Cover Page

Title:	Acute Neural and Immune Effects of Alcohol in People Living with HIV Infection
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BROWN UNIVERSITY
CONSENT FOR RESEARCH PARTICIPATION

Acute Neural and Immune Effects of Alcohol in People Living with HIV Infection
Version 4 | Date: 12/20/2022

KEY INFORMATION:
You are invited to take part in a Brown University research study. Your participation is voluntary.

- PURPOSE: The study examines the effects of alcohol on the immune system and the brain in people living with HIV infection and in people who do not have HIV infection.
- PROCEDURES: You will be asked to complete assessments of your medical health, mental health, and illegal activity, and to give samples of your blood, breath, saliva, and urine. If eligible, you will be asked to return for a second visit. You will be asked to fast overnight before the visit and will be given meal bars at the visit. Then you will be given a drink that may contain alcohol, fill out questionnaires, perform mental tests, and receive a magnetic resonance imaging (MRI) scan of your brain.
- TIME INVOLVED: There are two study visits. Today's visit will take up to 4 hours and will tell us if you are eligible for the second visit. The second visit takes up to 7 hours.
- COMPENSATION: You will receive up to $125 for today's visit and up to $275 for the second visit, for a possible total of $400 for your time and effort.
- RISKS: Although your information is protected, there is some risk to your confidentiality. Risks of drinking alcohol include nausea, injury, medication interactions, and harm to an unborn fetus. Risks of having your blood drawn include infection, pain, bleeding, and fainting. Risks of MRI scan include injury if there is metal in the body or from pre-existing health conditions.
- BENEFITS: You are not likely to benefit personally from this research. The outcome may increase scientific knowledge and help people in the future.
- ALTERNATIVES TO PARTICIPATION: This is a research study and your participation is voluntary. If you would like to learn about alternatives, you can talk to your doctor about other studies for which you might be eligible.

1. Researchers:
The Principal Investigator is Mollie Monnig, PhD (phone: 401-863-3491). The site investigator at The Miriam Hospital is Karen Tashima, MD (phone: 401-793-7152).

2. What is this study about?
The purpose of this study is to see whether drinking alcohol leads to inflammation in people living with HIV infection.

You are being asked to be in the study because you are a healthy person, either with or without HIV infection; are between the ages of 21-60; are able to drink alcohol safely; and are able to undergo MRI scan safely.

3. **What will I be asked to do?**

Your participation in this study will last up to 4 hours at today's visit (**Visit 1**) and up to 7 hours at **Visit 2**.

VISIT 1

You will be asked questions about your medical history, mental health, alcohol and drug use, and illegal activity. You will complete questionnaires about your social and medical history. For example, you will be asked whether you have used any illegal drugs recently and whether you have had symptoms of serious mental illness. You may skip any question that you do not wish to answer.

Your height, weight, blood pressure, and breath alcohol will be measured. A urine sample will be taken for drug testing. For women, the urine sample will be tested for pregnancy hormones. A blood sample will be taken to test for levels of liver enzymes. The amount of blood taken is up to 50 ml, or about 3.5 tablespoons. A saliva sample will be taken to test for the types of bacteria that are in your mouth. You will be told if you have high blood pressure, or a positive pregnancy test, or very high liver enzymes.

If you are eligible for the second visit, we will schedule a time for you to return. You will be given instructions to follow before the next visit.

You will be paid $125 for completing Visit 1. If you are not eligible to complete all of today's visit, you will receive a pro-rated payment of $35/hour.

VISIT 2

You will be asked to fast overnight prior to Visit 2. At the visit you will be given meal replacement bars and **we will give you a beverage to consume**. The study will have two different groups of research participants. One group will receive a moderate dose of alcohol, and the other group will not. To decide which group you are in, we will use a method of chance. This method is like flipping a coin or rolling dice. You will not know which group you are in. Some members of the research team will know. This information needs to be kept secret so that the study is based on scientific results, not on peoples' opinions. However, we can give this information out if you have a medical emergency.

