Informed Consent

Human Laboratory Screening of Semaglutide for Alcohol Use Disorder

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University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: 02/09/2023 (v5)
IRB Study # 21-1689
Title of Study: Human Laboratory Screening of Semaglutide for Alcohol Use Disorder
Principal Investigator: Christian Hendershot
Principal Investigator Department: Psychiatry - General
Principal Investigator Phone number: (919) 962-5565
Principal Investigator Email Address: christian_hendershot@med.unc.edu
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Concise Summary

This study is being done to evaluate how the medication *semaglutide* affects responses to alcohol in people who drink alcohol. Semaglutide is a medication that aids in reducing blood sugar and body weight and is approved for the treatment of Type II diabetes and weight control. This study will help to answer the question of whether semaglutide could be helpful as a treatment for people who are trying to reduce their drinking.

You are being asked to participate because you report drinking alcohol regularly, and report that you are not currently trying to stop drinking alcohol. If you agree to participate, your participation will last up to approximately 16 weeks, including all scheduled follow ups. During this time you will be asked to complete several study components, including weekly clinic visits, questionnaires, brief daily surveys, and additional visits that involve consuming alcohol. Examples of potential risks of participation include medication side effects (such as nausea), discomfort from study procedures (e.g., blood draws), and risks related to alcohol administration (e.g., temporary loss of coordination). The information contained in this consent form is to help you decide whether you want to take part in the study. Please take the time to read all the information carefully. This consent form is only part of the process of informed consent. If you would like additional details about something mentioned here, or information not included here, please ask at any time.

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary.

You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider,

or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this study is to evaluate how the medication *semaglutide* affects responses to alcohol, as well as patterns of alcohol intake, in people who drink alcohol. Semaglutide is approved by the U.S. Food and Drug Administration (FDA) to treat Type II diabetes and for weight management. The medication is routinely prescribed to help people control blood sugar and body weight. Research with animals has shown that this medication may influence responses to certain commonly used drugs. Therefore, the goal of this study is to examine how semaglutide influences responses to alcohol in people who drink. Because you are not being prescribed the study medication for diabetes or weight management, this study involves "off-label" use of the medication.

You are being asked to be in the study because you reported recent heavy drinking, along with least two symptoms that are common to alcohol use disorder (such as tolerance to alcohol, or drinking more than intended). Being eligible for this study does not represent a diagnosis of any kind.

Are there any reasons you should not be in this study?

Because this is not a treatment study, you should not be in this study if you are 1) currently seeking or receiving treatment for alcohol use, or 2) actively trying to quit drinking alcohol.

How many people will take part in this study?

The study will aim to recruit 36 people who complete all study procedures. It is possible that more than 36 people will take part overall, although the exact number is undetermined. This study is only taking place at UNC-Chapel Hill.

How long will your part in this study last?

Participation in this study will take place over approximately 16 weeks. The reason for this time is that the medication dosage will be increased slowly over 9 weeks. In addition to the visit today, which will take up to 3-4 hours, you will be asked to attend 10 scheduled weekly follow-up visits for study medication and check-ins (up to one hour each), as well as 4 lab visits that involve drinking alcohol (these sessions will last most of the day). You will also be asked to complete a brief questionnaire (1-2 minutes) each day during the study (which can be completed via mobile phone), and to complete several brief phone calls (approximately 5 minutes each) to monitor side effects at various points in the study. At week 15, we will complete a final telephone call check-in. Overall, we expect your participation in this study to last up to 40-50 hours over up to 16 weeks. In the event that additional assessments or testing (e.g., blood tests) are necessary to evaluate

side effects or to protect your safety, the study physician may request additional assessment procedures as needed.

If you think you might be unable to commit to the timeframe of the study (16 weeks), or if you plan to travel out of town during this period, please let us know now. This may affect your availability to attend study visits and complete the study.

What will happen if you take part in the study?

