COVER PAGE

Official Study Title: Enhancing Prolonged Exposure with Cannabidiol to Treat Posttraumatic Stress Disorder: A Pilot Study

NCT number: NCT05132699

IRB Approval Date: 03-25-2022

Unique Protocol ID: HCS20210711H

Concise Summary

Important Information

This information gives you an overview of the research. More information about these topics may be found in the pages that follow. You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with us.

1. What problem is this study trying to solve?

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future**.** In this study, we are evaluating whether cannabidiol (CBD) can be combined with Prolonged Exposure (PE), an evidence-based, gold standard talk therapy for posttraumatic stress disorder (PTSD) to improve treatment response. For more information see the ***Why is this study being done*** section in the next pages.

2. What will happen to me during the study and how is this different from continuing with usual care? What are all my options for treatment, including the pros and cons?

After consenting to be in the study, you will be asked to complete a baseline assessment of your psychological and physical health that will determine whether you are able to participate in the study. Following the baseline, you will be randomly assigned to receive 18 consecutive days of CBD (Epidiolex®) or placebo. Everyone will also participate in 10 PE therapy sessions (90 minutes each) provided over 2 consecutive weeks. At the first treatment session and at the end of each treatment week, you will be asked to complete additional assessments. Finally, you will be asked to complete a follow-up assessment 1-month after you finish with treatment. In addition to questionnaires and interviews, assessments will include a blood draw, saliva collection, and wearing a watch to monitor your heartrate. Not all assessments will be done at every assessment time.

Comparison to Usual Care: PE is care typically provided to treat PTSD and is considered a standard treatment. Other treatments for PTSD can include other talk therapies or medications that may help manage PTSD symptoms. It may be possible that a community physician will prescribe CBD (Epidiolex®), but this is not currently a usual practice. Additionally, there may be other research studies that treat PTSD. For more information, see the ***What will be done if you decide to be in the research*** section in the next pages.

3. How much time will I spend on the study?

You will be asked to complete a total of 13 visits, which includes 2 assessment visits (up to 4 hours each), 1 medication review appointment (up to 60 minutes), and 10 PE treatment visits (90 minutes each day) 3 of which will also include some assessments. Altogether, you will spend up to 26 hours in this study over the next one to two months.

4. Could taking part in the study help me and are there risks?

Participating in this study may help you reduce your PTSD symptoms. Research on CBD has found that is safe and well-tolerated by most individuals. Common risks of CBD may include diarrhea or drowsiness. Other side effects that can occur are reduced appetite, dry mouth, vomiting, weight loss, and elevated liver function. Risks of PE talk therapy may include temporary increases in emotional distress, PTSD, depression, or anxiety symptoms. For more information, please *see* ***How could you or others benefit from your taking part in this study*** section in the next pages. For details and a list of risks you should know about, please see the ***What are the risks of participation in the research*** section in the next pages.

5. What else should I consider before I make my decision?

The daily format of therapy in this study can be time intensive. It is helpful to select a two-week period in which you can minimize outside appointments and obligations.

Please review the rest of this document for additional details about these topics and other information you should know before making a decision about participating in this research.

Title of Study: Enhancing Prolonged Exposure with Cannabidiol to Treat Posttraumatic Stress Disorder: A Pilot Study

Consent to be part of a Research Study
To be conducted at
The University of Texas Health Science Center at San Antonio (UT Health San Antonio)

Information about this form

You may be eligible to take part in a research study. This form gives you important information about the study. Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you. Please tell the researchers or study staff if you are taking part in another research study.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are entitled.

General Information – "Who is conducting this research?"

Principal Investigator
The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety, and welfare as a participant in the research. The PI for this study is Casey Straud, PsyD, a board-certified psychologist who is part of the faculty of the Division of Behavioral Medicine, Department of Psychiatry and Behavioral Sciences, UT Health San Antonio.

Partnering Senior Investigator
The grant award supporting this study supports early career investigators. The Partnering Senior Investigator is the primary mentor for the PI on this this study. The Partnering Senior Investigator for this study is Alan Peterson, PhD, a board-certified psychologist who leads the Division of Behavioral Medicine, Department of Psychiatry and Behavioral Sciences, UT Health San Antonio.

Study Physician
The Study Physician Investigator on this study is Van King, MD, who is a Professor in the Department of Psychiatry and Behavioral Sciences, UT Health San Antonio. Dr. King will be prescribing the study drug.

Funding
This project is supported by the National Center for Advancing Translational Sciences, National Institute of Health, a non-profit, federal government organization.

