

Cover page

Official Title of study: Marijuana's Impact on Alcohol Motivation and Consumption

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**Study Consent**

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Name of Participant

**BROWN UNIVERSITY**  
**CONSENT FOR RESEARCH PARTICIPATION**

***Marijuana's Impact on Alcohol Motivation and Consumption***

Version 10, 6/20/2020

**Key Information:**

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

- PURPOSE: The study is about whether smoking marijuana may influence alcohol drinking choices and influence drinking behavior.
- PROCEDURES: The study involves one videoconference screening session, an in-person physical exam screening, online questionnaires, and three in-person study sessions (S1, S2, and S3). At each in-person visit you will be asked to provide a urine sample to be tested for recent drug use, and if you are able to become pregnant, will also be tested for pregnancy. For study sessions S1, S2, and S3, you will be asked to refrain from all smoking and marijuana use starting at least 15 hours before your sessions, to avoid drinking alcohol for 24 hours before sessions, and to also avoid eating and caffeine for 2 hours before your sessions. You will be asked to breathe into a tube to test for alcohol and carbon monoxide in your lungs. You will be asked to complete questionnaires; smoke a marijuana cigarette; and will be given the opportunity to drink alcohol.
- TIME INVOLVED: The remote videoconference screening session will take 1-1.5 hours, the in-person physical exam screening will take about 30 minutes, the online questionnaires will take about 1 hour, and the in-person sessions S1, S2, and S3 will be 5-6 hours each, for a total up to 21 hours of participation.
- COMPENSATION: You will receive compensation as an electronic Amazon gift card (in-person screening visit) and through a pre-paid card similar to a debit card (experimental study sessions). You will receive a minimum of \$310 and up to \$407 for your time (if completing all study sessions).
- RISKS: You may feel uncomfortable responding to questions; and may experience impaired judgment or motor coordination and other adverse reactions to marijuana and alcohol.
- BENEFITS: There are no direct benefits from participating in this study.

**Principal Investigator.**

Jane Metrik, Ph.D., Center for Alcohol and Addiction Studies, Brown University School of Public Health, Box G-S121-4, Providence, RI 02912.

You are being asked to take part in a Brown University research study.

The researcher will explain the purpose of the project. He or she will explain how the project will be carried out and what you will be expected to do. The researcher will also explain the possible risks and possible benefits of being in the project. Please read the form and ask the researcher any questions you have about any of these things before you decide whether you wish to take part in the study. This process is called informed consent.

**1. The Project.**

We are interested in learning whether smoking marijuana may influence alcohol drinking choices and influence drinking behavior. This project is sponsored by the National Institute on Alcohol Abuse and Alcoholism.

## **2. What Will Be Done.**

The study has three parts. First, you will complete an online screening survey and interviews about your substance use and medical and psychiatric history to establish initial study eligibility using a videoconference (Zoom) session with our project staff. The interview portions will be audio recorded for supervision and quality assurance purposes. Second, if eligible, you will complete an in-person screening including urine screen, height, weight, and vital signs measurement, and physical exam to establish full eligibility. Third, if eligible, you will complete online study questionnaires prior to S1 and then three in-person study sessions (S1, S2, and S3).

At each in-person visit, you will also be asked to give a urine sample, which will be tested for recent drug use. At the first in-person screening visit, this urine test has to be positive for marijuana in order for you to participate. If you are able to become pregnant, the urine will also be tested for pregnancy. If you are pregnant, you will not be able to participate. In the event of a positive urine test for illicit drugs other than marijuana, you may reschedule the session once.

### ***In-person Screening/Physical Exam***

If you still appear eligible after the remote screening, you will complete an in-person screening visit to establish full eligibility. This visit includes providing a urine screen, height, weight, and vital signs measurement, and physical exam with our study physician or nurse practitioner (hereafter referred to as the “study physician”). We may learn things about your health that require medical attention as part of the research physical exam. If this happens, this information will be provided to you at the time of the physical exam. You may need to meet with a medical professional with expertise to help you learn more about your research results and/or provide necessary treatment. The study team/study will not cover the costs of any follow-up consultations or actions.

