Consent to Participate in a Research Study

Project Title: A translational human laboratory Pavlovian conditioning model of individual differences in risk for alcohol cue incentive salience sensitization and longitudinal assessment of problematic alcohol use **-** Sips and Shapes 3

Principal Investigator Name: Roberto U. Cofresí, University of Missouri

Sponsor: National Institutes of Health (NIH) National Institute on Alcohol Abuse & Alcoholism (NIAAA)

IRB Assigned Project Number: 2106127

Please read this form carefully and take your time. Let us know if you have any questions before participating. The research team can explain words or information that you do not understand.

Key Information About the Study

You are being asked to participate in a research study. The purpose of this study is to examine how the brain processes newly learned alcohol reward cues and whether it can predict current or future level of risk for alcohol and other substance use disorders.

The research study involves 3 laboratory visits in 1 week and completing a survey packet 5 times, up to 12 months after the last lab visit. During the lab visits, you will be asked to complete a computerized learning task in which you are presented various visual stimuli, some of which predict receipt of a small amount of alcohol (your preferred alcohol beverage commercially available). Your electroencephalogram (EEG) will be recorded so that we can visualize how your brain processes visual stimuli and liquid reward.

You will not benefit directly from this study, but you may gain appreciation and understanding of how health-related research is conducted in the field of cognitive neuroscience. Some possible risks may include breaches of confidentiality and mild physical and/or emotional discomfort from study procedures. Steps will be taken to minimize these risks (see below).

Participation is voluntary and you can choose not to participate. If you do not want to participate or choose to start then stop later, there will be no penalty or loss of benefits to which you are otherwise entitled.

Purpose of the Research

This research study is being funded by the National Institutes of Health (NIH), specifically, the National Institute on Alcohol Abuse and Alcoholism (NIAAA). Dr. Roberto Cofresí is leading this study with the help of student and staff research assistants.

The purpose of this study is to increase understanding of factors that can lead to alcohol and other drug use-related problems in some people. More specifically, this research has two goals. The first goal is to explore how the brain's processing of a visual stimulus changes as a result of new experiences with that stimulus (e.g., when we learn that it predicts drug or food reward). The second goal is to explore if between-person differences in learning-related changes in how the brain processes a visual stimulus are related to between-person differences in the use of alcohol and/or other drugs. We hope that the insight we gain from this study will improve our understanding of factors that might put people at risk for developing problems with alcohol or other drugs, or that might protect people from developing such problems.

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What will happen during the study?

If you choose to participate in the research study, you will be asked to do the following:

Complete 3 lab visits on MU Campus:

- Travel to 115 Melvin H. Marx Building, University of Missouri, 1416 Carrie Francke Drive, Columbia MO **3 times in 1 week**. The first visit is expected to take 3 hours. Visits 2 and 3 are expected to take 2.5 hours.

During the lab visits:

- Provide government-issued ID to confirm eligibility for the study.
- Provide urine sample to verify pregnancy status (if applicable) and recent use of various drugs.
    - Note: The urine sample collected will be discarded immediately after it is processed. It will not be used or shared for future research studies.
- Provide breath sample to verify sobriety (breath alcohol concentration = .000 g%).
- Complete a form about sleep duration, time of last meal, time of last alcohol use, time of last other drug use (if applicable), and time of most recent physical exercise.
- Rate the taste of your alcohol beverage of choice, and the appeal of various colored shapes.
- Complete computer-based tasks in which you will be viewing colorful shapes on a computer screen. Your brain and muscle activity will be recorded. (see description below).
    - During the tasks, y**ou will be consuming sips of your fruit juice of choice (apple, orange or cranberry), as well as sips of your alcohol beverage of choice (to be determined during the Zoom call).** The liquid will be delivered directly into your mouth through **some tubes that you will be asked to hold in your mouth**. The amount of alcohol will be titrated to your age, height, weight, and sex
    - It will be the equivalent of consuming approx. 1 standard drink
    - It will give a maximal breath alcohol concentration no greater than about .03 g%
- Multiple times during the visit:
    - Complete various forms and questionnaires relevant to the research (e.g. current emotional state and craving).
    - Provide breath samples to track breath alcohol concentrations over time in the lab.
- To ensure your comfort and safety during the study, we will use a closed-circuit surveillance camera to monitor the experiment room in real time while you are completing study tasks. This monitoring allows research staff to attend to your needs promptly and detect and respond to any signs of discomfort or adverse reactions that may occur. For example, if you want to take a break or need to adjust the cap, staff can quickly respond to help make your experience as comfortable as possible. **No video recordings will be made or stored.** Our goal is to create a safe and positive environment where you can relax and focus on participating in the study.
- Stay in the building, in a comfortable waiting room with research staff monitoring your status and providing you with access to snacks, water, and TV, until your breath alcohol concentration is at or below .02 g% (for the average person, this will take about 30 minutes).
- Provide identifying information (name, permanent mailing address, social security number) required by University of Missouri policy for us to pay you for your time.
- Receive compensation in cash for your time.

EEG recording:

We will record your EEG ("brain waves") during the lab visits.

→ We will place EEG sensors embedded in a hair net on your head. The hair net will feel cool and wet because it is bathed in an electrolyte (salty water), baby shampoo and distilled water solution before application. Once the hair net is on your head, we will adjust the EEG sponges to make sure they are in contact with your scalp. It will feel like a gentle scrub through your hair. We may

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need to add more electrolyte solution to the sponge using a plastic pipette which, again, may feel cool and wet.

- → We also will gently clean some spots on your face, throat, and fingers so that we can place some sensors using adhesive tape. These sensors require an electrolyte gel which washes off easily with warm water.
- → Although the electrolyte solution should not leave any residue on your hair or scalp when it dries, you may elect to wash your hair after the EEG recording in a private bathroom stocked with soap, shampoo, conditioner, fresh towels, and a handheld hairdryer. Also, we will provide you with a protective smock (like ones used in barbershops and hair salons) to wear to prevent any of the electrolyte from getting on your clothes.

<u>In preparation for the lab visits:</u>

- → Abstain from use of alcohol, cannabis and other intoxicating drugs for 24 hr before the lab visit. You do not have to abstain from caffeine, nicotine or your regular medications.
- → .
- → Try not to eat a heavy meal within 2 hours of your visit, as having a light stomach can help prevent nausea from the liquids administered during the study. However, you know your body best—if eating something light helps you feel better or more stable, please do so.
- → You're encouraged to stay hydrated before your visit. Feel free to drink water, juice, tea, or other non-solid beverages
- → Wash your hair the night before or morning of each lab visit so that it is dry by the time you arrive. Avoid using conditioners or hair styling products.
- → Avoid wearing make-up and remove removable jewelry.

<u>Complete the survey packet 5 times:</u>

- → The survey packet will ask about your alcohol and drug use. The packet is sent electronically to you by email. You will complete it remotely. The first time you will complete the packet is approximately 1 week *before* the first lab visit. You will complete it again at 3, 6, 9, and 12 months *after* the last lab visit. It takes ≤15 min to complete each time.

Your involvement in the research study is expected to be 12 months and 2 weeks. Your participation in the study will be completed when you finish the last survey packet (12 months after the last lab visit).

There will be about 32 people participating in this study.

Weather and Personal Safety

Your safety, comfort, and accessibility are important to us. If there are hazardous weather conditions (e.g., ice, snow, severe storms) or events that could impact safe travel to or from the lab, we will reach out to delay or reschedule your appointments. If you are ever unsure about road conditions or feel unsafe traveling, please contact the research team before your visit — we will work with you to delay or reschedule your appointments.

Will you share with me any results or health problems/issues that you learn about me while in the study?