I. Screening Visit and Baseline Questionnaires (Week 0 visit)

To determine your eligibility, a study team member will conduct a conduct an interview about your substance use, medical history, and other exclusion/inclusion criteria. This interview will typically take place remotely (e.g., by Zoom), but may be completed in person. If eligible, we will ask you to complete an in-person visit at UNC that includes additional questions, as well as assessment of vitals (heart rate, blood pressure, weight/height) and a blood draw via needlestick. You will also be asked to provide a breath alcohol test, an expired carbon monoxide (CO) test (a breath test that can detect recent smoking), and a urine sample to test for the presence of several drugs. You will be able to collect the sample in a bathroom without anyone watching you. Women in this study will also be asked to complete a pregnancy test. These procedures are intended primarily to rule out any factors that would make it unsafe for you to take the study medication. If you test positive for drugs (other than marijuana) or pregnancy (either today or later in the study), you will not be eligible for the study.

If any lab or physical results are abnormal or suggest that it may be unsafe for you to take the medication (e.g., very low blood sugar), the medical staff will notify you of the findings and you may be withdrawn from the study. Part of your blood sample will be stored in order to examine additional questions, such as whether certain genetic factors, including factors that influence nicotine metabolism, might relate to the study outcomes. Your blood sample will be labeled only with a special number (code), which will remain linked to your identity (this process is outlined in a separate consent form).

Assuming you are eligible, you will be asked to complete questionnaires (about personality, substance use, and related factors) on paper. You are free to decline to answer any question. Overall, the screening and baseline visit is expected to last up to roughly 3-4 hours in total. If any study components cannot be completed in one day (e.g., depending on your availability and availability of medical staff), you may be asked to split the screening procedures into two visits. In addition, the study physician may ask to meet with you (via telephone or videoconference) to clarify questions about medical history or medication. You may also request a conversation with medical staff.

II. Medication procedures and visits

The study medication, semaglutide, is a medication for the management of type II diabetes. More recently (in 2021), semaglutide was approved for the purpose of weight control. This medication has been shown to reduce blood glucose levels and promote weight loss. Semaglutide is one of several medications called “GLP-1 agonists”. GLP-1 is a hormone that is naturally produced by

the body, and is stimulated by eating meals. Semaglutide (and other GLP-1 agonists) are designed to mimic some of the actions of the GLP-1 hormone.

The medication is taken once per week using a "subcutaneous" method, which means depositing a small medication dose under the skin. Specifically, the medication is delivered using a micro-needle (about the width of 2 human hairs), which is relatively easy and painless to administer. The amount of medication administered by the needle is extremely small (almost unmeasurable). People who are prescribed semaglutide usually take the medication themselves at home. For purposes of this study, we will ask that you attend lab visits to receive the study medication and complete side effects questionnaires. The medication dose will be increased gradually over the course of the study (from 0.25mg to 0.5mg to 1mg), to limit side effects. Side effects of the medication are described under the "potential risks" section below.

This study also involves "placebo" medication doses. A placebo is an inactive version of the medication. Some participants will receive doses of semaglutide that increase gradually over the course of the study, and some participants will receive placebo doses. Which medication condition you receive will be determined randomly (like flipping a coin). The study investigators and research team will not be aware of your condition. However, if there is a reason to suspect a safety concern, the investigators will be able to determine your study condition at any time.

While participating you will be required to keep your assigned medication at home and bring it in with you to study visits. Medication will be provided in a sealed, tamper-resistant bag. It is important *not* to open the bag at any point during the study as this could disqualify you from further participation. A UNC medical staff member or pharmacist will be the only person responsible for opening and resealing bags. In addition, it is important to store the medication in a safe location in your possession at home, and to store the medication at room temperature. Please see attached medication instructions for more information. Finally, it is important to bring your medication bag to every medication visit. Failure to bring your medication bag will result in rescheduling the visit. If medication is lost, this could disqualify you from further participation.

III. Phone call and questionnaire assessments

In between visits to UNC you will be asked to complete brief phone calls (four scheduled 5-10 minute calls) to check in about potential side effects. You will also be asked to complete daily surveys (estimated 2-3 minutes per survey). We will provide a booklet for you to complete the daily surveys. With your permission, we will also send a reminder text message about the survey each day.