Purpose of this study – "Why is this study being done?"

This study is being done to see if cannabidiol (CBD) can be combined with Prolonged Exposure (PE), an evidence-based, gold standard talk therapy for posttraumatic stress disorder (PTSD) to improve treatment response. CBD (Epidiolex®) comes in an oil-based solution and is taken orally using a dropper. The use of CBD in combination with PE may reduce hyperarousal symptoms associated with PTSD and help process the traumatic event more effectively during therapy.

The researchers hope to learn if the combination of CBD+PE is safe and effective. We also hope to identify biomarkers that explain how CBD interacts with the body to reduce PTSD symptoms.

Investigational Use of Procedures & Drug for PTSD: This study involves the use of an investigational drug (CBD-Epidiolex®) to augment treatment for PTSD. "Investigational" means that this drug has not yet been

approved by the U.S. Food & Drug Administration (FDA) for treating PTSD; however CBD is FDA-approved for the treatment of some types of seizure disorders. The safety of this drug in humans has been tested in prior research studies; however, the amount of benefit of CBD to treat PTSD above and beyond placebo in combination with PE therapy has not been determined.

This trial will be registered on www.ClinicalTrials.gov, a publicly available registry of clinical trials. This web site will not include information that can identify you. At most, the Web site will include a summary of the study results. You can search this web site at any time.

Information about Study Participants – "Who is participating in this research?"

You are being asked to take part in this research study because you are experiencing trauma-related symptoms consistent with posttraumatic stress disorder (PTSD). This pilot study will enroll up to 24 study participants.

Information about Study Procedures – "What will be done if you decide to be in the research?"

The preferred method of assessment and therapy is face-to-face in San Antonio. However, there may be circumstances when you can complete some of the assessments electronically or over the telephone and part of the therapy through telebehavioral health (i.e., by phone or using a HIPAA-compliant video calling platform like Zoom). Decisions will be made on a case-by-case basis as issues arise for individuals (e.g., childcare) and in discussion with the treatment team. Patients who do not have internet access may need to receive treatment in person if a phone call is not sufficient for the type of visit. You will need to be seen in person to receive the medication.

Baseline/Screening: After you sign this consent to participate, you will be asked to complete a series of questionnaires and then meet with an evaluator who will assess your mental and physical health. All participants will complete a urine drug test and females who are able to become pregnant will complete a urine pregnancy test. You cannot take part in this study if you are pregnant or breastfeeding. You will also be asked to complete liver function blood tests (LFTs) and provide them to the study team for review prior to randomization. The baseline/screening process will take approximately 3-4 hours. The results of these screening procedures will be reviewed to determine whether it is appropriate for you to continue in the study. If at any point during the baseline process it is determined that it ***would not*** be appropriate for you to continue in the study OR if you choose not to enroll, then the researcher will discuss the reasons with you and coordinate appropriate follow-up outside of this study.

You have my permission to use assessments collected as part of the screening for another UT Health San Antonio STRONG STAR study or program as baseline data for my participation in this study.

Circle one: N/A YES NO _____ _____
Initials of Participant Date

Study Procedures: As a participant, you will be asked to:

- Meet with a member of the research team to review your assessment findings and discuss treatment.
- Participate in a medication review appointment (up to 60 minutes) prior to beginning CBD/placebo and Prolonged Exposure (PE). This appointment will include a blood draw and saliva collection participants will be given materials for a saliva collection the following morning
- Participate in 10 PE sessions on weekdays over two consecutive weeks. Sessions will be held weekdays at the UT Health San Antonio STRONG STAR offices or by telebehavioral/telemedicine health and will each last approximately 90 minutes. At sessions 3, 5, and 10, you will also wear a hear rate monitor wristwatch during the 90 minute session.
- Complete three interim assessments during treatment to complete blood draw and psychological self-report measures.

- You will receive instructions for collecting 2 saliva (spit) samples at home before each interim assessment. You will be given plastic vials to store the samples in and an insulated lunch bag with an ice pack to bring the samples into the research office with you.
- Complete out-of-session treatment assignments daily. (e.g., listen to session audio recording and complete a real world exposure).
- Complete 18 consecutive days of the medication regimen of CBD or placebo taking two liquid doses orally twice a day, morning and evening.
- Refrain from or postpone changing your medications or working with another provider on problems related to PTSD while you are in the study. This will help us better understand how the treatment in this study impacts you. However, if you feel that you do need to work with another provider on your PTSD, please be sure to let us know so that we can coordinate your care accordingly. Also, if you and your prescriber feel that a change in your medication is needed please let a member of the research team know so that we can record the change in your research file.

