NYU Langone MEDICAL CENTER

Research Subject Informed Consent Form

Title of Study:	A PHASE I/II RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL OF CANNABIDIOL AS A TREATMENT FOR ALCOHOL USE DISORDER COMORBID WITH POSTTRAUMATIC STRESS DISORDER *S17-00949*
Principal Investigator:	Charles Marmar, MD NYU School of Medicine, Department of Psychiatry One Park Ave. Charles.Marmar@nyumc.org 646-754-4855
Emergency Contact:	Charles Marmar, MD Cell: (415) 299-7472

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called "subjects" or "research subjects." These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form, either by written signature or electronic signature. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

You are being asked to participate in this study because you have alcohol dependence comorbid with PTSD and you want to stop or decrease your drinking and your PTSD symptoms, but are not currently receiving any professional alcohol or PTSD treatment. If you are currently participating in a 12-Step Recovery program, you may want to speak with your 12- Step Sponsor before enrolling in this research.

The purpose of this research study is to see how safe and effective cannabidiol (CBD) is for the treatment of alcohol dependence comorbid with post-traumatic stress disorder (PTSD). We also would like to assess its effects on thinking, behavior and habits of people with alcohol use disorder (AUD) and PTSD.

CBD is a naturally occurring, non-psychoactive compound found in the marijuana plant. The United States Food and Drug Administration (FDA) has not approved this formulation of CBD as a safe or effective treatment for alcohol dependency or PTSD. Therefore, the use of CBD to treat alcohol dependency and PTSD is considered experimental.

CBD works by activating receptors in the brain that might affect the way you respond to stressful situations. Even though CBD is found in the marijuana plant, it does not make people feel "high" the same way that marijuana does.

If you agree to participate in this study, you will be randomly assigned (like a flip of a coin) to either a CBD or a placebo group. The placebo looks like the study drug but has no CBD or other drugs in it. You are more likely to receive the study drug (CBD) than placebo (5:3 ratio).

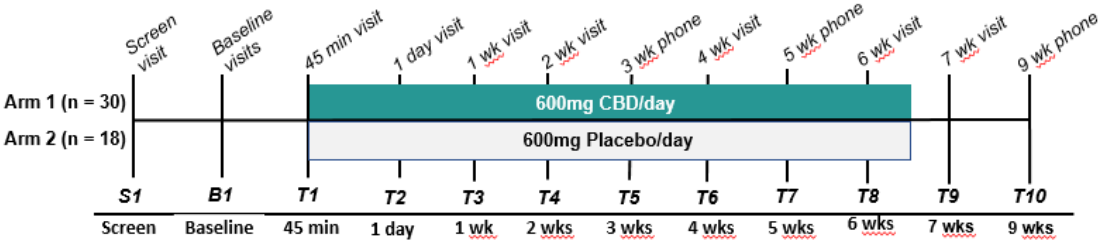
3. How long will I be in the study? How many other people will be in the study?

After meeting study criteria, approximately 48 subjects will receive medication or placebo in this study at NYULMC. ~150 people are expected to be consented in the study in order to randomize 48 participants.

Participation in this study will take a total of about 30-35 hours over a period of 9 weeks; you will receive the study drug or placebo for 6 weeks.

4. What will I be asked to do in the study?

The following figure summarizes the visits of the study, which are described in more detail below:



	S1 Screen	B1 Baseline	T1 45 min	T2 1 day	T3 1 wk	T4 2 wks	T5 3 wks	T6 4 wks	T7 5 wks	T8 6 wks	T9 7 wks	T10 9 wks
Inclusion / Exclusion Criteria	✓											
CBD/THC/AEA Serum Levels		✓	✓	✓	✓✓	✓✓		✓✓		✓✓	✓	
Safety		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Psychomotor & Subj. Effects		✓	✓	✓	✓	✓		✓		✓	✓	
Cognitive Function				✓						✓		
AUD-Related Domains		✓			✓			✓		✓	✓	
PTSD-Related Domains		✓				✓		✓		✓	✓	
Cue/Stress Script Interview		✓										
Cue/Stress Task								✓				
Alcohol Use		✓		✓	✓	✓		✓		✓	✓	✓
CDT		✓						✓		✓		

Below is a list of each study visit that is part of the study. This list includes about how long each visit should take and a list of the research tests and procedures to be done at each visit and/or blood work to be completed. We may be able to schedule procedures over two separate days within the same week if you are unable to stay for an entire visit due to scheduling conflicts.