### ***Experimental Sessions S1, S2, and S3 (3 study visits)***

Each experimental session should be completed from 5 days to 3 weeks from the previous experimental session. If you are unable to complete them within this time frame, you may be withdrawn from the study at the discretion of the Principal Investigator.

For sessions S1, S2, and S3, you will be asked to: (a) refrain from all smoking and marijuana use starting at least 15 hours before your sessions; (b) avoid drinking alcohol for 24 hours; and (c) stop eating food or consuming any caffeinated beverages 2 hours before your scheduled appointment.

At sessions S1, S2, and S3: (a) You will be asked to breathe into a tube that will measure the amount of carbon monoxide in your lungs and this information will be used to confirm that you have avoided all smoking prior to today's session. If the test suggests you have smoked within the past 15 hours, you will not be able to complete the session and will be given one more opportunity to come in for a session without smoking; and (b) You will be asked to blow into a machine that will tell us whether you drank any alcohol before coming in. If there is alcohol in your breath, we will have to re-schedule the interview.

At each experimental session, you will fill out paper-and-pen questionnaires throughout the session. Shortly after arrival, you will be provided with a light meal. At S1, you will complete an interview about your substance use and psychiatric history. This interview portion will be audio recorded for supervision and quality assurance purposes. You will be asked to smoke a marijuana cigarette. Each session, you will receive a marijuana cigarette of a different strength (“Dose A”, “Dose B”, and “Dose C”). These three doses vary in their concentrations of delta-9-THC in the low to moderate potency range from session to session. The cigarettes will be provided by the National Institute of Drug Abuse. We will have your blood pressure and heart rate monitored before and after the smoking.

You will be asked to hold, smell, and taste an alcohol beverage of your choice for a number of minutes. You will fill out some brief questionnaires. There will be a period when you can consume beverages containing alcohol (of your choice that you indicated earlier). The total amount of alcohol available is not intended to raise the level of alcohol in your breath to greater than .10 g/dl. During these periods, you will be given a \$24 credit and can pay \$3 for each beverage up to 8 beverages. After this period, you will complete more paper-and-pen questionnaires. We will test your blood pressure and heart rate a few times during these sessions. You will remain in the laboratory for at least 4 hours after smoking marijuana and until your breath alcohol level is at or below .04 g/dl. You will also be evaluated for signs of intoxication and will complete a field sobriety test. Following successful completion of the sobriety test, we will provide a taxi service for your transportation. You will be able to leave on your own if your breath alcohol level is at or below .02 g/dl as long as you avoid driving. When you are finished with the study, you will be provided information on the health effects of alcohol and marijuana.

In order for this project to have scientific value, we will make every effort to contact you with reminders and confirmations of the upcoming sessions. At S1, we also will ask you to provide the names of two friends or relatives whom we can contact in the event that your phone number or email address changes and we are not able to locate you. These individuals would be asked to provide your updated phone or email. We would not share any information with them that you have provided us.

### **3. Time Involved and Compensation**

The remote videoconference screening session will take 1-1.5 hours, the in-person physical exam screening will take about 30 minutes, the online questionnaires will take about 1 hour, and the in-person experimental sessions S1, S2, and S3 will be 5-6 hours each, for a total up to 21 hours of participation.

To receive your initial payment, you must be found eligible based on the videoconference screening and attend your first in-person screening visit. You will be paid \$10 for your time and effort if found ineligible for the study at this screening based on the results of your urine drug or pregnancy screen, height, weight, or vital signs measurement. If eligible, you will receive \$25 for completing the physical exam. If eligible after the physical exam, you will be paid \$25 for completing online questionnaires prior to S1. You will receive this payment at S1.

