Medical University of South Carolina

CONSENT TO BE IN A RESEARCH STUDY

Approach bias modification for the treatment of cannabis use disorder

Concise Summary

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. The purpose of this study is to evaluate the effectiveness of Approach Bias Modification (ABM) in the treatment of Cannabis Use Disorder (CUD). ABM is a new treatment that involves using a joystick to respond to cannabis and neutral pictures presented on a computer screen. ABM has been shown to reduce alcohol and nicotine use, but has not yet been tested for marijuana use.

If you agree to participate, you will undergo a screening visit where you will be asked questions about your psychiatric and substance use history, and recent marijuana use. If after evaluation you are eligible to participate in the study, you will be randomly assigned to receive active ABM or fake ABM. You will have a 50:50 chance (like the flip of a coin) of being in the active ABM group. Neither you nor your study therapist will know what group you are in. You will have once weekly study visits for 4 weeks that will include ABM training; three visits will also include a marijuana use therapy session. There are follow-up visits one month later and 6 months later, so that the total duration you are in the study will be approximately 8 months. You will be asked to complete questionnaires about substance use at each visit, and at visits 1, 4, and the follow-up will complete cognitive tasks that assess memory and concentration. Visits will last from 1-2 hours.

Participation in this study may lead to a reduction in your marijuana use or marijuana craving, however, that cannot be guaranteed. You do not have to participate in this study to have your condition treated. Alternative treatments include individual or group therapy. There are risks to the study treatment that are described in this document. Some of the risks include boredom, fatigue, or feeling upset at the review of your psychiatric status; and craving for marijuana.

If you are interested in learning more about this study, please continue to read below.

A. PURPOSE AND BACKGROUND:

You are being asked to volunteer for a research study. This research study is sponsored by the Medical University of South Carolina. The purpose of this study is to determine if Approach Bias Modification (ABM) can reduce cannabis (marijuana) craving and cannabis use in adults with cannabis use disorder.

You are being asked to participate in this study because you are currently using marijuana on a regular basis and have expressed an interest in quitting or cutting down. The investigator in charge of this study is Brian Sherman, Ph.D. This study is being done at the Addiction Sciences Division and will involve approximately 136 volunteers.

B. PROCEDURES:
If you agree to be in this study, the following will happen:

On your first visit (screening):

1. You will be evaluated first to see if you meet the study requirements. You will be asked about your psychiatric and substance use history and recent marijuana use. If you are female and of child-bearing potential, you will be tested for pregnancy. If your pregnancy test if positive you will not be allowed to participate in the study. If your pregnancy test is negative, or if you are male, a urine drug screen will be performed.
2. If after evaluation you are eligible to participate in the study, you will be asked to fill out additional questionnaires about your substance and personality traits. If you are female, you will be asked to complete a calendar tracking your menstrual cycle for the past 90 days. You will then be scheduled for your next study visit.
3. Remote screening visit: The initial visit may also be done remotely. In that case, the consent will be emailed to you prior to the screening appointment. You will be asked to find a private location to have a video call with study staff using an online program called Doxy.me. On the video call, study staff will obtain informed consent and do the initial interview. If you are eligible, you will be sent survey links to complete questionnaires. If you are female, your pregnancy test will be completed at Study visit 1.

Study visits (visits 1-4):

1. You will be asked to abstain from marijuana and alcohol for 12 hours prior to each study visit and other drugs (except nicotine) for 3 days prior. When you arrive for each visit, urine, saliva, and breath samples will be collected to assess for alcohol and drugs of abuse. If you test positive for alcohol or other drugs (besides marijuana), or if you appear to be under the influence of any substances, you will not be able to participate that day and attempts to reschedule will be made.
2. At visit 1 you will be randomly assigned to receive either ABM or sham ABM.
3. During each treatment visit you will complete ABM procedures which involve a computerized task assessing reaction time (described below).
4. At three of these visits you will also meet with a therapist to discuss your marijuana use. At visits 1 and 4 you will complete a cue-exposure task (described below), and a series of computer- and paper-based tasks measuring things like memory, attention, and processing speed.
5. In some cases, the questionnaires and interviews from Study visits 1-4 may be completed remotely rather than at the clinic visits to limit face-to-face exposure.

One-month follow-up visit (visit 5):

1. You will be asked to complete the same computerized ABM procedures, self-report questionnaires, and cue-reactivity tasks as in previous visits. You will also be asked about your substance use since your last study visit. If you are female, you will be asked to update the menstrual cycle calendar.

