Official title: Subjective Response to Alcohol and Associated Neural Systems in Bipolar Disorder

NCT number: NCT04063384

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Document information: Overall study protocol and change in behavior and functional connectivity (primary outcomes) statistical analysis approach.

Consent to Participate in Research

Basic Study Information

Title of the Project: **Subjective Response to Alcohol and Associated Neural Systems in Bipolar Disorder.**
Principal Investigator: **Elizabeth Lippard, Ph.D., UT Austin**

Invitation to be Part of a Research Study

You are invited to be part of a research study. This consent form will help you choose whether or not to participate in the study. Feel free to ask if anything is not clear in this consent form.

Important Information about this Research Study

Things you should know:

- **The purpose of the study is to** investigate how you respond to alcohol.
- **In order to participate, you must** be diagnosed with bipolar disorder.
- **If you choose to participate, you will be asked to complete** clinical interviews, behavioral assessments, complete MRI scanning and drink alcohol on two separate occasions. This will occur over a 2-3-day period at the University of Texas at Austin.
- **Risks or discomforts from this research include** feeling nauseous following alcohol consumption, feeling dizzy, uncomfortable during an MRI scan, or feeling stressed during clinical interviews.
- **There is no direct benefit for participating in this study.** However, your participation may lead to knowledge that will help others
- **Taking part in this research study is voluntary.** You do not have to participate, and you can stop at any time.

More detailed information may be described later in this form.

Please take time to read this entire form and ask questions before deciding whether to take part in this research study.

What is the study about and why are we doing it?

You have been asked to participate in a research study that studies experiences of alcohol intoxication on the brain and behavior. The purpose of the study is to investigate how the brain responds to alcohol in bipolar disorder.

In order to decide whether or not to be a part of this research study you should know enough about its risks and benefits to make an informed decision. This form gives you detailed information about the research study that a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, and any risks and possible benefits. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

What will happen if you take part in the study?

If you decide to participate in this research study, you will be asked to participate in the parts of the study listed below.

a. *An Interview and tests of mental functions:* This interview will include questions about symptoms of psychiatric illnesses and tests of mental functions. Depending on the

results, we will arrange for you to participate in the other parts of the study. Interviews will also assess your history with alcohol and other drugs. The interview and the tests of your mental functions will take about 3 and ½ hours.

b. *Genetic Testing:* We will ask you to give a saliva sample by spitting into a tube until it is filled to a certain level (approximately ½ a teaspoon). This process may take up to 20 minutes.

We will use the DNA taken from your saliva:

- to learn more about the connection between genes and a person's behavior;
- to locate genes that might make people more likely to have an emotional or certain behavioral character;
- to learn about the differences between genes in groups of people with different conditions; and
- to try to understand which genes are important for brain function and structural development.

You are asked to allow some of your saliva samples (called specimens) and related information to be stored (banked) for future research. This may help researchers in the future learn more about how to prevent, find and treat Mood Disorders.

Your specimens will be stored for an unlimited time. Future genetic analysis may possibly include finding out the details of how your DNA is put together, such as whole exome or genome sequencing, or genome wide association studies (that is, looking at genetic markers throughout the entire genome).

When your specimens and information are stored, we are careful to try to protect your identity from discovery by others. Your samples and information will receive a unique code. Other researchers will only receive coded samples and information, and will not be able to link the code to you. Strict security safeguards are in place to reduce the chance of misuse or unplanned release of information.

Using your specimens for research will probably not help you. We do hope the research results will help people in the future.

The choice to take part in the genetic testing is up to you. You may choose not to let us store and use your samples, and your care will not be affected by this decision. If you decide that your samples can be kept, you may change your mind at any time. Contact the study staff by phone [(512) 495-5216] or mail [The University of Texas at Austin, 1701 Trinity Street, 3rd Floor, Austin, Texas, 78712] to let them know you do not want your samples used any longer. Your samples will be made anonymous (the code linking them to you will be destroyed).

