COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

YALE UNIVERSITY SCHOOL OF MEDICINE

Study Title: Does Endotoxin Administration Increase Alcohol Consumption in Individuals with AUD?

Principal Investigator (the person who is responsible for this research): Terril Verplaetse, PhD, 2 Church Street South, Suite 201, New Haven, CT or 40 Temple Street, 5B, New Haven, CT.

Phone Number: 203-737-6496

Modified for Alternative Lab Locations and Timing

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to find out about the effects of inflammation on responses to alcohol and alcohol consumption.
- Study procedures will include: **the study eligibility intake, a physical examination, a laboratory session at Church Street Research Unite (CSRU), Clinical Neuroscience Research Unit (CNRU) or our office (Suite 109) at 2 Church Street South or 40 Temple Street, 5B, a phone appointment, and an in-person follow-up appointment.**
- **4** visits are required.
- These visits will take **15** hours total.
- There are some risks from participating in this study; these include **alcohol self-administration, endotoxin (or lipopolysaccharide [LPS]) administration, nicotine withdrawal for smokers of up to an 8-hour period, and the drawing of blood during the physical examination and during the laboratory session.**
- The study may have no benefits to you. **However, we expect that the results of the study will benefit science through increasing knowledge about the effects of inflammation on alcohol use.**
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Why is this study being offered to me?

We are asking you to take part in a research study because **you drink alcohol and are not seeking treatment for drinking**. We are looking for **32** participants to be part of this research study.

Who is paying for the study?

National Institute of Alcohol Abuse and Alcoholism

What is the study about?

The purpose of this study is to find out about the effects of inflammation on responses to alcohol and alcohol consumption. The proposed study will fill a major gap in our understanding of neuronal inflammation and alcohol consumption. This study is not designed to provide treatment to decrease alcohol use.

What are you asking me to do and how long will it take?

If you agree to take part in this study, this is what will happen:

This study will be conducted in two separate phases. If you agree to participate, the first phase is done to find out if you are eligible to participate. This visit is done at 2 Church Street South or 40 Temple Street, 5B, New Haven, CT. During the first interview, you will be asked to fill out questionnaires, mostly about your alcohol use. You will be asked to provide a urine sample to test for illegal drugs. If your urine drug test is positive for illegal substances (i.e., cocaine, downers, opiates), you may not continue in the study. Drug test results will be recorded in study documentation but will remain confidential. You may not use any street drugs while you are participating in this study. You will be asked to complete a breath alcohol and breath carbon monoxide reading. You will also be asked for a heart rate and blood pressure reading. If you are a woman of childbearing age, you must agree to use a reliable form of birth control. This appointment will take up to three hours.

After the interviews and questionnaires, if you are eligible, we will schedule you for a complete physical examination, which will take place at the Central Medical Unit, One Long Wharf, 3rd Floor, New Haven. The physical exam will include an electrocardiogram (ECG), and blood and urine tests, which will take about 1.5 hours of your time. The urine test will include tests for illegal drugs. If you are positive for illegal substances, you will be dismissed from the study. If you are eligible after the physical examination, you will continue to the second phase of the study.

Laboratory session:
The second phase of the research study consists of a laboratory session. The laboratory session will be done at the Church Street Research Unit (CSRU), Clinical Neuroscience Research Unit (CNRU), or our office at 2 Church Street South Suite 109 or 40 Temple Street, 5B. The laboratory session will start at 9:00am and you will be discharged at 6:15pm.

We will ask you not to drink any alcohol for 24 hours prior to these appointments. When you arrive at 9:00am, we will test your breath alcohol level by asking you to blow into a meter. This will tell us if you have remained alcohol free. If you had any alcohol, then we will have to re-schedule your session.

A urine drug test will also be done prior to the laboratory session. If the urine drug test is positive for illegal substances (i.e., cocaine, downers, opiates), you will be dismissed from the study. Drug test results will be recorded in study documentation but will remain confidential. If you are female, we will collect a urine sample for a pregnancy test. Pregnant women may not be in this study.