We will take **blood samples** before and several times after you consume the study beverage. An IV catheter will be used. An IV catheter is a small, flexible tube that is inserted into a vein in your arm. It will remain in your arm for about 4 hours to allow access to your vein. If there are technical problems, or if it makes you uncomfortable, a different device such as a winged

infusion set ("butterfly needle") may be used. The total amount of blood taken is up to 150 ml, or about 10 tablespoons.

You will be asked to complete **tests and questionnaires** on paper and by computer. You will be given tests of mental abilities such as memory and concentration. You will be asked whether you are having various sensations such as "excited" or "sluggish."

After these procedures, you will be given food and non-alcoholic beverages. Then you will receive an **MRI scan** on Brown University main campus. We use MRI to study your brain. This is a non-invasive method of imaging, which means there are no injections, drugs, or radioactive tracers used while you are in the scanner. The brain images are used to answer research questions about how the brain works.

Before MRI, you will fill out a questionnaire about your health. You will be screened for "MR Safety" by answering questions about surgeries you have had and any medical devices or metal your may have on or in your body. The MRI session will last 1 hour 15 minutes, which includes 15 minutes of screening/setup and 1 hour of physically being in the scanner.

You will be paid $275 for completing Visit 2. At the end, you will have the opportunity to ask questions about the study.

4. Will I be paid?

You will receive $125 for completing Visit 1, or a prorated payment of $35/hour if you are not eligible for Visit 2. You will receive $275 for completing Visit 2, or a prorated payment of $35/hour if you discontinue the visit before completing. This will add up to $400 total if you complete both visits.

You also may receive reimbursement for transportation. You must not drive to Visit 2. The study will reimburse you for the cost of transportation if you use a taxicab, a ride-sharing service such as Uber, or public transportation.

Payment and reimbursement will be made using ClinCard, a pre-paid Mastercard that works like a debit card. You will be given one card for the entire time of your participation and this card may be used to pay you in any future Brown University studies that use ClinCard. You will also get information about how to use this card and whom to call if you have any questions. Be sure to read this information, including the cardholder agreement from Greenphire. Money will be added to your card based on the study's payment schedule. You may use this card online or at any store that accepts Mastercard. Please read the FAQ information sheet from your study coordinator for details about the ways you can use the card, some of which may involve fees that will reduce the amount of money on the card. This card is administered by an outside company called Greenphire. Greenphire will be given your name, address, and date of birth. They will use this information only as part of the payment system, and it will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating. If your card is lost or stolen, please call the study coordinator for a free

replacement card. If you request a replacement card from Greenphire directly, you may be charged a fee.

Money will be added to your card based on the study's payment schedule. You may use this card online or at any store that accepts Mastercard. Please read the FAQ information sheet that is given during payment. This sheet details the ways you can use the card, some of which may involve fees that will reduce the amount of money on the card.

If you earn $600 or more from Brown University in a single calendar year (either in one study or across multiple studies), Brown will request your social security number to correctly identify you in the payment system and issue you an IRS 1099 Form. You may also be asked to complete a Form W9. This may affect your taxes. Only payments for being in research studies will be used to decide if you should receive the IRS form. Money for study-related parking, food, and other expenses are not included in this IRS disclosure.

This card is administered by an outside company called Greenphire. Greenphire will be given your name, address, and date of birth. They will use this information only as part of the payment system, and it will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

If your card is lost or stolen, please call the study RA for a free replacement card. If you request a replacement card from Greenphire directly, you may be charged a fee.

5. What are the risks?

There are risks of being in this study. If you experience a study-related injury, illness, or distress, call the Principal Investigator, Dr. Monnig, at 401-863-3491.

