Functional Outcomes of Cannabis Use (FOCUS) in Veterans with Posttraumatic Stress Disorder

NCT04565028

Informed Consent Form

Document Date: April 9, 2025

Participant Name:	**Date:**
Study Title: Functional Outcomes of Cannabis Use (FOCUS) in Veterans with Posttraumatic Stress Disorder	
Principal Investigator: Jean C. Beckham, PhD	**VAHCS**: Durham VAMC

OVERVIEW AND KEY INFORMATION

Please read this form carefully. You are being asked to participate in this research study because you have posttraumatic stress disorder (PTSD) and may or may not use cannabis. This study is voluntary and will include only people who choose to take part. Ask your study doctor or study staff to discuss this consent with you, please ask him/her to explain any words or information that you do not understand. It is important that you understand the information on this form.

The purpose of this study is to assess the impact of reduced frequency and quantity of cannabis use on functioning in Veterans with PTSD. If you agree to participate in this study, you will attend two to three in-laboratory sessions. In the first, you will complete several self-report questionnaires, and be interviewed by a study team member about psychiatric symptoms and substance use disorders. You will be asked to do some home monitoring, which may include electronic diary readings and cannabis saliva test readings. You will do this home monitoring for two weeks. After this 2-week period of home monitoring, you will be asked to attend an in-person study visit to provide a urine sample.

If you do not use cannabis or you are a light to moderate user, you will come in for a final study visit six weeks later. If you are a heavy cannabis user, you will be asked to reduce or abstain from cannabis use. You will continue monitoring for six weeks. After that, we will ask you to come in for a final study visit. During the final study visit, you will complete some questionnaires about your mood, functioning, and substance use.

If you are a heavy cannabis user, you may benefit by quitting or reducing your cannabis use. Risks to participating in the study include the risk of discomfort or distress in answering questions. Reduction of cannabis use can cause withdrawal symptoms. Symptoms can last for a few days to several weeks. These may include headache, trouble sleeping, sweating, night sweats, anxiety and/or depression, nightmares or vivid dreams, irritability, and cravings for use. There is a risk of frustration due to payment delays, and a risk of loss of confidentiality.

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WHY IS THIS STUDY BEING DONE?

The study is being done to assess the impact of reduced frequency and quantity of cannabis use on functioning in Veterans with PTSD

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 250 people will participate in this study at the Durham VA Health Care System (DVAHCS).

HOW LONG WILL I BE IN THIS STUDY?

Your participation in this study will last about eight weeks.

WHAT IS INVOLVED IN THIS STUDY?

If you agree to participate in this research study you will be asked to sign and date this consent form. After that, we will determine if you are eligible to continue with the rest of the study. You will be interviewed about any psychological symptoms. The interview will include questions about PTSD, mood, substance use, and other psychological symptoms. You will be asked to complete questionnaires related to trauma history, PTSD symptoms, substance use, general health, suicidal thoughts, sound sensitivity, the COVID-19 pandemic, impulsivity, discrimination, and general functioning. You will also complete some tasks to measure your working memory. You will be asked to provide a urine sample so that we can test your urine for cannabis and other drugs. Part of your urine sample will be sent to MCI Diagnostic Center, LLC in Texas for a special analysis of cannabis. You will also be asked to provide a saliva (spit) sample to test for more recent use of cannabis. Part of your saliva will also be sent to MCI Diagnostic Center, LLC for another analysis of cannabis. If you are a cannabis user, you will also be asked to perform a task in which you roll a joint, pack a bowl, etc. (based on how you normally use cannabis) with catnip. This will help you estimate the amount of cannabis you use each day.

If you are ineligible to participate in the study, we will pay you $50 for participating in the screening session. If you are eligible to participate in the study, you will be paid $125 for the first visit.