The study PI (Dr. Verplaetse) and co-investigators (Drs. McKee and Cosgrove) can dismiss a participant or discontinue a lab session at any time should the participant act in an unsafe way (i.e., threatening to staff).

Participants who are deemed to be belligerent by study staff will be immediately discontinued at the discretion of the PI. They will be asked to remain in their room until reaching a safe BAC at which time they will be dismissed. If they continue to behave in a threatening manor, building security should be called to supervise the participant until they can be safely discharged from the CSRU, CNRU, or safely dismissed from our office suite.

Description and order of procedures:
A nurse will place a normal saline lock IV into a vein in one of your arms so that we can draw blood at regular intervals. Once the IV is placed, baseline blood samples will be obtained. You will have blood drawn at regular intervals throughout the course of the day. If you are female, we may also collect blood to assess hormone levels to determine the phase of your menstrual cycle.

You will then be asked to fill out some questionnaires. In addition, vital signs will be taken at regular intervals throughout the course of the day.

After this, you will have a 2-hour rest period where you will be able to read or watch TV.. If you are a smoker, you will have the opportunity to have a 15-minute smoke break during the laboratory session at 10:00am.You may smoke up to 2 cigarettes.. Your cigarettes will then be locked up until you are discharged. E-cigarettes will not be allowed.

After providing you with breakfast we will ask you to be seated in your room. At 10:15am, you will be administered endotoxin or placebo (saline) through an IV. Endotoxin is a substance produced by bacteria to activate your immune system. When endotoxin is injected into a person, the immune system “believes” that bacteria have entered the body, and an immune response happens. Your immune system acts as if you have been infected, although you actually have not been infected. In some respects this is similar to a vaccine. Vaccines also activate the immune system without causing an infection. From prior studies we know that endotoxin causes symptoms similar to the flu, such as chills, body aches, headache, and tiredness. Sometimes it can cause nausea. The effects of endotoxin are very short-lived compared to having the flu; these symptoms will only last 1-3 hours.

You will not be allowed to watch TV or use any electronic devices from 11:00am to 2:15pm.

At 12:00pm, you will participate in a 2-hour alcohol self-serve session. The alcohol self-serve session will end at 2:00pm. We will be drawing blood at regular intervals. You will be asked to fill out some questionnaires. A video camera will be present in the room during this session to monitor your drinking. This means how often you drink and how much you drink. Before the start of the session, you will be asked to complete some questionnaires and rating scales. We will also check your heart and blood pressure and monitor your breath alcohol levels with a breathalyzer throughout the session.

You will be seated in your room and provided with the preferred alcoholic beverage of your choice (e.g., wine, beer, alcohol, mixed-drink). The entire amount will be provided at the beginning of the alcohol self-serve session. The amount of your preferred beverage will depend on alcohol concentration, gender, your height, weight, and age and will be equal to

approximately 8 drinks. During the 2-hour alcohol self-serve session, you can choose to drink as much or as little as you like.

At the start of the session, you will be informed that for each minute you wait to drink, you will earn money. For example, if you delay drinking for 5 minutes, you will earn $1.25. If you delay drinking for 30 minutes, you will earn $6.75. If you decide to drink at any point during the 2-hour alcohol self-serve session, you will not earn any additional money beyond what you already earned. You have the potential to earn $16.20 if you choose not to drink for the entire 2-hour alcohol self-serve session. A table of potential money to be earned per minute will be provided at the start of the session.

The drinks will be removed at 2:00pm at which time the session will be over.

At 2:00pm, a nurse will then remove the IV. Your cigarettes will remain locked up until you are discharged but you will be offered nicotine gum or lozenge. You will be given lunch at 2:15pm. You will be able to relax and watch TV. Breath alcohol and carbon monoxide levels as well as heart rate and blood pressure will be checked once every hour after the drinking session and there will also be questionnaires for you to complete until 6pm.