For each of the 3 experimental sessions S1, S2, and S3, you will be paid \$60, plus the amount that you can earn during the drinking periods (up to \$24 in each session). In addition, if you keep the study appointments as scheduled, you will receive a bonus \$10 for the first experimental session and \$15 for the second experimental session. You will receive these bonus payments if you keep the appointments as scheduled or rescheduled in advance, no less than 2 business days, as notified and confirmed by the study staff. If you complete all study sessions, you will receive an \$80 bonus at the third experimental session. The total possible payment you may receive for participating in this study will be \$407, and the minimum you will earn for completing all four in-person sessions is \$310.

You are free to stop the study at any point during the session. If you choose to stop participating before the experimental sessions are complete, you will receive a prorated payment of \$10 for the session in which you terminated early.

Payment for participating in this study will be made using an electronic Amazon gift card (initial in-person screening visit/physical exam), or by using ClinCard, a pre-paid card that works like a bank debit card

(experimental sessions S1, S2, and S3). We will give you the debit card at the end of your first experimental session. You will be issued one card for the duration of your participation and this card may be used to pay you in any future Brown University studies you choose to participate in. You will also receive information about how to use this card and whom to call if you have any questions. Be sure to read this information, including the cardholder agreement.

Money will be added to your card according to the study's payment schedule. You may use this card at any store that accepts Mastercard. You may also use an ATM with the Mastercard logo to withdraw cash. If you use the card to withdraw cash, or if the card is not used within any six (6) month period, you will be charged a fee that will reduce the total amount of money left on the card. Please read the FAQ information sheet for details about fees.

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

If your card is lost or stolen, please call 401-863-6688 or ask the study coordinator for a replacement card. You may be charged a fee if you request a replacement card from Greenphire directly.

If you are unable to utilize an Amazon e-Gift Card, you will be able to request that staff mail you a money order for any payments made prior to completing S1.

#### **4. Discomforts or Risks and Protection Against Risk.**

There are some possible risks to participating in this study. Some of the questions may be of an embarrassing or sensitive nature and may make you uncomfortable. Therefore, you are free not to answer any questions you do not wish to answer. Some of the tasks you complete may be challenging and may cause stress or frustration. You will be asked to smoke marijuana. You will be offered the choice to drink beverages containing alcohol. Your judgment and motor coordination may be impaired, which is why you will need to stay with us for 4 hours after the smoking and until your blood alcohol level is at or below .04 g %.

Other possible adverse reactions to marijuana and alcohol include (1) dizziness, nausea and/or vomiting (and aspiration of vomit if asleep or unconscious); (2) injury due to slips, falls, cigarette burns, or physical constraint in response to aggressive behavior; (3) fetal damage; (4) adverse interactions between alcohol or marijuana and medications for which alcohol and marijuana use are contraindicated (e.g., psychotropic drugs, antihistamines) or between alcohol and other illicit drugs; (5) exacerbation of medical problems for which alcohol or marijuana use is contraindicated; (6) aggravation of pre-existing alcohol or marijuana problems; (7) stomach and intestinal discomfort and (8) breach of confidence and embarrassment due to uninhibited behavior after drinking alcohol or smoking marijuana.

Due to potential adverse effects of alcohol or marijuana on a fetus, it is important for female participants to use a reliable means of contraception if engaging in sexual intercourse with a man during the course of this study. If you are capable of becoming pregnant and want to participate in this study, you must agree to complete a pregnancy test that we will provide and to use a medically accepted means of birth control. Let us know if you change your mind and decide to become pregnant during the study. You are not eligible to participate in the study if nursing your child, due to the medical risks and/or harms it causes to your child during development.