Six-month follow-up visit (visit 6):

1. You be asked to complete a six-month follow-up visit either in person or over the phone. At this visit you will be asked about marijuana- related symptoms and recent marijuana use. If you complete the visit over the phone, you will be given the option to complete surveys from a link sent securely to your

email. If you complete the visit in person you will provide a urine sample to be tested for drugs of abuse. If you attend this visit in person you will be compensated.

Approach bias modification:

You will be asked to either push or pull a joystick depending on the border color of pictures (yellow or blue) presented on a computer screen. Pictures will contain either neutral or marijuana-related items. It is important to be as fast and accurate as possible during this procedure. You will respond to 2 sets of images (approximately 5 minutes total) during the testing phases and 2 sets of images (approximately 10 minutes) during each treatment phase.

Cue exposure:

On study visits 1, 4, and 5 you will complete a cue-exposure task. A sensor will be placed on your finger to measure skin response during the task. Approximately 5 minutes later you will begin the cue-exposure. You will be asked to view and handle two sets of items (neutral and marijuana-related) while listening to audio scripts of a day at the beach or a recent marijuana session. Before and after each set of items we will ask you about your craving.

C. DURATION:

Participation in the study will take about 8 months. You will be seen for 1 eligibility assessment, 4 weekly study visits, and 2 follow-up visits. The eligibility assessment visit is expected to last approximately 60 minutes, visits 1 and 4 will take about 2 hours, and visits 2, 3, and 5 will last approximately 60 minutes. Visit 6 will last approximately 20 minutes.

D. RISKS/DISCOMFORTS:

1. Interviews: The interviews that you will receive during the course of the study involve no specific risks or discomforts beyond those of a standard clinical interview situation, such as boredom, fatigue, or feeling upset at the review of your psychiatric status. If a question makes you uncomfortable you may refuse to answer it.
2. Marijuana cues: Exposure to marijuana cues may produce some craving for marijuana or other discomfort. However, this discomfort is usually brief and you will be in the safety of a marijuana-free laboratory environment.
3. Unknown risks: Participation in the study may have unknown side effects. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

<u>Risks regarding Confidentiality:</u>

Despite efforts to maintain your confidentiality, there is always some minimal risk of people other than the study investigators gaining access to your health information. Information we collect from you will be labeled with your initials and a code number rather than your name. Your urine and saliva will be screened for the use of cannabis and other potentially abused or illegal drugs. Every effort will be made to protect the confidential nature of this information. There may however be circumstances under which the investigator would be legally

required to release this information.

If you are pregnant and test positive for illegal drugs, SC state law requires that the SC Department of Social Services (DSS) be notified if your drug use is endangering your developing fetus if you are 24 weeks or greater of gestation. You will be at risk of going to jail or losing custody of your children. If you are pregnant however, you will not be eligible to participate in the study, and we will not test your urine, or saliva.

E. MEDICAL RECORDS:
Information about your study participation will not be in your medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record.

F. CERTIFICATE OF CONFIDENTIALITY:
This research is covered by a Certificate of Confidentiality from the Federal government. This means that the researchers may not disclose information or biospecimens that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, nor can the information or biospecimens be used as evidence, unless you have consented to this disclosure. Information or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless you have consented to the disclosure. More specifically, identifiable information or biospecimens will not be shared with your medical providers who are not involved in this research unless you authorize the study to disclose information to them, or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Information about your study participation will not be in your MUSC medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record. 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 authorize the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Examples of required disclosure include: child abuse and neglect, or harm to self and others, but there could be others.

Finally, a Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating federally funded projects or information needed by the FDA.

G. BENEFITS:
There is a 50% chance that you will receive both ABM and a validated marijuana counseling course. The combination of these treatments may help you quit or cut down your cannabis use. All participants will receive the marijuana counseling, and there is a chance that this counseling will help you quit or cut down your cannabis use. These procedures also may not be helpful, so there may be no benefit from participating in this study. Additionally, it is hoped that the information gained from this study will help the investigators learn more about how ABM affects cannabis use, craving, and aspects of memory and attention.

H. COSTS:
You will not be charged for any of the study procedures. The costs of all tests associated with this study will be covered by the study.