You will be discharged at 6:15pm. Prior to discharge, a nurse will place a normal saline lock IV into a vein in one of your arms to draw blood. The total amount of blood drawn at the laboratory session is about ½ cup. Your breath alcohol level must be below 0.02% in two independent readings for you to be allowed to go home. If needed, at the end of the laboratory session, participants will be provided with transportation home (i.e., taxi).

We will call you for a phone appointment 1-week after your laboratory session. During this phone appointment, you will be asked to report your drinking and smoking behavior.

As close to 4-weeks after your laboratory session as possible, you will be asked to return to 2 Church Street South or 40 Temple Street for a follow-up appointment. During this appointment, you will be asked to report your drinking and smoking behavior. We will measure your blood pressure and heart rate. At this appointment, you will be provided with a brief motivational interview.

You will be told of any significant new findings that are developed during your participation in this study that may affect your willingness to continue to participate.

What are the risks and discomforts of participating?

1) Alcohol: The amount of alcohol available to you in this study may produce intoxication resulting in unsteady balance, slurred speech, and increased heart rate. During the time that you are consuming alcohol, you will remain seated and under supervision at the session. Individuals who drink this amount of alcohol regularly are at increased risk of having serious problems, such as relationship difficulties, an increased risk of injuries while intoxicated, and negative health consequences. Alcohol is known to contribute to hypertension, produce brain damage, decrease the body's ability to fight disease, increase the risk of certain cancers in the head, neck, and mouth, increase the risk of liver disease, and increase the risk for depression.

Additionally, regular heavy alcohol use may increase your risk for developing or meeting criteria for an alcohol use disorder.

When some individuals stop drinking they experience more severe symptoms like extreme restlessness, nervousness, disorientation, confusion, hallucinations (hearing things that are not here) and seizures, but these are extremely rare. To reduce this risk, individuals with a history of serious withdrawal, individuals who have repeatedly undergone alcohol detoxification, and individuals with other significant medical problems may not be in this study.

Symptoms of alcohol withdrawal will be assessed at each study appointment. If significant alcohol withdrawal is assessed, your participation in the study will be discontinued and you will be referred to treatment.

2) Endotoxin (or lipopolysaccharide [LPS]) administration: This is a substance of the cell wall of bacteria. Endotoxin is sterile and does not cause an infection, however it tricks the body's immune system into reacting as if there were an infection. The dose used in this study may produce a vague feeling of getting sick (or flu-like symptoms) in most subjects. These symptoms will be mild to moderate and only last 1-3 hours. We expect that after receiving endotoxin you may feel mild tiredness, nervousness, reduced interest, reduced appetite, and sleepiness. These symptoms should only last for 1-3 hours and then disappear. Although very unlikely, it is possible that these symptoms last longer. If this is the case, we would monitor you until the symptoms improve (meaning that nursing staff and/or the study PI will ask you about how you are feeling, about any adverse events, and take your blood pressure and heart rate), or refer you for appropriate treatment.

COVID-19 Precaution: Administration of endotoxin in this study may produce fever, a primary symptom of COVID-19. Fever is expected to be short-lived in this study and should only last 1-3 hours. Prolonged fever could be a sign/symptom of COVID-19 infection. If your fever persists after being discharged from the laboratory session, please let study staff know and consult your physician about getting tested for COVID-19.

Endotoxin has been given to over 2,500 human subjects over the past 20 years. Among all these subjects, only 4 experienced serious side-effects. These 4 subjects had a slowing of the heart rhythm which had to be treated, but there was no lasting harm. This happened in four subjects with higher doses of endotoxin (2.5 – 5 times as high as in this study), and only in subjects who were either dehydrated (had too little fluid in the body) or who fainted easily. In this study, we will ensure that you have enough fluid in your body and that you do not have a history of fainting in the past 10 years or any history of unexplained fainting. Importantly, the dose used in this study has never before caused any dangerous effects in human subjects, and no human subject receiving endotoxin at any dose has ever died or suffered any permanent damage. Some changes in blood pressure and heart rate have been found with higher doses, though such changes are unlikely to occur at the dose used in this study. It is possible that you are more sensitive to endotoxin than most people and you could experience an unpredictable reaction. If you have a history of asthma you may be more likely to have a reaction. This is a potential risk with any substance that is introduced into the body, including approved medications that you can buy over the counter. In the very unlikely event that a serious side-effect occurred, it would be treated appropriately. A nurse and research staff will be present during endotoxin administration, and a nurse will be present throughout the entire laboratory session. If you have any symptoms after you go home, you can contact a member of the research staff.

