveries resulting from tests using the samples may have the potential to be used for commercial purposes or products. In the highly unlikely event that commercial products are developed from studies using your samples, there are no plans to share the profits with you. The same risks to confidentiality of your other data also apply to samples stored in a specimen bank. It is unlikely but theoretically possible that your privacy could be compromised by a security breach.

If you provide consent for your samples to become part of the specimen bank, you can withdraw your consent at any time. To withdraw your consent, please notify Dr. Monnig in writing at: Dr. Mollie Monnig, Brown University, G-S121-5, Providence, RI 02912. Samples that retain links to identifiers will be destroyed. However, any de-identified or used up samples cannot be destroyed or withdrawn.

PLEASE INITIAL HERE to provide consent for specimen banking: _____

12. Consent to participate

Your signature on this consent form indicates that the following are true:

- You have read and understand the information on this form;
- You have had an opportunity to ask any questions related to the study;
- Your questions have been answered satisfactorily;
- You agree to participate.

You will be given a copy of this form to keep.

I, _____ (print name), have read this consent form and fully understand it. All of my questions have been satisfactorily answered. I agree to participate in this project. I will receive a copy of this completed form.

_____ _____
Signature of participant Date

_____ _____
Signature of researcher Printed name of researcher

Copies to: Participant
Investigator's files