Also, the sample may be shared with investigators not associated with this project. If this is done, all identifying information will be removed from the sample. The researcher may have access to your age, sex, race/ethnicity, and/or diagnosis. Because samples shared with other investigators will not have any identifying information, those samples cannot be linked to you.

c. *Urine Testing for Pregnancy and Substance Abuse:* Since this research may have bad effects on an unborn child and should not be done during pregnancy, it is necessary that

a pregnancy test be done in females capable of becoming pregnant. If you are a female capable of becoming pregnant, you will be asked to provide a urine sample for a urine pregnancy test to be done before the MRI scanning sessions. The results will be discussed only with you.

Since substances of abuse can alter brain function and response to alcohol and therefore could make study results very difficult to understand, all study participants will be asked to give a urine sample which will be tested for substances of abuse. The results will be discussed only with you.

d. *MRI Scanning (brain scanning):* You may not participate in the brain scanning part of the study if you have braces or metal implants or fragments (due to routine MRI restrictions), if you are claustrophobic (afraid of small spaces), or if you have a neurological disorder.

   If the results of the interview indicate that there is a reason that you cannot participate in the brain scanning, we will tell you so. A baseline MRI scan will be done at Dell Medical School in the Health Discovery Building at the University of Texas at Austin. You will be asked not to drink any alcohol or use any other non-prescribed medications that could change brain function within 24 hours of the MRI scanning session. You will also be asked not to drink caffeinated beverages (coffee, tea, cola drinks) or smoke cigarettes the morning of the MRI scanning session.

   The baseline MRI scanning phase of the study should last about 50 minutes. You will lie down on a cot. The cot will slide inside of the MRI machine, which is a large tube-shaped magnet, until your head is within the machine. The MRI machine will make a loud clanking noise when it takes pictures. During the MRI session you will lie quietly and watch video(s). Pictures of your brain will be taken during the MRI session. You will be able to talk to the staff at all times during the scanning session and can be taken out of the MRI magnet at any time. If it is not possible to complete the full MRI scanning session in 50 minutes we will tell you and arrange for a second scanning session on another day within two weeks.

   On the day of baseline scanning, you will complete some scans to look at structure of your brain and scans while you watch movies. We will ask about one of these movies after you complete the scan and record your audio response. You will also practice the task that will be given to you in the MRI scanner when you come back for your alcohol laboratory sessions so that you are familiar with it. This task will involve looking at pictures or shapes and following simple instructions about them such as pressing a button. This practice will last about 5 minutes.

e. *Alcohol Session(s):* You will be invited to participate in **two** alcohol-drinking sessions. These sessions will occur within 1-3 days of each other and will be done at the Biomedical Imaging Center (BIC) at the Health Discovery Building at the University of Texas at Austin. We require a minimum of 24 hours between the two alcohol-drinking sessions. During these sessions you may consume alcohol. The amount of alcohol you may be given will not exceed a targeted maximum blood alcohol concentration (BAC) of 0.08g%. You will be required to stay in our laboratory until your breath alcohol concentration (BrAC) has reached a 0.04g% (a level considered safe by the National Institute on Alcohol Abuse and Alcoholism). Prior to the start of your laboratory session, you will be asked to refrain from consuming alcohol for 24 hours, from eating for 4 hours, and from consuming caffeine or tobacco for 3 hours. Upon arrival to our laboratory, you will be required to provide written informed consent and photo identification as proof of legal drinking age. You will also be required to provide a zero-breathalyzer test (to ensure that you have not been drinking alcohol). Individuals for whom a zero-

breathalyzer test is not obtained will be unable to participate during that laboratory session and may be rescheduled for a different session at the discretion of the Principal Investigator.