A review of the literature from 2007, describes all studies wherein endotoxin was given to human subjects. All articles were reviewed for any potential adverse effect, morbidity or mortality; however, no long-term morbidity or mortality was reported in these more than 1,000 healthy volunteers. A critical review of all the cases of endotoxin administration in human subjects concludes that endotoxin has been used for well over a century and has proven to be remarkably safe. All available data support that endotoxin administration in healthy human subjects is safe.

Combination of alcohol and endotoxin: The combination of alcohol and endotoxin may further increase tiredness. Endotoxin by itself can increase headache, tiredness, and sometimes nausea, but when combined with alcohol it may further increase these effects. There is also the possibility that endotoxin may alter alcohol intoxication or that alcohol can increase side effects associated with endotoxin. For this reason, we will collect blood samples throughout the alcohol self-administration session and at discharge to determine levels of endotoxin in your body.

3) Nicotine withdrawal: There may be up to a 17-hour period during the laboratory session in which you won't be able to smoke. It is possible that you may experience symptoms of nicotine withdrawal such as craving cigarettes, mild anxiety, restlessness, irritability, difficulty concentrating, loss of energy, and excessive hunger. These are normal symptoms that people get when they do not smoke, and they can be uncomfortable but not life threatening.

4) Blood drawing: At the physical exam, we will draw less than 1/8 cup of blood. For the laboratory session, we will draw about 1/2 cup of blood. This is a minimal risk in healthy subjects. Some people feel "lightheaded" while having blood drawn, but this effect is temporary. Other possible, but less common risks include pain, bruising at the withdrawal site, and fainting. You should not have donated blood in the last 6 weeks or plan to donate blood in the 6 weeks following the study.

In addition, pregnant women may not participate in this study because alcohol may be harmful to an unborn child. The following precautions are necessary if you are female: 1) A pregnancy test will be performed, using a blood sample at the physical exam and a urine sample at the start of the laboratory session. A positive pregnancy test will mean that you will not be able to participate in the study; and 2) If you are breast feeding, you may not participate in the study.

To see if you are eligible for the study, and at every study appointment, a urine sample will be collected to test for the presence of illegal drugs. If the test is positive, you may not continue in the study.

How will I know about new risks or important information about the study?

We will tell you if we learn any new information that could change your mind about taking part in this study.

How can the study possibly benefit me?

This study is not designed to have a direct benefit to you.

How can the study possibly benefit other people?

The benefits to science and other people may include a better understanding of the effects of acute neuroinflammation and stress on alcohol use.

Are there any costs to participation?

You will not have to pay for taking part in this study. The only costs include your time coming to the study visits.

Will I be paid for participation?

You will be paid for taking part in this study.

You can earn up to $506.20 for completing all phases of the study. You will not be charged for any of the tests or procedures conducted to determine eligibility for the study.

You will receive $50 for the initial screening interview to be conducted at 2 Church Street South or 40 Temple Street. If your urine drug screen is positive for illegal drugs or prescription medications not previously reported, you will be dismissed and not receive payment for this appointment.

You will receive $20 for completing the physical exam to be conducted at the Central Medical Unit.

You will receive $50 for endotoxin administration.

Payment for completing the laboratory session will be $350. If you do not complete the laboratory session (for example, if you decide to withdraw from the study in the middle of the laboratory session), your payment will be prorated on an hourly basis.

You can earn up to $16.20 for the laboratory session depending on how long you wait to start drinking.

You will receive $20 for completing the follow-up appointment to be conducted at 2 Church Street South or 40 Temple Street.

Payment for the study is by cash.
You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments.