IV. Follow-up Visits

Weekly Follow-Ups (Weeks 1-10 Visits). There will be weekly follow-up visits to the UNC Medical Center or a UNC Medical Office Building (Eastowne) during the study. The purpose of these visits is to give you the next dose of medication or placebo and to conduct a brief assessment (e.g., weight, blood pressure, side effects). At some visits we will ask to take a blood sample, which is done using a finger-prick test or blood draw (depending on the study visit day). These blood draws will be taken because it is important to monitor your blood sugar levels regularly during the study. You will also complete follow-up questions and questionnaires with the study staff or a member of the medical team, which will focus on topics related to alcohol,

nicotine, and food intake. If the study medical staff have any reason to believe that continuing in the study would not be safe, you may be withdrawn from the study.

Possible reasons for discontinuation might include abnormally low blood sugar, severe side effects, or testing positive for drugs other than cannabis during the study. At the final study visit (Week 10, discharge visit) you will not be given medication. You will be asked to complete a final blood draw and questionnaires and will receive your final compensation at this visit. The team will try to schedule you for the same weekly time for each of your study visits. If it is not possible to attend at your regular time in each week, the team will work with you to find an alternate time that works with your schedule.

Alcohol Visits. Four of the scheduled visits will involve an alcohol administration procedure. Two visits are scheduled between the baseline visit and week 1, and the other two are scheduled around weeks 8 and 9. The purposes of these sessions is to examine potential effects of medication on responses to alcohol. The four visits will include two different types of alcohol sessions.

In one type of alcohol session you will be asked to consume alcohol and a mixer, using an amount intended to raise your blood alcohol concentration (BAC) to a target of .06g% (roughly 2-3 standard drinks for most people of average weight). Drinks will be consumed over a standardized period of 10 minutes. For the period after alcohol is consumed, we will monitor your breath alcohol level (using a breathalyzer) regularly and ask you to complete questionnaires throughout the session. In the other type of alcohol session, you will receive portions of your preferred alcohol beverage, and you will decide when to start drinking and how much to drink over a period of 2-3 hours. We will also ask you to complete questionnaires and measures of heart rate/blood pressure throughout the sessions.

At the end of each alcohol session, you will be provided with snacks, water, and reading materials and given a private room. Because you will be asked to consume alcohol at these visits, you will be asked to spend the full day (e.g., 9am-5pm or 10am-6pm) on site. Therefore, we ask that you do not schedule any outside appointments or commitments on these days, and bring reading or other materials to keep busy during breaks. You will also be provided with options to watch movies. You will also be asked not to drive to these sessions. Instead, you should arrange to have a ride (or take public transit) to/from the research site. If you are not able to locate a ride, the study team can reimburse you up to $25 for an Uber or Lyft ride to your home address.

We will ask you not to consume alcohol or use recreational drugs within 24 hours of these visits, and not to eat for 4 hours before arriving at UNC. After arriving, you will be asked to provide a urine sample for a urine drug test and a breath alcohol reading that morning to confirm recent abstinence from alcohol and drugs. For females, the urine screen will also be used for a pregnancy screen. If you test positive for recent use of recreational drugs (with the exception of marijuana) you may be rescheduled or withdrawn from the study.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. This research study could help to develop new treatments for people who have concerns about their substance use. Your participation in this study could therefore benefit others in the future. However, you are not expected to benefit personally from being in this research study.

What are the possible risks or discomforts involved from being in this study?

Medication. Semaglutide is a commonly used medication. You will receive an informational handout today that describes the study medication. Most medications have certain risks/side effects. The most common side effects are gastrointestinal side effects (i.e., stomach or digestive discomfort). In studies where semaglutide was taken for a long period of time (at least one year), the most commonly reported side effects (i.e., greater than 5% of participants and more common than placebo) included:

- nausea
- diarrhea
- vomiting
- constipation
- abdominal pain

Additionally, the rarer reported side effects (greater than 1% but less than 5%) included:

- hypoglycemia (low blood sugar)
- indigestion (dyspepsia)
- eructation (burping)
- cholelithiasis (gallstones)
- gastroesophageal reflux

In this study, semaglutide will be taken for approximately 9 weeks. Side effects are most common after a dosage increase, and are expected to normally go away quickly. We encourage you to tell us about any potential side effects you experience, or side effects that don't go away on their own. We will check for side effects at every visit as well as during scheduled telephone calls. The study staff may choose to stop the medication if you are showing signs of serious side effects.