You will be asked to complete an electronic diary using a survey system called Qualtrics. This electronic diary will send two alarms per day to you, and we will ask you to respond to the alarm. Questions in the electronic diary will include items about urges to use cannabis, recent use of cannabis, and your surroundings (e.g., where are you, what you are doing). If you are a cannabis user, we will give you a small scale to help you estimate how much cannabis you use. You will be asked to complete additional diary entries at the beginning and end of each day. You will be paid for completing the diary entries, too. We will pay you $50 each week, and if you miss no more than one alarm per day, you will also be paid a $25 bonus each week.

If you are a heavy cannabis user, during this period, you will be asked to do additional tasks. We will give you some saliva test kits. With each alarm you receive, you will be asked to record a video of you doing a saliva test kit reading. You will use your own personal phone. . After recording the video, you will upload it to Qualtrics for the study team to review. About once per week, the saliva reading you do will test for drugs other than cannabis, too. Each time you provide a saliva test kit reading, you will be paid $2.50, with a maximum earning of $5 per day.

At the end of the 2-week period, you will be asked to come to an in-person lab visit to provide a urine and saliva samples. These samples will be sent to MCI Diagnostic Center, LLC for analysis. You will be paid $25 for this visit.

If you are not a heavy cannabis user, or you don't use cannabis at all, you will stop monitoring at this visit. You will return the lab six weeks later for a final study visit.

If you are a heavy cannabis user, we will review your diary entries and your saliva video uploads for this 2-week period. If you have completed at least ten nightly diaries and at least 22 saliva video uploads, we will ask you to continue to do home monitoring for another six weeks. If you did not complete at least ten nightly diaries at 22 video uploads, your participation in the study will be over.

During that six-week period, you will be asked to reduce or abstain from cannabis use. You will be paid for providing saliva test kit readings, and you will be paid a $10 bonus if both of your readings suggest you have abstained from cannabis use. Each day that you remain abstinent from cannabis use, your bonus payment will increase by 50 cents. About once per week, the saliva reading you do

will test for drugs other than cannabis, too. You will be paid up to $1130.50 for this portion of the study. You will be asked to return to the lab after this 6-week period for a final study visit.

In this final study visit, we will ask you to provide urine and saliva samples. These samples will be sent to MCI Diagnostic Center, LLC for analysis. We will ask you to complete some of the same questionnaires you completed in the first session. You will also complete the working memory task again. These tasks will take about forty minutes. If you are a heavy cannabis user, we will ask you some questions about your experience with home monitoring. This interview will take about 30 minutes, and it will be audio-recorded. No matter which group you're in, you will be paid $150 for attending this session.

Your data may be stored and used for future studies without additional consent from you if identifiable private information, such as your name or medical record number, are removed.

The VA has recently approved use of an email program that will allow us to securely email you regarding study procedures. If you are comfortable receiving appointment reminders, study questionnaires, or other study messages via email, you can give your email address to the study coordinator. Also, we may send you text reminders of your upcoming appointments. If you do not want to receive text messages from a member of our study team, please let a study team member know.

Future Use of Data and Contact For Future Research:

Option 1. If you consent to participate in this research study, we will collect information about how to contact you in the future. We will store this contact information along with your interview results in a database called "Contact Database." This database is stored at the DVAHCS. This information will be used to determine if you may be eligible for future studies run in the Traumatic Stress and Health Research Laboratory and to contact you about participation. These future studies include studies related to smoking, posttraumatic stress disorder (PTSD), and trauma. This permission is optional. Your choice to give permission to be re-contacted or not to give permission to be re-contacted will not affect your enrollment in the current study. If you do not wish for us to keep your information, we will not contact you in the future about other studies.

I agree to be re-contacted about participating in future research studies: ☐ Yes ☐ No

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Option 2. Only if you grant permission, data collected from you during participation in this study may be entered into a large database called "Trauma Database." This data will be used for future research. Data will not include any identifying information, and will be stored at the DVAHCS.

I agree to future use of my data: ☐ Yes ☐ No

Option 3. Only if you grant permission, your data, with no identifying information at all, will be sent to Duke University Medical Center. Your data will be combined with data from another study about cannabis reduction that is taking place at Duke. Dr. Beckham is an investigator on the Duke study.