You will be compensated for parking for study appointments, including your overnight laboratory session. You must show your parking ticket to the Research Staff for verification. Parking tickets will be returned to you, so you can exit the parking lot. You will sign a Parking Voucher for the money received.

To receive payment, you must compete the entire study appointment. If you are dismissed or drop out of the overnight laboratory you will be compensated hourly for your time.

What are my choices if I decide not to take part in this study?

The only alternative is to decline participation in this study.

This study is not designed to provide treatment to decrease alcohol use. During the study if you decide to quit drinking, or if you are currently interested in quitting, we will provide you with a treatment referral and you will not be eligible to participate in this study.

How will you keep my data safe and private?

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute on Alcohol Abuse and Alcoholism which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law about suspected or known sexual, physical, or other abuse of a child or older person, or a subject's threats of violence to self or others. If any member of the research team is given such information, they will make a report to the appropriate authorities.
We will keep information we collect about you confidential. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. For example, we will tell somebody if you we learn that you are hurting a child or an older person.

Participants are referred to using coded numbers and identifiable information is kept within locked cabinets within locked offices. De-identified data is stored on secure servers

We understand that information about you obtained in connection with your health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the principal investigator will get information that identifies you and your personal health. This may include information that might directly identify you, such as your name and date of birth. This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, and this link will be kept secure and available only to the principal investigator or selected members of the research team. Any information that can identify you will remain confidential. All

identifying research materials are kept in locked cabinets and de-identified data is stored on a secure server with limited password protected access. The research team will only give this coded information to others to carry out this research study. The link to your personal information will be kept for 7 years, after which time the link will be destroyed and the data will become anonymous. The data will be kept in this anonymous form indefinitely.

Information about your study participation will be entered into your Electronic Medical Record (EMR). Once placed in your EMR, these results are accessible to all of your providers who participate in the EMR system. Information within your EMR may also be shared with others who are appropriate to have access to your EMR (e.g. health insurance company, disability provider.)

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we would ask you for your permission.

We will also share information about you with other researchers for future research but we will not use your name or other identifiers. We will not ask you for any additional permission.

Identifiers might be removed from the identifiable private information or identifiable biospecimens and, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative.

What Information Will You Collect About Me in this Study?

The information we are asking to use and share is called “Protected Health Information.” It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

- Research study records
- Medical and laboratory records of only those services provided in connection with this Study.
- The entire research record and any medical records held by ***Yale University and Yale-New Haven Hospital*** created from: ***May 15, 2021*** to ***April 30, 2023.***
- Records about phone calls made as part of this research
- Records about your study visits
- Video recordings of alcohol administration session, if authorized
- Audio recordings, if authorized
- Information obtained during this research regarding
    - HIV / AIDS test results
    - Hepatitis infection
    - Sexually transmitted diseases
    - Other reportable infectious diseases
    - Physical exams
    - Laboratory and other test results

- Questionnaires
- The diagnosis and treatment of a mental health condition
- Use of illegal drugs or the study of illegal behavior
- Records about any study drug you received

How will you use and share my information?

We will use your information to conduct the study described in this consent form.
We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- The U.S. Food and Drug Administration (FDA) This is done so that the FDA can review information about ***endotoxin*** involved in this research. The information may also be used to meet the reporting requirements of drug regulatory agencies
- Those providers who are participants in the Electronic Medical Record (EMR) system
- The study sponsor or manufacturer of study drug
- Those individuals at Yale who are responsible for the financial oversight of research including billing and payment
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- Health care providers who provide services to you in connection with this study
- Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan
- Principal Investigator of the study
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Why must I sign this document?

By signing this form, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

However, this is a single/double blinded treatment study and if you sign this permission form, you will not be allowed to look at or copy your study related information until after the research is completed.

What if I change my mind?

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any

time. You may withdraw your permission by telling the study staff or by writing to ***Terril Verplaetse, PhD, 2 Church Street South, Suite 201, New Haven, CT or 40 Temple Street, 5B, New Haven, CT***.

If you withdraw your permission, you will not be able to stay in this study but the care you get from your doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to insure the integrity of the study and/or study oversight.