Screening Visit (~4-6 hours)
If you agree to be in this study, the first visit will be the screening visit. The purpose of the screening visit is to make sure that you meet all of the requirements to take part in the study. Procedures marked with an asterisk (*) must be completed in-person. The study investigator will review the results of these tests and procedures and we will let you know whether you are eligible to participate in the study. At this visit, the following procedures will take place:

- Medical history
- Family history
- Vital signs (heart rate, blood pressure, and temperature)*
- Concurrent medications
- Menstrual calendar (if applicable) to minimize the risk of undetected pregnancy during the study
- Physical exam*
- Your breath alcohol concentration will be measured (breathalyzer test)*
- You will be assessed for signs of alcohol withdrawal
- We will ask you in detail about your recent use of alcohol and drugs

Blood Sample*:
22 cc of blood (approximately 1.5 tablespoons) will be drawn with a needle from a vein in your arm for safety tests. A serum pregnancy test will also be completed for women who may become pregnant.

Urine Samples*:
Urine samples will be collected for urinalysis and to test for the presence of certain drugs, including cocaine, methamphetamine, opiates, and marijuana. This test will be performed on-site. You will be able to collect this urine in a bathroom without anyone watching you. You will be informed of the results of the laboratory tests when they become available. You may be excluded from participating in the study if you test positive for certain drugs or substances. Women of child bearing potential without any pregnancy exclusions will also have a urine pregnancy test completed; you will be excluded from the study if you are pregnant. We will inform you of the results when they become available. The results of the urine drug screen will NOT become part of your medical record. These test results WILL become part of your research record.

Questionnaires:
We will ask you to complete forms about your demographics, alcohol and substance abuse, psychiatric disorders, quality of life, and alcohol withdrawal. We will also collect contact information for yourself, your emergency contact, and primary care physician.

Diagnostic Interview:
You will receive a diagnostic interview assessing substance use and psychiatric disorders. One of our trained staff members will ask questions about your mood, mental health history and diagnoses, assess for traumatic brain injury (TBI), post-concussive symptoms (CSI) and suicidality. We will ask you whether we can record your diagnostic interview for quality control purposes and voicemarkers analysis on a separate consent form.

Health Release Form:
We will ask you to sign a health release form so that we can see your personal information in records from hospitals, clinics, or doctor's offices where you may have received care in the past. We may also ask to speak with clinicians who have treated you for medical and/or psychiatric conditions, but will not reveal the nature of the study without your permission. We will only access this information if it is needed to determine your eligibility for the study.

Locators:
In order to participate in this study, you will also need to identify at least two people who would know your

whereabouts in case study personnel needed to find you during the study. The locator people may be told that we are calling from NYU, and may be given the name and phone number of study staff, but will not be given any other information about your participation without your permission. If we are unable to reach you with the information you have provided on the locator form, we may use publicly available data on the internet, like Facebook, in an effort to find updated contact information.

Clinical Re-Screen
If there is a delay between your screening visit and baseline visit, we will conduct a "clinical re-screen" to confirm you are still eligible for the study. The following measures will be conducted at the clinical re-screen:

- Breath alcohol concentration (BAC)
- Urine drug screen
- Urine pregnancy test (if applicable)
- Vital signs
- Questions about PTSD symptoms, alcohol use, craving, suicidality, and current medications
- If deemed necessary by the study clinicians, blood may be collected for safety tests and urine may be collected for urinalysis

If the delay between your screening visit and baseline visit is longer than 3 months, a trained staff member will also reassess your PTSD, AUD, depression, and suicidality symptoms, ask if you have sustained any new head injuries, and check that any drug use has not risen to the level of a disorder diagnosis.