I agree to allow my data to be combined with the Duke cannabis study: ☐ Yes ☐ No

WHAT ARE THE RISKS AND DISCOMFORTS OF PARTICIPATING IN THIS RESEARCH STUDY?

There is a risk of discomfort or distress in answering questions in the interviews and questionnaires. However, distress and discomfort related to questionnaire completion and the psychiatric interview are usually temporary and well-tolerated. You may refuse to answer any questions while completing the questionnaires. Risks also include discomfort related to reducing cannabis use. Reduction of cannabis use can cause withdrawal symptoms. Symptoms can last for a few days to several weeks. These may include headache, trouble sleeping, sweating, night sweats, anxiety and/or depression, nightmares or vivid dreams, irritability, and cravings for use.

There is a risk of frustration related to delays that sometimes happen with providing your study payment. There is a potential risk of loss of confidentiality. If you express feelings about wanting to harm yourself or others, we will need to refer you for appropriate care.

WILL I BENEFIT FROM TAKING PART IN THIS RESEARCH STUDY?

You may not personally benefit from taking part in this study, but your participation may lead to knowledge that will help people in the future. If you are a heavy cannabis user, you may benefit from reducing your cannabis use, but this is not guaranteed.

WHAT OTHER OPTIONS OR ALTERNATIVES DO I HAVE?

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Taking part in this study is your choice. You may choose to not participate.

HOW WILL MY RESEARCH DATA BE PROTECTED AND SECURED?

Your information used for this study will be kept confidential as required by law. The results of this study may be used for scientific purposes or for publication, but these results will not include any information that would identify you. Your identity will not be disclosed without your consent, or unless required by law. Your research records will be maintained and destroyed according to VHA records retention requirements.

Paper copies of any data collected from you for this study will be stored at DVAHCS's main hospital site or at VA-leased space at 3022 Croasdaile Drive, Durham, NC. Data are stored in a locked filing cabinet in a locked office suite. Electronic data, including audio-recordings of the interview you may be asked to do, will be stored in password-protected databases on a secured server at DVAHCS. Only study team members will have access to these data.

Your urine samples will be sent to MCI Diagnostic Center, LLC, Inc. in Texas for analysis. The specimen cups will not contain any identifying information except for a code to which only our research study staff at the VA have access.

Your research records may be reviewed by Durham VA staff who are responsible for the safe conduct of this research. We may also provide your research records to federal agencies such as the Office for Human Research Protections (OHRP), the VA Office of the Inspector General (OIG), and the Office of Research Oversight (ORO). The Food and Drug Administration (FDA) may choose to inspect research records that include your medical records. We may also disclose your information to VA's Financial Services so that you can be paid for participation We will not share any information with these groups outside the VHA unless they agree to keep the information confidential and use it only for the purposes related to the study. Any information shared with these outside groups may no longer be protected under federal law. These groups may disclose your information to other groups. If the sponsor receives identified information, it is then the sponsor, and not the VA, who is responsible for the security of the information.

Certificate of Confidentiality: To further protect your privacy, this study has been issued a privacy permit to help protect your research records if requested for a court case or for other proceedings.

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DOES PARTICIPATION IN THIS RESEARCH STUDY COST ANYTHING?

There will be no costs to you for any of the research treatment or research testing done as part of this research study. Some Veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

WILL I RECEIVE ANY COMPENSATION (MONEY OR OTHER) FOR TAKING PART IN THIS RESEARCH STUDY?

You will be paid up to $2075.50 for participation in this study if you are a heavy cannabis user. You will be paid up to $425 if you are a light to moderate cannabis user or you don't use cannabis. Please be aware that we have been informed that payment can take anywhere from 6 to 10 weeks from the time we request it.

WHAT WILL HAPPEN IF I AM INJURED WHILE PARTICIPATING IN THE RESEARCH STUDY?