Who will pay for treatment if I am injured or become ill due to participation in the study?

If you are injured while on study, seek treatment and contact the study doctors, Drs. Julia Shi or Jeanette Tetrault and the study PI (Terril Verplaetse, PhD) as soon as you are able.

Medical treatment will be offered to you for any physical injuries you may suffer as a direct consequence of participation in this research. In case of medical emergency at the CSRU, CNRU, or 2 Church St. South or 40 Temple Street, 911 will be called. Yale School of Medicine and Yale-New Haven Hospital do not provide funds for the treatment of research-related injury. If you are injured because of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of treatment. No additional financial compensation is available. You do not give up any of your legal rights by signing this form. If you suffer an injury during this study, please contact Drs. Julia Shi or Jeanette Tetrault at (203) 781-4640.

What if I want to refuse or end participation before the study is over?

Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

We would still treat you with standard therapy or, at your request, refer you to a clinic or doctor who can offer this treatment. Not participating or withdrawing later will not harm your relationship with your own doctors or with this institution.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part.

The researchers may withdraw you from participating in the research if necessary. At the judgment of the principal investigator (Dr. Verplaetse) and primary co-investigators (Drs. McKee and Cosgrove), you might be dismissed from the study if you repeatedly do not show up, lie about your drinking, smoking or drug use, or act in a threatening or aggressive manner to any research personnel at any point during the study. You will have to withdraw from the study if you become pregnant or imprisoned at any point during the study.

Participants who are deemed to be belligerent by study staff will be immediately discontinued at the discretion of the PI. They will be asked to remain in their room until reaching a safe BAC at which time they will be dismissed. If they continue to behave in a threatening manor, security

should be called to supervise the participant until they can be safely discharged from the CSRU or CNRU or dismissed from our office suite.

What will happen with my data if I stop participating?

You may withdraw or take away your permission to use and disclose your health information at any time. You may withdraw your permission by telling the study staff or by writing to the Principal Investigator, Terril Verplaetse, PhD, at Yale University, 2 Church Street South, Suite 201, New Haven, CT or 40 Temple Street, 5B, New Haven, CT.

If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to ensure the integrity of the study and/or study oversight.

Who should I contact if I have questions?

Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator, Terril Verplaetse, PhD at **203-737-6496.**

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

A description of this clinical trial will be available on *http://www.ClinicalTrials.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.

Authorization and Permission

Your signature below indicates that you have read this consent document and that you agree to be in this study.

We will give you a copy of this form.

Participant Printed Name	Participant Signature	Date

Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date

Request to videotape and audiotape as part of this study

We are requesting your permission to videotape and audiotape you as part of this study. If you agree to the taping, we will use the tapes for research purposes and training within the discretion of Terril Verplaetse, PhD. In addition, we would like your permission to keep the tapes for drinking behavior training and program development. The taping is optional. You may choose to give permission for one or both uses of the tapes, or you may decide not to participate in taping at all. Your decision will not affect your ability to remain in the study.

If you agree to participate, we will keep the tapes in a locked cabinet or on a secured server. To protect your confidentiality, we will not label the tape or file with your name.

I agree that videotape and audiotape may be taken of me as part of the study entitled: Does Endotoxin Administration Increase Alcohol Consumption in Individuals with AUD?

The films may be used for (Check all that apply):

a. _____ Any purpose relevant to research, medical evaluation, training
b. _____ Purposes of the study only

You have the choice of how long we may keep your tapes:

a. _____ My tapes may be kept permanently for research, educational, or training purposes.
b. _____ My tapes must be destroyed after completion of the study.

I understand that my consent for this part of the study is optional, and I am free to refuse this request and still participate in the study. I understand that I may request at any time during the research that the videotapes or audiotapes of me be destroyed and the research staff will honor my request promptly. To withdraw, call the PI (Dr. Terril Verplaetse) at 203-737-6496.

My signature below indicates my consent for the use of these tapes.

Participant Printed Name	Participant Signature	Date

Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date