If you qualify to participate in the study, you will be scheduled for the following visits over the next 9 weeks:

Baseline Visit (5-6 hours)
At the baseline session, the following procedures will be performed:

- Vital signs
- Menstrual calendar (if applicable)
- Your breath alcohol concentration will be measured (breathalyzer test)
- We will ask you in detail about your recent use of alcohol and drugs

Questionnaires:
You will be asked to complete a number of questionnaires and interviews, many of which will be repeated at later assessment sessions. These include questionnaires about any recent drug and alcohol use (since the last visit), problems you may have experienced related to alcohol, your motivation and confidence to cut down or stop drinking, your craving for alcohol, and your current mood.

Urine Sample:
A urine sample will be collected to test for the presence of several drugs, including cocaine, methamphetamines and marijuana. You may be excluded from participating in the study if you test positive for certain drugs or substances. Women of child bearing potential without any pregnancy exclusions will also have a urine pregnancy test completed.

Interview:
We will interview you about an experience you had in the last year that was associated with an urge to drink alcohol, an experience you had in the last year that you found traumatic, and an experience you had in the last year that you found relaxing. These interviews will be used to create personalized scripts that you will listen to at the week 4 visit; if you consent to audio recordings for study purposes, this interview will be audio-recorded.

Blood Samples:
We will collect a blood sample (1.5-2 tablespoons) to test for levels of CBD, a marker of alcohol consumption called carbohydrate-deficient transferrin (CDT), and several other chemicals related to CBD (delta-9-tetrahydrocannabinol (THC), 11-Hydroxy Delta-9 THC, Delta-9 Carboxy THC, and anandamide) prior to your first study medication dose. This sample will be sent to outside laboratories for testing, and will be accessible only to laboratory personnel.

Study Drug (CBD or Placebo):
We will give you the study drug (CBD or placebo) at this visit. We will collect a blood sample (~20 mls or 1.5-2 tablespoons) to measure your blood levels of CBD, THC and anandamide prior to and after administering the first dose of the study drug in the laboratory and you will remain in the laboratory under supervision of study staff for 45 minutes following administration of the study drug.

45 Minutes After You Receive the Study Drug:
We will collect another blood sample (1.5-2 tablespoons) for safety labs after the first dose of medication. If there are no safety concerns after 45 minutes, we will give you instructions on how to use the study drug at home, and enough of the study drug to last until your next scheduled visit. You will be given the study drug to take home with you, and you will be instructed to take the study drug every day. For the next 6 weeks of the study, you will take two capsules in the morning and 1 capsule in the evening with food. Sometimes we will ask you to bring your morning dose with you to the research visit to take in the laboratory.

Study Drug Adherence:
There are two ways that we can make sure you are taking the study drug as instructed:

1. **Optional Emocha App:** You may choose to use the Health Insurance Portability and Accountability Act (HIPAA)-compliant application "emocha." If you choose this option, we will show you how to record a video of yourself taking the study drug each time you take it. The app will record the time and day you took the study drug. The recordings will be used to make sure you are taking the study drug correctly and will not be used for any other purpose. The app is available for phones or tablets. You can communicate with the principal investigator and study staff on the app if you have any issues. At the end of the study, all video records taken using the app will be destroyed. Only the documentation of the records will be securely kept for research purposes.

2. **In-Person Pill Count:** If you choose not to use emocha, you will be asked to assure medical adherence through meeting with the study nurse practitioner/physician at each scheduled visit. The study nurse practitioner/physician will ask questions regarding your medication and also count the pills you return.

Intermediate Visits (1-4 hours each)
Nine additional assessment sessions will be scheduled. Some will take place in person and some will take place over the phone.