As you are required to fast from eating for 4 hours prior to the session, we will ask you to consume a light snack of pretzels while completing the questionnaires (and before you are served alcohol). A gluten free option will be available. You will then have 20 minutes to consume two glasses of beverage which contain a mixture of cranberry juice, lime juice, diet cherry 7-up, and alcohol. The amount of beverage you will be given will be based on your age, gender, height, and weight and will be selected so that it does not exceed a maximum targeted level of 0.08g%. Your height and weight will be measured by a research staff member. Consumption of alcohol may result in lightheadedness, dizziness, and/or nausea. Following a 10-minute absorption period, and again at various intervals throughout the session, you will be asked to provide breathalyzer tests and to complete measures describing feelings you may be experiencing. You will then be asked to complete a MRI scan. During the MRI session, at times you will lie quietly and watch a video (similar to your baseline scan), and at other times you will do the task you completed in the practice session on the day of your baseline scan. We will go over the MRI task with you again before you get into the scanner. The MRI scanning phase during the two alcohol sessions will each last about 30 minutes.

f. *Tests of mental functions:* Following the MRI scans on the two days you drink alcohol you will be asked to complete some self-report questionnaires and tests examining cognitive functioning. The questionnaires and the tests of your mental functions will take around 1 hour.

g. All participants will be detained as necessary until their BrAC has reached an acceptable level (0.04% according to the National Institute on Alcohol Abuse and Alcoholism Guidelines for Ethyl Alcohol Administration in Human Experimentation). The time you must remain in the laboratory depends on the amount of alcohol you consume and the rate at which you metabolize alcohol. We anticipate that you will need to stay in the laboratory for up to 6 hours. When your BrAC has reached an acceptable level, you will be able to receive a ride home from a sober friend or family member.

h. *The Two-Year Study:* In order to study ways that the brain develops differently in bipolar disorder, we would like you to return again in approximately 1 year to repeat clinical and behavioral assessments and repeat an MRI scan. You will not drink alcohol during this follow-up visit. We may also call you to get more information about your symptoms or diagnosis. If you are interested, we could also contact you if we have new studies that you might be eligible for. You are under no obligation to do so and participation in any future project would require you to sign another consent form. In order to stay in touch with you we would like to send cards periodically (e.g. at your birthday and holidays and will sometimes ask that you return a stamped card with information regarding changes in contact information). We also ask that you provide, if possible, the phone numbers and addresses of two friends or relatives who could help us contact you if you move and you forgot to inform our staff.

How long will you be in this study and how many people will be in the study?

Your total participation time in the first study visit will take approximately 5 - 6 hours to complete and different parts may be completed on different days if you prefer. You will subsequently be invited to return for two more laboratory sessions during which you will drink

alcohol (each of these sessions can last between 3-6 hours). You may be invited to return in one year to repeat some parts of the study. We may also contact you by phone or mail in between visits. All parts of the study will take place at the University of Texas at Austin.

This study will include 30 participants diagnosed with bipolar disorder and 30 study participants not diagnosed with bipolar disorder and with no relatives who have been diagnosed with bipolar disorder.

What risks and discomforts might you experience from being in this study?

There are some risks you might experience from being in this study. These are detailed below:

a. *Interview, questionnaires, and mental function tests:* The interview, questionnaires, and mental function testing will involve concentration and personal questions about issues that may be considered sensitive and may be stressful, although many people find it helpful to talk about their experiences or symptoms. You do not have to answer any questions that upset you. You may stop the interview at any point. If the results of the interview suggest that you are a danger to yourself or others, your primary physician will be notified or you will be advised to go to an emergency room immediately.

b. *Saliva Testing:* Donating saliva is not harmful. If you are giving a saliva sample for genetic testing, your mouth may become dry from spitting into the tube. Under some circumstances, it can be a risk for genetic information about you to become known. Variation in some genes can be related to risk for certain illnesses. Since the results of these genetic tests may allow prediction of risk of illness in some cases, we will keep the results confidential (only scientists working on this research project will know the results).

   We will not make any of our laboratory results available to you, nor will we add them to your medical record. (If you want to know your risk for genetic diseases, we will refer you to a genetic counselor).