The VA will provide necessary medical treatment should you be injured by being in this study. You will be treated for the injury at no cost to you. This care may be provided by the Durham VAHCS or arrangements may be made for contracted care at another facility. Every reasonable safety measure will be taken to protect your well-being. You have not released this institution from liability for negligence. In case of research related injury resulting from this study, you should contact your study team. If you have questions about compensation and medical treatment for any study related injuries, you can call the medical administration service at this VA Medical Center at 919-286-6957.

WHAT ARE MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You can choose to not be in this study, or, if you agree to be in the study, you can withdraw at any time. If you withdraw from the study, no new data about you will be collected for study purposes. We will keep and use the data that we already collected before you withdrew your consent.

If you choose to not be in the study or if you withdraw from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled. This will not affect your relationship with or

treatment by the Veterans Health Administration (VHA) or your rights as a VHA patient. You will still receive all the medical care and benefits for which you are otherwise eligible.

If your identifying information, such as your name or medical record number, are removed from your samples, we will no longer be able to identify and withdraw the samples.

Withdrawal of Data for Future Use

If you agree to allow your data with information that would link the data to you to be kept for future research or for re-contacting, you can change your mind at any time. To withdraw your data, contact Dr. Jean Beckham in writing and let her know you are withdrawing permission for your identifiable data to be used for future research. Dr. Beckham's mailing address is:

Durham VA Health Care System
Attn: 151 (Beckham)
508 Fulton Street
Durham, NC 27705

If your identifying information, such as your name or medical record number, are removed, we will no longer be able to identify and withdraw your data.

ARE THERE REASONS THAT MY RESEARCH PARTICIPATION MAY END EARLY?

Dr. Beckham may withdraw you from the study without your consent for one or more of the following reasons: You have serious side effects, your condition worsens, the study team decides it is no longer in your best interest to continue in the study, inability to perform study procedures, or failure to follow instructions of investigator and/or study staff.

We will tell you about new information that may affect your health, condition, welfare, or willingness to participate in this study.

WILL THE RESULTS OF THIS RESEARCH STUDY BE SHARED WITH ME?

If you would like to be notified about any published results of this study, please let the study coordinator know. We will provide you with a copy of any manuscript describing primary study results.

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DO ANY OF THE RESEARCHERS HAVE A FINANCIAL INTEREST RELATED TO THIS RESEARCH STUDY?

Portions of the salaries of Dr. Beckham's staff are paid by this research study.

WHERE CAN I FIND OTHER INFORMATION ABOUT THIS RESEARCH STUDY?

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.

WHO DO I CONTACT IF I HAVE QUESTIONS OR CONCERNS ABOUT THE RESEARCH STUDY?

If you have questions about the research or need to talk to the study team, you can contact Dr. Beckham at (919) 286-0411, ext. 134040 at during regular business hours, or at (919) 286-0411 (and ask the operator to call Dr. Beckham at home) after hours. You may also contact the study coordinator at (919) 286-0411, ext. 134056 during regular business hours. If you are experiencing a psychiatric crisis, contact the Veterans' Crisis Line by calling 988, by texting to 838255, or by internet at www.veteranscrisisline.net. If you have questions about the research or your rights as a research participant, would like to obtain information, offer input, or have other concerns or complaints, you may contact the administrative officer of the research service at (919) 286-0411, extension 177632. If you would like to check that this study is approved by the Durham VAHCS's Institutional Review Board, please call the research office at (919) 286-6926 or (888) 878-6890, extension 176926.

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AFFIRMATION FROM PARTICIPANT

I have read this form or it has been read to me. My rights as a research participant have been explained to me, and I voluntarily consent to participate in this study. I have received an explanation of what the study is about and how and why it is being done. I authorize the use and disclosure of my identifiable information as described in this form. I will receive a signed copy of this consent form.

Signature of Participant	**Date**
Signature of Person Obtaining Consent	**Date**