The study investigators are not medical doctors and the tests are being conducted for research purposes only. Positive urine pregnancy test results will be shared with you and you would no longer be eligible to participate in the study. In the event of a positive pregnancy test, you will be provided with information about community resources for unanticipated pregnancy and told to seek additional testing to verify the result. Positive test results for drug metabolites will be shared with you to verify that the obtained results are in keeping with your recent use of the detected drugs. The primary purpose of the EEG is research and the way we record EEG is not designed to detect or identify health problems.

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What are the expected benefits of the study?

You will not benefit directly from this study, but you may gain appreciation and understanding of how health-related research is conducted in the field of cognitive neuroscience. Your participation will benefit society by helping the researchers better understand factors related to alcohol and drug use, and the problems that can arise from these behaviors. The findings shared with the scientific community could, ultimately, lead to changes in healthcare or health-related policy-making.

What are the possible risks of participating in this study?

Risks to participants associated with this research are presumed to be greater than minimal, but no serious risk is likely. EEG recording systems are routinely used in healthcare and research settings, and are generally considered not to pose significant risks to the individual. In contrast, alcohol consumption poses significant risk to the individual, even at the very low level used here. This section describes foreseeable risks and how we will attempt to minimize them.

Alcohol consumption in the laboratory. Alcohol consumption is medically contra-indicated for some individuals including those who are pregnant. Additionally, adverse reaction to alcohol administration can occur. Adverse reactions are transient (lasting only a few hours) and can include mild to severe reactions depending on the dose consumed, such as drowsiness, flushing or warmth, elevated mood, dizziness, nausea and vomiting.

- → Individuals for whom alcohol consumption is medically contra-indicated will be excluded from participating. Female participants will be required to complete a pregnancy test in a nearby private restroom. The results of the pregnancy test will be kept confidential. If the result is positive, the participant will no longer be eligible for the study and will be provided with informational material from the University of Missouri Hospital.
- → Fasting and alcohol sensitivity: To reduce the likelihood of nausea or other adverse effects during alcohol administration, we recommend that participants refrain from eating a heavy meal for about 2 hours before their lab visit. That said, you know your body best—if eating something light helps you feel more balanced, please do so.
- → Participant selection: To minimize the likelihood of an adverse reaction to alcohol administration, we will only enroll participants who self-reported (1) having consumed alcohol on at least two days in the past 30 days and (2) having at least once in their lifetime consumed alcohol on 3 consecutive days. Low dose administration: we have designed the task such that participants' blood alcohol concentration (BAC) is expected to rise from .000 to no greater than .030 g% (for reference, in Missouri the legal BAC limit is 0.08% for drivers 21 and older). Together, these steps will ensure that the planned alcohol administration does not exceed participants' recent maximal consumption.
- → At least two trained experimenters will be present such that in the event of an adverse reaction to alcohol or unforeseen medical complications, emergency personnel can be called immediately while one experimenter remains with the participant.
- → For safety reasons, you will be asked to remain in a comfortable room of the building until at least two consecutive breath alcohol concentration (BrAC) tests, spaced 15 minutes apart, confirm that BrAC is at or below .020 g%. Snacks, water, and TV will be provided in the room.

Consuming snacks. To ensure participants remain comfortable and able to complete the study without interruption, snacks are provided for those who may experience hunger or a drop in energy. Snacks will be available at any point throughout the lab visits. Their consumption is optional and not necessary to carry out the protocol.

- → Snacks will be provided in their original packaging with ingredient labels available for your review. You are responsible for reviewing ingredient labels to ensure the snacks are safe for your consumption. If you have food allergies or dietary restrictions, please inform the research team

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before consuming any snacks. While we will make an effort to provide a variety of options, we cannot guarantee snacks for all dietary needs. If none of the provided snacks meet your dietary needs, we kindly ask that you refrain from consuming them. You are welcome to bring your own snacks if desired.