   There is a federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans, and most employers, except those with less than 15 employees, to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term insurance.

c. *Alcohol Consumption:* Any time alcohol is consumed there is the potential for negative emotional or medical consequences. You will not receive a dose of alcohol that is targeted to be greater than the legal limit of intoxication. Additionally, you will be asked to remain in the laboratory until your BAC is below a safe limit (0.04 g%) and will be provided transportation home. If you wish to discuss these or any other risks you may experience, you may ask questions now or call the Principal Investigator listed on the front page of this form. In the unlikely event you experience significant emotional distress as a result of your participation, treatment will not be provided by the research staff, but we can provide the names and telephone numbers of agencies that may alleviate your concerns or distress. These resources include a 24-hour Austin/Travis County MHMR Hotline (512-472-4357), Capital Area Mental Health Center (512-302-1000), and Austin Recovery (512-697-8600 or 800-373-2081).

d. *Reproduction Risks:* Alcohol is hazardous to a developing fetus (unborn child). If there is any chance that you might be pregnant, you may not participate in this research study unless you have a negative pregnancy test prior to alcohol consumption. You must inform the investigators if you have any reason to suspect you are pregnant at the beginning of the laboratory session. Additionally, while MRI scanning is generally not believed to be hazardous to a developing fetus (unborn child), only a few investigations have examined the potential risks to the fetus from this imaging method. If there is any chance that you might be pregnant, you may not participate in this research study unless you have a negative pregnancy test prior to the MRI scan (even if you are completing a scan that doesn't involve alcohol consumption). You must inform the investigators if you have any reason to suspect you are pregnant at the time of the MRI scan.

   A pregnancy test is required before consuming alcohol and before entering the magnet (MRI machine).

e. *MRI Scan:* No serious ill effects have been reported to date from facilities in the United States operating with a magnetic field strength of 3 Tesla (the magnetic field strength used in this study); these types of magnets are widely used for clinical practice. Since the study involves entering a confining space, you may not be able to participate if you have a history of claustrophobia or if you experience anxiousness when entering the magnet tube.

   The risks due to exposure to the magnet itself are primarily related to the slight possibility of a sensation of dizziness or nausea as you move in and out of the magnet or move your head in the magnet. The magnet is thought to be able to exert a force on the fluid within the semicircular canals near the ears thus possibly giving a sensation of dizziness. The sensations go away if your head is not in motion or if you are not moving in/out of the magnetic field. Less than 10% of subjects experience this dizziness, which generally lasts 1-2 minutes or less. You will be exposed to noise from the machine for which earplugs and/or earphones are provided. There are no other known risks to being in the magnetic field.

   Magnetic items move in a high magnetic field and by doing so, can be dangerous. The Biomedical Imaging Centers (BIC) at the University of Texas at Austin is careful to maintain an environment safe from these objects. We require you to do the same, being careful to ensure that you carry no metallic items into the MRI room. You will be asked to change into MRI-approved clothing for the MRI scans.

   We want you to read and answer very carefully the questions on the MR Safety Questionnaire related to your personal safety. Take a moment now to be sure that you have read the MR Safety Questionnaire and be sure to tell us any information about you that you think might be important.

   The MRI scan being done is designed to answer research questions, not examine your brain medically. This MRI scan is not a substitute for one a doctor would order. It may not show problems that would be picked up by a medical MRI scan. However, if we believe that we have identified a medical problem in your MRI scan, we will ask a doctor who is trained in the reading of MRI scans, a radiologist, to help us review the scan. If the radiologist thinks that there may be an abnormality in your MRI scan, we will contact you and will help you get medical follow-up for the problem. If you have a primary care

doctor, we can contact your doctor, with your permission, and help him or her get the right follow-up for you. No information generated in this study will become part of a hospital record routinely. However, if the study detects an abnormality in your MRI scan, then this information may become part of the hospital record if requested by your physician. It is possible that you could be unnecessarily worried if a problem were suspected, but not actually found.

f. *Medication at your first visit and at the 1-year follow-up visit*
If you are already on medications, we will not make you stop and/or change the medication that you are prescribed in order to be in this study. The potential risks of delaying or stopping medication can be serious and include worsening of your mood symptoms, including potential risk of increased thoughts about suicide and risk of hurting yourself or others.