Visit Name	Visit Type	Visit Length
1 Day	In Person	1 to 4 hours
Week 1	In Person	1 to 4 hours
Week 2	In Person	1 to 4 hours
Week 3	Phone Call	1 hour
Week 4	In Person	1 to 4 hours
Week 5	Phone Call	1 hour
Week 6	In Person	1 to 4 hours
Week 7	In Person	1 to 4 hours
Week 9	Phone Call	1 hour

In Person Visits (1 Day Visit, Week 1, Week 2, Week 4, Week 6, and Week 7)
At each in-person visit, you will have the following procedures done:

- Concurrent medications
- Vital signs
- Your breath alcohol concentration will be measured (breathalyzer test)
- We will review your adherence to the study drug procedures (pill count or emocha)
- Evaluate safety, cognitive function, and psychomotor effects
- Record your alcohol use

- Menstrual calendar (if applicable)

Urine Sample:
A urine sample will be collected at each in-person study visit. You may be excluded from participating in the study if you test positive for certain drugs or substances or if you become pregnant.

Blood Draws:
We will collect one blood sample at the Day 1 Visit and we will collect two samples at weeks 1, 2, 4, and 6. On the days that two samples are collected, one sample will be collected before you take the study drug and one will be collected 45 minutes after you take the study drug. Each sample is about 1.5-2 tablespoons of blood. The samples will be used for liver function tests, CBD, THC, 11-Hydroxy Delta-9 THC, Delta-9 Carboxy THC, anandamide, and CDT testing.

Questionnaires:
You will be asked to complete several questionnaires asking about the effects that you experienced while taking the study drug, any desire to use CBD or marijuana in the future, and how satisfied you were with the study drug you received in the study.

Week 4 Script:
At Week 4, you will listen to recordings based on the interview you gave at your Baseline Visit. Each recording is approximately 2-5 minutes long. During these sessions, we will measure your pulse, skin conductance, heart rate, and blood pressure. You'll be recorded before listening to the recordings, during, and after. You'll complete questionnaires about how vivid your memories were, your alcohol craving, and your anxiety and emotional response.

Phone Calls (Week 3, Week 5, and Week 9)
During each phone call, we will:

- Review concurrent medications
- Review your adherence to the study drug procedures
- Complete menstrual calendar (if applicable)
- Ask you about any effects you have experienced while taking the study drug
- Ask study drug completion questions to evaluate your safety
- Ask questions about your alcohol use

Note: Some of your visits may be conducted remotely, over the phone or over WebEx.

5. What are the possible risks or discomforts?

Risk of Study Drug

The available evidence suggests that CBD is safe and well tolerated in human participants. Previous studies have shown few side effects of CBD orally in doses ranging from 10 mg to 1500 mg per day; there have been no reported effects on blood pressure, heart rate, or respiratory rate, no negative mood effects, and no negative impacts on coordination or the ability to think or concentrate. The most common side effects reported in studies of CBD for Lennox-Gastaut or Dravet Syndrome include:

- Diarrhea
- Sleepiness
- Mild fever
- Decreased appetite
- Vomiting
- Fatigue
- Lethargy (lack of energy)
- Convulsion (seizure)
- Elevated liver enzymes (seen on blood test result; may not cause physical symptoms)

It is possible that participation in this research study may involve risks that are currently unforeseeable. For more information about risks and side effects, ask a study investigator.

Risk of Placebo:
There is a chance you will not actually be taking an active drug. In this case, your condition might not improve or could get worse. You could miss the benefits or harms (if any) of the study drug.

Blood Draw Risks:
Drawing blood may cause temporary pain and discomforts from the needle stick, occasional bruising, sweating, feeling faint or lightheaded, and in rare cases infection.

Risks of Assessment Procedures:
There are no known psychological risks associated with the questionnaires used in the study, most of which have been used extensively in clinical populations. It is possible that discussion of substance use and psychiatric symptoms may cause you some emotional discomfort or temporary stress. One of the investigators of the study will be available to meet with you if you become distressed about any aspect of the study and wish to discuss it.