One potential side effect of the medication is low blood sugar. Therefore, it is important that we take measurements for blood sugar at each visit. This will require a finger prick test at some visits, or a blood draw at selected visits. The study staff will also explain symptoms of low blood sugar that you may experience. If you experience low blood sugar, please alert the study team. If you visit a physician or are prescribed any medications while enrolled in this study, you should inform your physician that you will be taking semaglutide while participating. In addition, please inform us if you start a new medication while participating in this study. For women in this study, it is important to not participant if you expect to become pregnant within the next 6 months, because the medication should not be taken while pregnant, or within two months before becoming pregnant. You will be asked to confirm that you are able to use a reliable method of birth control during the study, and for the two months after stopping the medication. We will also ask women to provide a urine pregnancy screen at study visits.

Blood Samples. Drawing blood may cause temporary pain and discomfort from the needle stick, occasional bruising, sweating, feeling faint or lightheaded, and in rare cases, infection or nerve pain.

Alcohol consumption. There are potential risks related to the alcohol sessions. The effects of alcohol intoxication may lead to temporary symptoms such as dizziness or impairment in motor coordination. You could experience hangover-like symptoms (e.g., headache) after the alcohol session. It is important not to drive to the alcohol sessions as you should not drive a motor vehicle or operate machinery for the rest of the day. If you arrive to an alcohol session with a positive breath alcohol reading, the visit will be postponed and you may be excluded from further participation. If you have driven to the session and arrive with a positive breath alcohol level, you will be asked to remain on site until your breath alcohol reading has reached zero.

Please initial below to indicate your agreement with these safety precautions for the alcohol sessions.

___ I agree not to drive to or from the research site on days involving an alcohol session.

___ At alcohol sessions I agree to remain on site until the study team decides it is safe to leave.

Alcohol can cause birth defects if you are pregnant. Additionally, alcohol can be transferred via breastmilk to infants/toddlers. Therefore, you should not take part in this study if you are potentially pregnant, trying to conceive, or currently lactating.

Interview and Questionnaire Responses**.** It is possible you could experience emotional stress, inconvenience or an invasion of privacy when answering questions in this study. However, you may refuse to answer any questions or perform any test that you do not wish to answer or do. Every effort will be made to protect the information you give us. Participation in this study may produce emotional stress (such as distress while answering personal questions), inconvenience or an invasion of privacy.

Genetic Analyses. The main aim of this analysis will be to examine genetic markers related to nicotine metabolism, such as CYP2A6. These analyses may also focus on genetic factors potentially associated with drug use or related behaviors, such as alcohol metabolism or impulsivity. DNA samples will be labeled with a number only (not your name) and will be stored and analyzed separately from any of your identifying information. The sample will not be used for diagnostic purposes or genomic sequencing. DNA samples may be stored indefinitely to allow for future analyses. You are free to ask the study team to destroy your genetic sample at any point. Please note that if your sample has been de-linked from your name (e.g., after the completion of the study), it may not be possible to identify and destroy the sample, so it may be unlikely that this request can be granted.

Unforeseeable risks. The most likely risks of participation have been outlined above. The study procedures could involve risks to the participant (or to the embryo or fetus, if the participant becomes pregnant) that are currently unforeseeable. Additionally, there may also be side effects or risks to study participation that are unexpected and not known at this time. Every effort will be made to protect the information you give us. However, there is a small risk of loss of

confidentiality that may result in stigmatization or hardship. Procedures we will use to protect the information you give us are described above.

Safety Precautions: Several safety precautions will be in place while you participate. We will monitor for side effects regularly, as described above. On days involving alcohol we will verify that your breath alcohol level reaches a safe level before you leave the lab. We will ask that you do not drive to the study site on alcohol session days, and will help you to determine alternative ways to get home.