If you are assessed to be a danger to yourself or others, then your primary physician will be notified or you will be advised to go to an emergency room immediately.

g. *The novel coronavirus, COVID-19,* has been declared a worldwide pandemic by the World Health Organization. COVID-19 is extremely contagious and is believed to spread by the kind of person-to-person contact that you may engage in by participating in this research study. Thus, as with any activity involving person-to-person contact, there is a risk that you might contract the virus and expose other individuals that you might come in contact with after participation in this study. In consideration of these risks, investigators are taking extra precautions based on recommendations of the Center for Disease Control. If you have questions about the safety measures that are in place, the investigators can provide you with this information.

How could you benefit from this study?

You will receive no direct benefit from participating in this study; however, your participation may lead to knowledge that will help others. We hope this study will help us to improve our understanding of bipolar disorder and help treat future patients with bipolar disorder or similar conditions. Potential benefits include an increased understanding of the effects of alcohol on health and risk behaviors. Such knowledge will ultimately lead to the development of more effective prevention and intervention programs in bipolar disorder targeting the negative consequences of alcohol use.

How will we protect your information?

Every effort will be made to maintain the confidentiality of your study records. All information learned through this study will be available only to investigators working on the study and the scientists working with them. We will not release any information about your genes or genetic makeup to you or to your doctors. However, if you wish us to discuss the results of the interview with your physician please ask us and we will do so. Otherwise, the results of the interview will be known only to the investigators of the study.

In all records of this study you will be identified by a number and letter code, and only the researchers will know your name. Any information obtained during this study and identified with you will remain confidential and will be disclosed only with your permission. All identifying information (name, birthdate, etc.) will be kept separate from data obtained from interviews, genetic testing, imaging, and audio recordings. If the results of this study are reported in medical journals or at meetings, you will not be identified by name, or by any other

means without your specific consent. Your identity will remain confidential unless disclosure is required by law.

Information about you may be given to the following organizations:

- Representatives of UT Austin and the UT Austin Institutional Review Board
- Other collaborating organizations: UT Austin Biomedical Imaging Center

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institute of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as outlined below.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects 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, or a member of your family from voluntarily releasing information about you 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.

Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as permitted by U.S. or State law. The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in this research project under the following circumstances: if during the study you report that you might hurt yourself or another or if there is reason to suspect a child or an incapacitated adult is being abused then the research staff will report it to the appropriate authorities. If some information about abuse comes up during the study, a member of the research team will always make an attempt to talk to you before protective services or any other agency is consulted.

A description of this study 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.

It may become necessary for organizations that have responsibility for protecting human subjects, including the University of Texas at Austin Institutional Review Board, to review study records. The University of Texas at Austin Institutional Review Board is required to keep all information in your study record strictly confidential. Information that can be linked to you will be protected to the extent permitted by law. Your research records will not be released without your consent unless required by law or a court order.

The data resulting from your participation may be made available to other researchers in the future for research purposes not detailed within this consent form. In these cases, the data will contain no identifying information that could associate it with you, or with your participation in this study.

Under certain situations, we may break confidentiality. If during the study we learn about child abuse or neglect, we will report this information to the appropriate authorities including the police and/or the Texas Department of Family and Protective Services.

Texas Education Code, Chapter 51, Subchapters E-2 and E-3, requires reporting incidents of sexual assault, sexual harassment, dating violence, or stalking committed by or against a person who was a student enrolled at or an employee of UT Austin at the time of the incident. However, the researchers working on this study have been designated as confidential employees. This means that if we learn about any incidents of sexual assault, sexual harassment, dating violence, or stalking, we are only required to report the type of incident reported and the date we learn about the incident. We will not report any information that could identify you.

If you test positive for COVID-19 after research participation you should notify the investigators of this study. Investigators will notify local health authorities that you have been on the UT Austin Campus. They will only provide the minimum information necessary and will not provide any details about the reason(s) for the participant's visit. By signing this form, you are agreeing that the investigator may do so without an additional signed release.

We plan to publish the results of this study. To protect your privacy, we will not include any information that could directly identify you.

What will happen to the information we collect about you after the study is over?

We will keep your research data to use for future research purposes. Your name and other information that can directly identify you will be kept secure and stored separately from the research data collected as part of the project.