- **Sensitive information:** This study asks questions about sensitive subjects, including drug use, medical problems, and psychiatric symptoms. We take many precautions to protect the confidentiality of your information, but no system is 100% guaranteed. Section 7 includes details about confidentiality protections.
- **Drinking alcohol:** Risks of drinking alcohol include dizziness, loss of coordination, nausea or vomiting, injury due to slips or falls, worsening of pre-existing medical problems, and embarrassment due to disinhibited behavior. Alcohol can interact with medications. It is very important to tell the researcher every medication you are taking. Alcohol can cause damage to an unborn fetus. If you are able to become pregnant and engage in sexual intercourse with a male partner, you must use effective birth control to participate in this study.
- **Blood draw:** Risks of blood draw include infection, pain or discomfort, bruising (which could vary in size), and fainting. Serious risks are not common when best practices are used. In this study, a licensed professional will use sterile instruments, disinfecting agents, and non-latex materials for all blood draws.
- **MRI:** There may be some discomfort from being in the MRI scanner because you will be

asked to lie down and be very still for one hour. The research team will try to make you as comfortable as possible before the imaging begins. If you feel claustrophobic or anxious, let the researcher know immediately. MRI scanning risks and discomforts are discussed in further detail in the MRI addendum to this consent form.

The study can be stopped at any time if you tell us that you do not want to continue.

6. What are the benefits?

You may not benefit directly from being in this research study. The outcome may increase scientific knowledge and help people in the future.

7. How will my information be protected?

Your study data, including biological samples, will be coded with an ID number so that it cannot be linked directly to you without knowing the code. Coded study data and your personal information are kept in separate, locked filing cabinets. The file linking the code to personal information is password-protected and accessible only to study staff. This file will be destroyed after data collection is complete so that there will no longer be a link between coded data and your personal information.

The consent process and all study procedures are conducted in private locations. Paper files and computer files are accessible only to study staff. Computer files are stored on Brown University's encrypted, secure servers. Your information is kept confidential, meaning that it is not shared with anyone outside of the study except under the circumstances below:

- Brown University staff sometimes review studies like this one to make sure they are being done safely and correctly. If a review of this study takes place, your records may be examined. The reviewers will protect your confidentiality.
- The National Institutes of Health, which sponsors this study, may review records for quality assurance purposes.
- If you report imminent risk of harming yourself or others, or abuse or neglect of a child or elderly person, these events will be reported to the appropriate authorities.

If you check the box at the end of this form, de-identified data will be kept and used for future research on chronic disease and substance use. This includes your biospecimens. We may share your de-identified data and biospecimens with researchers at Brown or other institutions. Once your data is de-identified, we will no longer be able to identify you and you will not be able to withdraw it from storage.

It is unlikely but possible that biospecimens may be used to generate discoveries or other applications for commercial profit. You will not share in any profit arising from such uses.

To help us protect your confidentiality, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal administrative, legislative, or other proceedings; for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify

you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse or neglect, or harm to self or others.

A description of this clinical trial will be available on http://www.Clinical Trials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

8. Are there any alternatives to this study?

If you would like to learn about alternatives, you can ask your doctor about other studies for which you might be eligible.

9. What if I want to stop?

You do not have to be in this study if you do not want to be. Even if you decide to be in this study, you can change your mind and stop at any time.

If you refuse to participate in or leave the study, your current or future relationship with Brown University, The Miriam Hospital, or your doctor will not be affected.

If you have positive breath alcohol and decide to stop the study, you will be asked to wait in a comfortable area until your breath alcohol decreases to a low level. You will be transported home at the study's expense, even if you do not complete the study.

10. Who can I talk to if I have questions about this study?

If you have any questions about your participation in this study, you can call Dr. Monnig at 401-863-3491 or the Research Assistant at 401-863-6679.

11. Who can I talk to if I have questions about my rights as a participant?

If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050 or email them at IRB@Brown.edu.

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12. Consent to Participate

Your signature below shows that you have read and understood the information in this document, and that you agree to volunteer as a research participant for this study.

You will be offered a copy of this form.

Do you consent for your de-identified biospecimens to be stored, shared with other researchers, and used for future research on links between substance use and chronic disease?

☐ YES ☐ NO

_____

Participant's Signature and Date / PRINTED NAME

_____

Research Staff Signature and Date / PRINTED NAME