Risks to Confidentiality and Potential Legal Consequences:
Information from this study may be submitted to the U.S. Food and Drug Administration (FDA). Medical records that identify you and the consent form you signed may be inspected by the FDA and the New York University School of Medicine's Institutional Review Board (the Human Research Protections Office). Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. The results of this research project may be presented at meetings or in publications. However, your identity will not be disclosed in those presentations.

Incidental Findings:
In some cases, the safety blood draw results may indicate an abnormality with (or without) a clinical significance. Every blood draw performed in this study is saved and handled under the standard PHI confidentiality restrictions and regulations employed for patients' information. The results are always reviewed by a licensed nurse practitioner or MD, who might then detect an abnormality. If clinically useful information is uncovered, we will speak to you in person or on the telephone regarding the new information. A copy of the original report will also be provided to you in person and you will be encouraged to follow up on the discovery with your treating physician.

6. Can I be in the study if I am pregnant or breastfeeding?

If you are currently pregnant, you will not be able participate in the study. You should not become pregnant while you are participating in this study. If you are able to become pregnant, you will be required to use a medically accepted method of birth control while you participate in the study. Examples of medically accepted methods of birth control are as follows:

- Hormonal methods like birth control pills, patches, vaginal rings or implants
- Barrier methods such as condoms or a diaphragm used with spermicide (a foam, cream or gel that kills sperm)
- Intrauterine device (IUD)
- Abstinence (no sex)

If you become or you think you have become pregnant during the study, you must tell us right away and must tell your obstetrician or other health care provider caring for you during your pregnancy that you took part in this study. If you become pregnant, you will have to stop taking part in the study for safety reasons. We may ask you to provide information about the outcome of your pregnancy and the health of your baby.

Note to Men: Because the effects of participating in this study on sperm are unknown, you will be required to use a medically accepted method of birth control while you participate in the study using one of the methods described above.

7. What if new information becomes available?

During the course of this study we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

8. What are the possible benefits of the study?

There may or may not be benefits to you from participating in this study. It is possible that some study subjects who receive CBD may experience an improvement in their PTSD symptoms and drinking problems during the study. However, if you receive such benefit, because CBD is not FDA-approved for alcohol use disorder, your doctor cannot prescribe it after you finish the study. Knowledge gained through this study may aid the development of more effective treatments for individuals with alcohol dependence and other addictive disorders.

9. What other choices do I have if I do not participate?

Standard of care for outpatient treatment of alcohol dependence is taking other medications with medication monitoring and/or evidence-based psychosocial treatment. These alternatives may be discussed with your personal physician.

The FDA-approved treatments for alcohol dependence are disulfiram (Antabuse), naltrexone (ReVia and Vivitrol), and acamprosate (Campral). FDA-approved treatments for PTSD include selective serotonin reuptake inhibitor (SSRI) drugs.

Evidence-based psychosocial treatments for alcohol dependence and/or PTSD include methods based on motivational interviewing (such as META), cognitive, behavioral, and cognitive-behavioral approaches, 12-step facilitation therapies, approaches involving the spouse and family, and standardized counseling approaches incorporating elements of these various approaches.

10. Will I be paid for being in this study?

In return for your time and the inconvenience of participating in this study, you will be compensated for the study visits you complete. You may be compensated in cash, by check, or ClinCard)

Visit	Compensation Amount
Screening Visit	$70*
Baseline Visit	$70
1 Day	$40
Week 1	$60
Week 2	$60
Week 4	$70
Week 6	$70
Week 7	$40

*If you choose a remote screening visit, you will be compensated $50 for the remote visit and $20 for the in-person visit.

In the case of a clinical re-screen, participants will be compensated $25-$40 depending on the length of the re-screen.

If you complete all study visits, you will be compensated a total of $480. You may also be provided with a gift card or $12 cash compensation for the purchase of a meal for visits that are 5 hours or longer. You may receive partial compensation for portions of study visits completed as applicable. You may also receive a $15 compensation for time/effort spent as a "standby" for a potential screening visit; you will only receive the $15 compensation once the clinical screen visit is completed as part of the study.