Your Data and the NIAAA Data Archive ($NIAAA_{DA}$)

Data from this study may be submitted to the National Institute on Alcohol Abuse and Alcoholism Database ($NIAAA_{DA}$) at the National Institutes of Health (NIH). $NIAAA_{DA}$ is a large database where deidentified study data from many NIAAA studies is stored and managed. Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. Sharing your deidentified study data helps researchers learn new and important things about alcohol problems more quickly than before.

During and after the study, the study researchers will send deidentified study data about your health and behavior to the $NIAAA_{DA}$. Other researchers across the world can then request your deidentified study data for other research. Every researcher (and institutions to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with $NIAAA_{DA}$. The study data provided to $NIAAA_{DA}$ may help researchers around the world learn more about alcohol problems and how to help others who have problems with alcohol. NIAAA will also

report to Congress and on its website about the different studies using NIAAA$_{DA}$ data. You will not be contacted directly about the study data you contributed to NIAAA$_{DA}$.

You may decide now or later that you do not want your study data to be added to the NIAAA$_{DA}$. You can still participate in this research study even if you decide that you do not want your data to be added to the NIAAA$_{DA}$. If you know now that you do not want your data in the NIAAA$_{DA}$, you will initial next to this option below. If you decide any time after today that you do not want your data to be added to the NIAAA$_{DA}$, call or email the study staff who conducted this study, and they will tell NIAAA$_{DA}$ to stop sharing your study data. Once your data is part of the NIAAA$_{DA}$, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NIAAA$_{DA}$, this is available on-line at https://nda.nih.gov/niaaa.

What if we learn something about your health that you did not know?

The MRI scan being done is designed to answer research questions, not examine your brain medically. This MRI scan is not a substitute for one a doctor would order. It may not show problems that would be picked up by a medical MRI scan. However, if we believe that we have identified a medical problem in your MRI scan, we will ask a doctor who is trained in the reading of MRI scans, a radiologist, to help us review the scan. If the radiologist thinks that there may be an abnormality in your MRI scan, we will contact you and will help you get medical follow-up for the problem. If you have a primary care doctor, we can contact your doctor, with your permission, and help him or her get the right follow-up for you. No information generated in this study will become part of a hospital record routinely. However, if the study detects an abnormality in your MRI scan, then this information may become part of the hospital record if requested by your physician. It is possible that you could be unnecessarily worried if a problem were suspected, but not actually found.

How will we compensate you for being part of the study?

You will be paid

-$30 for the initial clinical and mental function (cognitive and behavioral) testing,
-$50 for the baseline MRI session (no alcohol),
-$50 for the 1st alcohol session,
-$50 for the 2nd alcohol session, and
-a $40 bonus if you complete both alcohol sessions.

You will not be provided any additional compensation for providing a saliva sample.
Total compensation you can receive is $220.

If you participate in the follow-up study visit (return one year later for a follow-up), you will be eligible for additional reimbursement as above for follow-up interview and mental function testing and baseline MRI session.

There are no plans at present to use the DNA samples for any commercial uses. Your specimens and information will only be used for research and will not be sold. However, if a discovery from research on your DNA sample results in a patent or becomes commercially useful in any way, you will not be notified. If this happens, there is no plan to share any financial gain with you. The University will maintain ownership of the specimen.

Who will pay if you are hurt during the study?

In the event of a research-related injury, it is important that you notify the Principal Investigator of the research-related injury immediately. You and/or your insurance company or health care

plan may be responsible for any charges related to research-related injuries. Compensation for an injury resulting from your participation in this research is not available from The University of Texas at Austin. However, you are not waiving any of your legal rights by participating in this study.

Who can profit from study results?

We are collecting biospecimens (i.e., saliva). Your samples may be used for commercial profit and there is no plan to share those profits with you.

Your Participation in this Study is Voluntary

Your participation is entirely voluntary. You are free to choose not to take part in this study and if you start the study, you may withdraw at any time. Withdrawal or refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled (such as your health care outside the study, the payment for your health care, and your health care benefits) and will not affect your current or future relationship with the University of Texas at Austin or Dell Medical School in anyway. However, you will not be able to enroll in this research study and will not receive study procedures as a study participant if you do not allow use of your information as part of this study.