I. PAYMENT TO PARTICIPANTS:

In return for your time and effort to participate in this study, you will be paid for attendance plus bonuses. For the screening visit, you will be paid $20 for the psychiatric interview and $20 for the questionnaires and urine drug screen. You will be paid for each study visit starting at $20 for baseline/week 1 and increasing by $5 each week; any missed visit will reset the payment to $20. You will also receive cash bonuses for completing baseline/week 1 ($25) and week 4 ($50). You will be paid $50 for the one-month follow-up visit and $20 if you complete the six-month follow-up visit in person.

You will also draw from a bowl containing 250 chips that are assigned a certain value. Two hundred and thirty chips denote a small amount ($1.00), 18 chips denote a larger amount ($10.00), one chip denotes $50.00 and one chip denotes a jumbo amount ($100.00). If you complete the urine drug screen at the screening visit, you will be allowed three draws and at each visit afterwards if your saliva drug screen is negative, you will be allowed five draws.

Payment for study visits will be made using a cash or a pre-paid debit card, called a ClinCard. It works like a bank debit card and you may use the card to purchase goods or services everywhere Debit MasterCard is accepted. Each time you receive payment for participation in this study, the money will be added to the card, as outlined in the payment schedule above. Details of the debit card system are explained on an additional sheet. You may have the ClinCard mailed to you or you will receive it at your first clinic visit.

The total amount that you may receive for participating in the study if you complete all study visits is $295 plus the sum of what you gather from the chip pick. You may be paid with cash or gift cards. If you choose not to complete the study, you will be compensated for the part(s) you have completed.

Compensation is broken down as follows:

Visit	Compensation
Screening	$40 ($20/$20)
Baseline/visit 1	Max $45
Study visit 2	Max $25
Study visit 3	Max $30
Study visit 4	Max $85
One- Month Follow-up visit	$50
Six-Month Follow-up visit (in person)	$20
Maximum Total	$295

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

J. RECRUITMENT OF SUBJECTS

You are invited to participate in the recruitment of subjects for this study. If you choose to participate, we will provide you with coupons that you may give to other people (e.g. peers, acquaintances) who you think would be

eligible and interested in this study. You may choose to tell people to whom you give these coupons to call the study office if they are interested in participating in the study. These individuals will not be identified unless they contact the study office themselves. If any of your coupons result in successful study recruitment, you will receive $10 for each one. Participants will be notified that they have earned referral compensation and may come by the office to pick it up. Participation in the recruitment process is voluntary, and if you elect not to participate your participation in this study will not be affected in any way.

K. ALTERNATIVES:
This is a scientific investigation and not part of standard clinical care. This study is voluntary and you may choose to not participate in this study. Whether or not you choose to participate in this study will not affect your relationship with any current treatment provider you may have, or your right to health care or other services to which you are otherwise entitled now or in the future.

L. DATA SHARING:
Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

M. DISCLOSURE OF RESULTS:
Individual research results will not be disclosed to participants unless requested.

N. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION
As part of this research study, your study doctor and his/her research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:
    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public

health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

O. NEW INFORMATION:

If there are significant new findings during the course of the study, you will be notified.

P. INVITATION TO PARTICIPATE IN FUTURE STUDIES

From time to time we have other research studies that you may be eligible to participate in. We are inviting you to allow us to contact you by phone, mail, or both to see if you would be interested in participating in any future studies. By checking the "yes" box below, you are indicating that you would like us to contact you by phone, mail, or both if another study becomes available that you might qualify for. To maintain your confidentiality, we will not leave identifiable messages or any identifiable information on letters or envelopes that are mailed to you. By checking the "no" box below, you are indicating that you do not want study personnel to contact you for any future studies. You may still participate in the current study if you check "no" and you will not suffer any adverse consequences in doing so. Please initial by your choice below for paper consents, or scroll down to the bottom of the screen and select your choice electronically:

☐ **Yes** I would like to be re-contacted for future studies. I give permission for study personnel to contact me by phone, mail or both to inform me of other available studies I may be eligible for. Please initial here_____.

☐ **No**. I do not wish to be re-contacted for any future studies. Please initial here_____.

Q. CLINICAL TRIALS.GOV

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

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency you should go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. The Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Brian Sherman, Ph.D. (843) 792-8174. I may contact the Medical University of SC Hospital Medical Director (843) 792-9537 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board (IRB) for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records. Please sign below for paper consents or scroll to the bottom of the screen to provide an electronic signature.

Signature of Person Obtaining Consent	Date

Signature of Participant	Date

Printed Name of Participant	Date