11. Will I have to pay for anything?

You will not be billed for the cost of tests and procedures directly associated with this study.

You and/or your health insurance may be billed for the costs of medical care during this study if these expenses would have happened even if you were not in the study, or if your insurance agrees in advance to pay. If you have health insurance, the cost of these services will be billed to your insurance company. If your insurance does not cover these costs or you do not have insurance, these costs will be your responsibility.

12. What happens if I am injured from being in the study?

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

There are no plans for the NYU School of Medicine or Medical Center to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

13. When is the study over? Can I leave the Study before it ends?

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

You will be informed of any significant new findings that become available during the course of the study, such as changes in the risks or benefits resulting from participating in the research or new alternatives to participation that might change your mind about participating.

The investigator reserves the right to withdraw you from this study without your consent if it is deemed necessary.

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped or your participation ended at any time by your physician, the study sponsor, or the Food and Drug Administration (FDA) without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision
- You have not followed study instructions
- The study sponsor, the principal investigator, the Food and Drug Administration (FDA) or other body responsible for monitoring the safety of the study has decided to stop the study

14. How will you protect my confidentiality?

Your medical information is protected health information, or "PHI", and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

Certificate of Confidentiality
To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data, documents, or biospecimens) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information 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, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

By agreeing to be in this research and signing below, you are giving your consent to share research information with others at NYU Langone Health. This means that your research information, including lab results, and information about the investigational drug used in this study, may be included in your NYU Langone Health electronic medical record.

15. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- The study sponsor: The National Institute on Alcohol Abuse and Alcoholism (NIAAA)
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA)
- Health care providers who provide services to you in connection with this study, and laboratories or

other individuals who analyze your health information in connection with this study
- The Data & Safety Monitoring Board
- The data team: DataCore at NYULMC to manage and maintain integrity of study data

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

16. 21 CENTURY CURES ACT

What is an Electronic Medical Record?
An Electronic Medical Record (EMR) is an electronic version of your medical chart within NYU Langone Health. An EMR is simply a computer version of a paper medical record.

If you are or have been a patient at NYU Langone Health in the past, you have an EMR at NYU Langone Health. Information from your research participation will be added to this EMR.

If you have never been a patient at NYU Langone Health, you may not have an EMR at NYU Langone Health. In connection with your participation in this study, an EMR will be created for you. The purpose of your EMR at NYU Langone Health will be to facilitate this research study and allow the researchers to maintain information arising from your participation in this research study. The creation of this EMR is a requirement of your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility, for example, your name, the name of your primary doctor, the type of insurance you have, your date of birth and other health-related information.

What may be placed in the EMR?
Information related to your participation in the research (e.g., laboratory tests, research-related notes, imaging studies, and clinical procedures, etc.) will be placed in your EMR maintained by NYU Langone Health.

This information will be accessible to other members of the NYU Langone workforce that are not part of the research team. Information within your EMR may also be shared with others who NYU Langone Health has determined may appropriately have access to your EMR (e.g., Health Insurance Company, disability provider, etc.).

Will I have access to research-related information within the Electronic Medical Record?

In this study, research-related information in your EMR will not be available to you until the end of the study. This information will not be accessible in your EMR immediately in order to protect the integrity of the research trial results. The researchers will provide you access to this research-related information in your EMR when the study is over.

- ***Results in the medical record that will not be immediately accessible****:* hepatic function panel test results, liver function test (LFT) results, complete blood count (CBC) with differential test results, basic metabolic panel test results, urinalysis test results, serum pregnancy test results (if female), and carbohydrate deficient transferrin (CDT) test results

Test results and other study information (e.g., progress notes and research notes) will be withheld until the end of the study unless the research clinicians determine that the results require follow-up with your medical provider.