While participating in the study, you cannot be using medications for which alcohol or marijuana is contraindicated. You are asked to report all prescription and over-the-counter medications during your participation to guard against interaction with the alcohol that is administered in the study. You cannot have any medical conditions for which you should not drink alcohol or use marijuana (e.g., heart conditions, liver disease, diabetes, or neurological disorders). You are required to report these conditions on the medical history form to ensure your safety in the study. We will monitor your heart rate, blood pressure, and your reactions to marijuana and alcohol at all times during the experimental session. If you experience an unpleasant reaction to marijuana or alcohol, a licensed psychologist or the study physician will talk to you about your reaction. If you have moderately serious or serious unpleasant physical reactions to marijuana or alcohol, the study physician will evaluate your need for emergency medical services.

You are free to stop smoking marijuana or drinking alcohol at any point during the study session. If you choose not to finish the marijuana smoking, you will not be able to continue in the study, but you will receive compensation for the sessions you did complete and a prorated payment of \$10 for the session in which you terminated early.

## **5. Benefits.**

We cannot and do not guarantee or promise that you will receive any benefits from this study. You will have a chance to contribute to a scientific study that may help people in the future. In addition, you may benefit by receiving information on the effects of alcohol and marijuana on health and behavior.

## **6. Confidentiality.**

Participation in this study and information gathered from the study will be kept confidential. All information obtained from you will be identified only by a code number. Audio recordings are used for supervision purposes and will be erased once reviewed. A record of your name (with address and telephone number) and your code number will be kept in a separate locked location, available only to the Brown University investigators and employees on this project. Your answers are confidential. To further protect your confidentiality, we will refer to ourselves during all telephone calls as "Brown University" and will not use any other identifying information. The findings of the study may be published but individual participants will not be identified. We may use or share your research information for future research studies but it will be de-identified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies. We may also share your de-identified information with other researchers here, at other institutions in the United States or around the world.

Any reports related to child abuse/neglect or elder abuse will be reported by us to the appropriate authorities. A description of this clinical trial will be available on <https://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. Because this research involves a substance regulated by the Food and Drug Administration (FDA), the FDA may choose to inspect and copy medical or research records that identify individual research subjects.

We have obtained a Certificate of Confidentiality from the National Institutes of Health, which authorizes us to protect the identity of our research participants from any civil, criminal, administrative, legislative, or other proceedings, whether federal or state and local. We cannot be compelled to reveal the identity of our participants unless 1) you provide us with written authorization to disclose your identity, or 2) such release is required by the Federal Food, Drug, and Cosmetic Act, or 3) the National Institutes of Health requests such information for audit or program evaluation purposes. The certificate does not govern the voluntary disclosure

of such information, nor does it represent an endorsement of the research project by the Department of Health and Human Services. Please be aware, however, that the certificate of confidentiality does not protect your identity in the event of your own disclosure of participation in this study. Therefore, it is important that you use your discretion with respect to participation in this study.

### **7. Decision to Participate and Right to Quit at Any Time.**

The decision whether to be in this study is entirely up to you. Participation is voluntary. Also, if you decide not to participate, you will be able to change your mind later and withdraw from the project. There will be no penalty if you decide not to be in the project or withdraw from the project later.

### **8. Who to Call.**

Questions about the study should be directed to Dr. Jane Metrik at (401) 863-6650. Questions about the rights of a research subject should be directed to the Brown University Human Research Protection Program at 1-866-309-2095 or IRB@brown.edu.

### **9. Consent to Participate.**

(Check Yes or No, and type your initials)

I agree to be re-contacted for future studies:

Yes  No \_\_\_\_\_ (initials)

Your signature below means that you have read the information on this form, asked any questions you have about the project, and agree to participate in this study as indicated above. You will be given a copy of this form to keep.

I HAVE READ THE CONSENT FORM AND FULLY UNDERSTAND IT. ALL OF MY QUESTIONS HAVE BEEN ANSWERED. I AGREE TO PARTICIPATE IN THIS PROJECT. I WILL RECEIVE A COPY OF THIS FORM.

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Signature of participant

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Date

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Signature of person explaining study

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Name of person explaining study

Copies to:      Participant  
                    Investigator's files

**(Version 10, date: 6/20/20)**