If you complete the first alcohol session you are free to choose not to take part in the second alcohol session. However, you will not be compensated for the second alcohol session or receive the additional bonus if you choose not to complete it.

If you decide to withdraw before this study is completed, you can call a member of the research team at any time and tell them that you no longer want to take part. This will cancel any future appointments. You may withdraw your permission by telling the study staff or by writing to Elizabeth Lippard, at the University of Texas at Austin, 1601 Trinity Street, Stop Z0600, Austin, Texas, 78712.

Once you have consumed alcohol as part of the study, however, you will not be permitted to leave the laboratory until you BAC is below a safe limit (0.04g%).

The researchers may withdraw you from participating in the research if necessary. This may occur, for example, if the researchers believe you may need more services than the ones provided in this research lab.

Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. It will not harm your relationship with your own doctors or with Dell Medical School or the University of Texas at Austin.

When you withdraw from the study, 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 insure the integrity of the study and/or study oversight.

This study has been reviewed and approved by The University Institutional Review Board and the study number is 2018-11-0045**.**

Is it possible that you will be asked to leave the study?

You may be asked to leave the study if it is determined by the research team that it is unsafe for you to continue. If any of the following issues come up, we will have to ask you to stop participating:

- If you are pregnant. (Note: a pregnancy test will be required).

- If you have contraindications to alcohol (such as a history of alcohol dependence or previous adverse reaction to alcohol) or the MRI environment (such as metallic materials on or in your body, this includes electronic implants such as a pacemaker or neuro-stimulator, metallic implant, or metal in the eye). It is also important that you inform the MRI technologist if you have any metallic implants such as orthopedic pins or plates, or aneurysm clips.

Contact Information for the Study Team

If you have any questions about this research or in case of injury, you may contact:
Dr. Elizabeth Lippard (Principal Investigator)
Phone: (512) 495-5216
Email: elizabeth.Lippard@austin.utexas.edu
Mailing Address: 1601 Trinity Street, Building B, Stop Z0600
Austin, TX, 78712

Contact Information for Questions about Your Rights as a Research Participant

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

The University of Texas at Austin Institutional Review Board
Phone: 512-232-1543
Email: irb@austin.utexas.edu
Please reference the protocol number: 2018-11-0045.

Your Consent

AUTHORIZATIONS

_____I am willing to complete interviews and mental function tests for this study.
INITIALS

_____I am willing to undergo the MRI scanning for this study.
INITIALS

_____I am willing to have an audio response recorded describing videos seen during the
INITIALS MRI scan.

_____I am willing to complete the alcohol laboratory sessions for this study.
INITIALS

_____I am willing to remain in the laboratory until my BAC has reached an acceptable
INITIALS level.

_____I would like to be considered for the return follow-up visits.
INITIALS It is OK to send cards to me by mail.

_____I am willing to give a DNA sample for this study.
INITIALS

While there is no expiration date to us re-contacting you in the future you can inform us at any time that you do not wish to be contacted again and your phone number and address that could allow us to contact you will be deleted from our database.

_____ I give the research team permission to contact me in the future for other studies.
INITIALS

_____ I do not give the research team permission to contact me in the future.
INITIALS

Persons the study team can contact if we lose contact with you:

1. Name_____, Phone_____,

Address_____

2. Name_____, Phone_____,

Address_____

Please select one choice below for if you are willing/not willing to have your data deposited to the $NIAAA_{DA}$.

_____ I give the research team permission to deposit my data to the $NIAAA_{DA}$.
INITIALS

_____ I do not give the research team permission to deposit my data to the $NIAAA_{DA}$.
INITIALS

By signing this document, you are agreeing to be in this study. We will give you a copy of this document for your records. We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.
I understand what the study is about and my questions so far have been answered. I agree to take part in this study. By signing this form, I am not waiving any of my legal rights.

_____
Printed Name

_____ _____
Signature Date

As a representative of this study, I have explained the purpose, procedures, benefits, and the risks involved in this research study.

_____
Print Name of Person obtaining consent

_____ _____
Signature of Person obtaining consent Date