Pregnancy Test (for women only): As a safety precaution, women will be asked to complete a pregnancy test at the beginning of the study, and at scheduled study visits. Participants will not be charged for the pregnancy tests. If you are planning to become pregnant during the next 6 months, or if you are sexually active and not using a reliable birth control method, you should notify the study physician or nurse, and you will not be eligible to participate. There are no risks associated with the pregnancy tests. However, if your pregnancy test is positive, you will no longer be eligible to participate in the study. The results of your pregnancy test will remain confidential; no one else will receive the results of your pregnancy test.

What if we learn about new findings or information during the study?

You will also be informed of any significant new findings that become available during the study, such as changes in the risks or benefits resulting from participating in the research or new alternatives to participation that might change your mind about participating. If, for example, we find out that there are newly reported serious side effects of the study medication, we would inform you of these side effects so that you could decide whether you wanted to continue participating.

Will I receive any other clinical results?

The study physician may choose to communicate clinical results to you if relevant to your safety. For instance, if we receive lab tests that indicate you have low blood sugar, these results may be communicated to you for safety reasons.

How will information about you be protected?

We will take measures to protect your privacy and the security of all your personal information. Your name and other identifying information will be maintained in locked files and/or restricted databases, available only to authorized members of the research team for the duration of the study. All of the information we collect about you will be coded with a unique research subject identifier and will be kept on password-protected computers and stored securely in restricted and protected databases according to local information security policies. De-identified data (meaning data that does not contain information that can directly identify you) from this study may be presented at meetings, published in journals/books, used in classrooms for training/teaching purposes, and may be used and shared with other researchers for future research purposes, which includes scientists at other universities and institutions. However, all participants' data will be merged together for such purposes, and your name and other identifying information will not be used in any published reports about this study. Participants will not be identified in any report or publication about this study.

The blood samples collected at study visits will be labeled with your subject number and date of study visit and stored in a secure space. These samples will be stored for up to 24 months after we complete all analyses. A portion of the blood samples may be sent to an outside laboratory for analysis, but your identifying information will never be shared outside of the research team. We may use de-identified data and/or specimens from this study in future research without additional consent. Your specimens will not be used for commercial profit.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. Examples of these special circumstances would be if the researcher or other members of the research team have reasonable grounds to believe that disclosing information is necessary to eliminate or reduce a significant risk of bodily harm to yourself or others, or where there is a court order to release records. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

Will my genetic information be shared?

Your blood and tissue samples contain genes that are made of DNA unique to you. To do more powerful research, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. Researchers can then study the combined information to learn even more about health and disease. If you agree to take part in this study, some of your genetic and health information might be placed into one or more scientific databases. There are many different kinds of scientific databases; some are maintained by this institution, some are maintained by the federal government, and some are maintained by private companies. For example, the National Institutes of Health (an agency of the federal government) maintains a database called "dbGaP." A researcher who wants to study the information must apply to the database. Different databases may have different ways of reviewing such requests. Researchers with an approved study may be able to see and use your information, along with information from many other people. Your name and other information that could directly identify you (such as address or social security number) will never be placed into a scientific database. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small but may grow in the future as technology advances. Researchers will always have a duty to protect your privacy and to keep your information confidential.

Federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers 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 proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

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 an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

By signing this informed consent document, you agree that some of the information generated by participating in this study and/or a copy of the consent form may be included in your UNC medical record and that this information may be viewed by other physicians or caregivers who provide healthcare services to you. This will allow the doctors caring for you to know what study medications or tests you may be receiving as a part of the study and know how to take care of you if you have other health problems or needs during the study. Additionally, the information may be shared with your medical insurance plan if the research services provided are billed to your insurance. If you do not have a UNC medical record, the medical staff assisting with this study will create a medical record for purposes of research participation.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped. If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

Will you receive anything for being in this study?

To compensate you for your time when participating in this study, you will be paid in cash. The total possible compensation for completing all study components is $1000. Different components of the study will have different compensation amounts. The compensation breakdown is described below.