Legality of consuming alcohol. Alcohol consumption is illegal for individuals younger than 21 years old.

→ Upon arrival to the laboratory, all participants will be required to provide a government-issued photo ID to verify identity and legal drinking age.

Legality of substance use. Some people may be hesitant to disclose illegal substance use, including underage use of otherwise legal substances, and may be concerned about legal consequences.

→ **To help us protect your privacy, this study is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH).** With this Certificate, we cannot be forced or compelled (for example, by court order or subpoena) to disclose information that could identify you or be used as evidence, in any federal, state, local, civil, criminal, legislative, administrative, or other proceedings (see full explanation in Privacy section).

Breach of confidentiality. There is the potential risk of breach of confidentiality of collected information.

→ The researchers have experience dealing with sensitive information and assuring that data are adequately protected. Safeguards to protect confidentiality include locked records and firewalls around password-protected electronic data. EEG data are stored on secure network storage maintained by MU and identified only by subject code, study code, and date of acquisition.

Electroencephalography (EEG). This procedure is routinely used in healthcare and research settings and is generally considered not to pose significant risks to the individual. Some people may experience mild scalp irritation or itchiness or dryness from the electrolyte solution and/or the electrolyte gel. There is also a possibility that some people may have an allergic reaction to the electrolyte solution and/or gel.

→ Only small amounts of the electrolyte solution and/or gel are applied at a time. If you feel like you are having an allergic reaction, please let us know immediately so that we can stop the study and call 9-1-1.

Some people may be anxious about the idea of having EEG recorded because they are worried about accidental or experimenter-administered electric shocks.

→ The risk of accidental electric shock while your EEG is being recorded is no higher than the risk while using any modern electronic device. Additionally, EEG sensors are passive: receiving but not sending signals. Our EEG recording system cannot be used to administer electric shocks.

Physical and/or emotional discomfort. Some people may experience mild fatigue or boredom from completing the computer-based tasks, or mild discomfort from swallowing the liquid. Some people may experience emotional discomfort from disclosing sensitive information (e.g., substance use, emotional state, and craving).

→ We will provide you with short rest breaks during and in-between each of the tasks. The computerized learning task is designed to deliver only small amounts of liquid at a time to minimize discomfort and the likelihood of an adverse reaction (e.g. vomiting). If you wish to take additional breaks or discontinue your participation, you may do so at any time without penalty.

→ You may skip any questions that you do not feel comfortable answering or stop the surveys or procedures at any time.

Unforeseeable risks. Procedures in this study may pose unforeseeable risks. If you are pregnant or become pregnant while in this study, there may be risks to you, the embryo or fetus that we do not know yet. It is for this reason that we ask you to provide a urine sample to be tested for potential pregnancy. Regarding positive urine pregnancy test results and positive test results for drug metabolites, see “Will you share with me any results” section above.

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Because this is a research study, there may be additional risks that we cannot identify at this time. We will tell you about any new important information we learn that may affect your decision to continue to participate in this study.

What other choices do I have if I don't want to be in this study?

You are not required to be in this study. You can simply choose not to participate. You can look for other research projects you may be interested in instead of this study.

Will I receive compensation for taking part in this study?

You will be compensated for taking part in this study. In total, you can earn up to $350. Please see the table below for the description of compensation.

For completing lab visits, you will be paid <u>in cash at the end of each visit</u>				
Laboratory Visits	Expected Duration (hr)	Base ($)	"Streak" Bonus ($)	Day Total ($)
1	3	60	-	60
2	2.5	50	-	50
3	2.5	50	60	110
			Total	**220**

For completing survey packets, you will be paid <u>in electronic gift cards sent to you by email</u>						
Survey Packet	Completion	Expected Duration (min)	Base ($)	"On Time" Bonus ($)	"Streak" Bonus ($)	Survey Total ($)
#1	1 week before first lab visit	15	10	10	-	20
#2	3 months after last lab visit	15	10	10	-	20
#3	6 months after last lab visit	15	10	10	-	20
#4	9 months after last lab visit	15	10	10	-	20
#5	12 months after last lab visit	15	10	10	30	50
					Total	**130**

To earn the "On-time" bonus, you must complete the packet within 48 hours of receiving the email prompt.