Additionally, some research-related information will never be made available to you in your EMR. This information will not be accessible in your EMR because the information is specific to this research and is not part of your medical history and clinical care.

- ***Results that will not be placed in the medical record:*** pharmacokinetic blood test results (concentrations of CBD, THC, and anandamide)

17. Optional Parts of Research

1. Option to Store, Use, and Share Health Information for Future Research

NYULMC would also like to store, use, and share your health information from this study in research databases or registries for future research conducted by NYULMC or its research partners. To give this additional permission, check the box below and write your initials where indicated. You may still participate in this study even if you do not give us this additional permission.

NYULMC will continue to protect the confidentiality and privacy of this information as required by law and our institutional polices. If you give this additional permission, you will continue to have the rights described in this form. You have the right to take back this additional permission at any time.

☐ **I agree** to allow the study team to store, use, and share my health information from this study in research databases or registries for future research conducted by NYULMC or its research partners.

☐ I **DO NOT** allow/s the study team to store, use, or share my health information from this study in research databases or registries for future research conducted by NYULMC or its research partners.

_____ _____
Signature of participant Date

2. Option to Use the Emocha App

To ensure medication adherence during your participation in this study, we ask that you use the emocha app on a smartphone or smart device. If you do not agree to this then medication adherence will be comprised of an interview with the nurse practitioner/physician who will also count the pills returned at each study visit.

☐ **I agree** to use emocha for the duration of this study, and have adequate device access and internet access to use it.

☐ I **do not agree** to use emocha for the duration of this study for the following reason(s):
- □ I do not have adequate device access
- □ I do not have adequate internet access to use it.
- □ Other

_____ _____
Signature of participant Date

3. Option to Link Study Information to Other NYULMC Psychiatry Department Studies

If you participate in another research study with the NYULMC Psychiatry Department, such as the cannabidiol as a treatment for alcohol use disorder study (#s17-01001), the investigators are interested in accessing the information obtained from you and linking it to the information collected from this study for further analyses. All confidentiality and safety procedures will still apply. Your signature below indicates your permission to access and link data collected.

☐ **I agree** to allow the study team to link information collected as part of this study with information collected in other NYULMC Psychiatry department research studies.

☐ I **do not** allow the study team to link information collected as part of this study with information collected in other NYULMC Psychiatry department research studies.

_____ _____
Signature of participant Date

4. Option to Receive Reimbursement via ClinCard

A new reimbursement program was introduced by the NYU Finance Department in 2016 called Greenphire. Greenphire uses reloadable debit cards, called “ClinCards” for reimbursement. Study staff will add funds to the ClinCards for compensation and travel reimbursement through a secure web-based portal. Access to the portal is granted to NYULMC designated staff by the vendor or NYU administrator.

ClinCards can be used to withdraw cash from a bank or ATM, as a PIN-based transaction, or as a credit card. No bank account is required. The system is in compliance with the HIPAA Act and stores your information securely using appropriate administrative, physical, and technical safeguards.

If a ClinCard is lost or damaged, we can de-activate the lost/damaged card and issue you a new card. You and designated NYU staff will be able to check your balance online at any time. We will not have access to information regarding where or how the card is issued.

☐ **I agree** to receive study reimbursement through the NYU ClinCard system.

☐ I **do not** want to receive study reimbursement through the NYU ClinCard system. I prefer to receive reimbursement by cash or check.

_____ _____
Signature of participant Date

5. Option to be contacted about future research

We would like your permission to contact you in the future to tell you about new research opportunities. If you are contacted, you can decide whether or not you are interested in participating in the particular study. You will then have the opportunity to contact the researcher to schedule an appointment to be fully informed about the research project.

☐ I **agree** to allow the study team to contact me in the future about new research opportunities at NYU's Department of Psychiatry.

☐ I **DO NOT** allow the study team to contact me in the future about new research opportunities at NYU's Department of Psychiatry.

_____ _____
Signature of participant Date

18. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of doctors, nurses, non-scientists, and people from the community.

19. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

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 website site at any time.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date