You will receive the following compensation for the in-person study visits:

$50 for completing the consent/screening/baseline sequence (Week 0)
$75 for alcohol challenge session 1 (To be scheduled between Weeks 0-1)
$75 for alcohol self-administration session 1 (To be scheduled between Weeks 0-1)
$100 for alcohol challenge session 2 (To be scheduled between Weeks 9-10)
$100 for alcohol self-administration session 2 (To be scheduled between Weeks 9-10)
$30 per visit for each follow-up/medication administration visit during Weeks 1-10 (10 visits x$30 per visit = $300)
Up to $150 for completing and returning daily questionnaires over the study period ($15 per weekly set of surveys x 10 weekly visits), which includes the week following the 1.0mg dose, to be paid at weekly medication visits)
A $50 bonus for completing at least 9 of 10 weekly assessments

If you complete the study, you will receive a final bonus of $100 for completing the study through Week 10 (to be paid at the final discharge visit).

The exact compensation amount will depend on the study visits/components you complete, as described above. In the event you are not able to complete the full study, you will be compensated based on the components completed to that point. In the event you are not able to complete a full study session (e.g., alcohol session), you will be compensated at a pro-rated amount of $20 per hour. In the event you are not able to pick up your final cash payment in person, we can send the final payment via electronic gift card to your email address.

Any payment provided for participation in this study may be subject to applicable tax withholding obligations, and as such a W-9 form will be required for reimbursement purposes.

Your name, address, and U.S. tax payer identification number (SSN or ITIN) are required to process payments and/or to report taxable income to the IRS. You must complete a W-9 (for U.S. persons) or

W-8BEN and the Foreign Vendor Withholding Assessment with supporting documents (for non-resident aliens) in order to receive payment for participation. U.S. person participants must complete Form W-9 in order to receive payment for participation. If payment by UNC equals or exceeds $600 per calendar year for U.S. persons, UNC will report the amount to the Internal Revenue Service on Form 1099. Nonresident alien participants must complete Form W-8BEN and the Foreign Vendor Withholding Assessment with supporting documents in order to receive payment for participation. Payments to nonresident alien participants may be subject to tax withholding and are generally reported to the Internal Revenue Service on Form 1042-S. This information will not be linked to any of the study data and will only be used for payment purposes. If you do not provide your SSN or ITIN, or complete the appropriate documentation noted above, we cannot issue you a payment for participation. However, you may still choose to participate in this study.

Will it cost you anything to be in this study?

If you enroll in this study, you may have costs of participating which include transportation and parking fees. We will reimburse you for parking at the UNC hospital for the in-person study visits. In addition, in the event you are not able to arrange for a ride home from the alcohol sessions, we will provide an Uber voucher for your trip home. Please speak with the research coordinator about parking and transportation reimbursement. You will not be responsible for paying for lab tests or medication associated with this study.

Who is sponsoring this study?

This research is funded by the National Institutes of Health.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

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

Interest in future studies.

There may be opportunities for you to participate in additional studies in the principal investigator's lab. If you are interested in being notified of future research opportunities, you can opt in to being contacted about future studies. If you opt in, we will retain your contact information indefinitely, and may contact you to ask if you'd like to come back for another study in the future. Your information will remain strictly confidential; we will never share your contact information with other researchers or organizations. If you agree to be contacted you are in no way obligated to participate in future studies and you may ask for your name to be removed from our follow-up contact list at any time (in which case your contact info will be deleted). If you agree participate in any future studies, we will ask for your consent for participation at that time, and will explain the study and any compensation at that time.

_____ Yes, please keep my contact information to hear about future research opportunities.

_____ No, please do not save my contact information after this study is complete.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____
Signature of Research Participant

_____
Date

_____
Name of Research Participant

_____
Signature of Research Team Member Obtaining Consent

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Date

_____
Name of Research Team Member Obtaining Consent

_____
Signature of Witness if applicable; e.g. literacy issues, visually impaired, physically unable to sign, witness/interpreter for non-English speaking participants using the short form)

_____
Date

_____
Name of Witness