Survey Packet #1: you will be paid by email after completion of the first lab visit. If you do not complete the first lab visit, you will not earn the "on-time" bonus for the pre-lab survey.

Survey Packet #2—#5: you will be paid by email within 48 hr of submitting the survey after verification of submission by a member of the research team.

We will need your Social Security Number in order to pay you. Any payment may need to be reported as income on your tax return. If you are not a resident/citizen (non-resident alien) of the United States, you will need to work with the MU Nonresident Tax Specialist at 573-882-5509.

If you withdraw from participation prior to the end of the study, your compensation will be pro-rated according to the amount of time spent in the laboratory or surveys completed.

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Are there any costs for participating in this study?

Costs to you from being in this study may include transportation, parking, childcare, and/or time off work. You should not expect any additional costs by participating in this study. You should discuss any questions about costs with the researchers before agreeing to participate.

Will information about me be kept private?

The research team is committed to respecting your privacy and keeping your personal information confidential. We will make every effort to protect your information to the extent allowed by law. Your records will be given a code number and will not contain your name or other information that could identify you. The code number that connects your name to your information will be kept in a separate, secure location. Information contained in your records will not be given to anyone unaffiliated with the study in a form that could identify you without your written consent, except as required by law. This research is covered by a **Certificate of Confidentiality** from the National Institutes of Health (NIH). 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;
- 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 NIH 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 for any purpose you have consented to in this informed consent document.

<u>We may share any and all information that have we collected from you as part of this research, after removing your identifiers, for future research without additional informed consent from you.</u> When the results of this research are shared, we will remove all identifying information so it will not be known who provided the information. Your information will be kept as secure as possible to prevent your identity from being disclosed.

National Institute on Alcohol Abuse and Alcoholism Data Archive ($NIAAA_{DA}$)

Data from this study will 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 deidentified study data helps researchers learn new and important things about alcohol problems more quickly than before.

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During and after the study, the study researchers will send your deidentified study data to the NIAAA$_{DA}$. Other researchers across the world can then request the deidentified study data for other research. Every researcher (and institutions to which they belong) who requests the 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. The 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 so, please tell the study researcher before leaving the lab today. 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 I am injured during the study?

It is not the policy of the University of Missouri to compensate human subjects in the event the research results in injury. The University of Missouri, in fulfilling its public responsibility, has provided medical, professional and general liability insurance coverage for any injury in the event such injury is caused by the negligence of the University of Missouri, its faculty and staff. The University of Missouri also will provide, within the limitations of the laws of the State of Missouri, facilities and medical attention to subjects who suffer injuries while participating in the research projects of the University of Missouri.

In the event you have suffered injury as the result of participation in this research program, you are to contact the Risk Management Officer, telephone number (573) 882-1181, at the Health Sciences Center, who can review the matter and provide further information. This statement is not to be construed as an admission of liability.

Who do I contact if I have questions or concerns?

If you have questions about this study or experience a research-related injury, you can contact the University of Missouri researcher Dr. Roberto U. Cofresí at CofresiR@missouri.edu, 573-723-1548 (cell phone) or 573-544-0192 (lab phone).

If you have questions about your rights as a research participant, please contact the University of Missouri Institutional Review Board (IRB) at 573-882-3181 or muresearchirb@missouri.edu. The IRB is a group of people who review research studies to make sure the rights and welfare of participants are protected.

Do I get a copy of this consent?

You can ask the researcher to provide you with a copy of this consent for your records, or you can save a copy of this consent if it has already been provided to you.

We appreciate your consideration to participate in this study.

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