Since the study is examining an outpatient treatment for PTSD, you have the option of having the study team coordinate with you and your employer to ensure you have the time to attend all of the treatment and assessment sessions. With your permission, one of the members of the research team will contact your supervisor to get his or her support for you to participate in this study. If you choose to have the research team contact your supervisor, supervisor will be told that you have agreed to participate in a research study and will be given your treatment and assessment schedule.

Assignment to Study Groups: When it is determined that you are eligible for the study, you will be assigned by chance (like flipping a coin) to receive 18 consecutive days of either CBD or placebo. You will have a 50% chance of being in the placebo group. A placebo is an inactive, harmless substance that looks like the study drug. Randomization will be double blinded which means that neither you nor the researchers will know whether you are receiving the study drug or placebo. In the event of an emergency, there is a way for the researcher to find out which drug you are receiving. All participants will receive 10 sessions of PE regardless of which group they are randomized to for the study.

Assessments: In addition to the treatment sessions, you will be asked to complete interim assessments prior to the first PE session, halfway through treatment, and at your final treatment session. These assessments will include a blood draw, saliva collection, wearing a watch to monitor heart rate, and self-report questionnaires and will add up to 30 minutes to your therapy appointment to complete. One month after you have completed treatment, you will be asked to complete a longer, more comprehensive assessment similar to what you did for the assessment prior to starting treatment.

Even if you choose to stop treatment, we will ask that you complete the 1-month assessment visit. This will help us understand how the treatment works even if you do not receive the full dose. Your participation in all parts of this study is very important.

Recordings: As part of PE treatment, you will be asked to listen to an audio recording of the session prior to your next session. Therefore, all therapy sessions will be audio-recorded using an independent recording device These recordings are only for the purpose of therapy and will be deleted once you have reviewed the session. We will not store any recordings for future purposes for this study. If you do not have an audio recording device, we can provide one for you during study participation. By signing this consent, you are giving your permission for recordings.

Time Commitment: While you are taking part in this study, you will be asked to attend approximately 13 visits, which includes 2 assessment visits (up to 4 hours each), 1 medication review appointment (up to 60 minutes), and 10 PE treatment visits (90 minutes each day). You will also complete 3 assessment visits prior to PE sessions 1, 5, and 10 for a blood draw, saliva collection, and completion of self-report psychological measures

that will add up to 30 minutes to each of these 3 appointments. You will take the medication every day for 18 consecutive days; however, therapy sessions will be completed on weekdays during regular business hours. Altogether, you will spend up to 26 hours in this study over the next one to two months.

Future Use of Your Information or Biospecimens Collected as Part of Your Participation

The researchers will be asking your permission to store your questionnaire answers and any left-over blood samples with your personal identifying information after this study is completed in the STRONG STAR Repository. The Repository is designed to be used for research investigating the causes, consequences, and treatment of PTSD and related conditions. Your consent to allow us to store your information will be given in a separate consent document. Your participation in the current study does not depend on your decision to participate or not in the Repository. Please note however that if you decide not to participate in the Repository, the researchers intend to keep and use the information collected as part of this study, but your personal identifiers (such as name, SSN, and contact information) will be permanently destroyed so that it can never be linked to you again.

The de-identified information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

Information about Optional Procedures – "What are other research activities that may be done but are not required for your participation?"

E-mail Authorization Agreement

The research team would like to communicate with you regarding your research visits via email. If you agree to receive emails about your research visits, we will ask that you sign a separate Email Authorization Agreement. You do not have to consent to receive emails.

Ending Participation Early – Could your participation end early? There are several reasons why the researchers may need to end your participation in the study (early withdrawal). Some reasons are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is stopped.

Risks – "What are the risks of participation in the research?"

Risks from the research

There are risks to taking part in this research study. One risk is that you may have side effects while in the study. Everyone taking part in the study will be watched carefully for any side effects. However, the study staff do not know all of the side effects that may happen. Be sure to tell your study therapist immediately about any side effects that you have while taking part in the study. The frequency that people experience a certain side effect can range from many (likely), few (less likely) or only one or two (rarely).

The following section will describe the risks related to your participation in this research study, including your participation in the psychological assessments, the Prolonged Exposure therapy, the medications, and the blood draw. These risks apply whether you complete the treatment program in person or by telebehavioral/telemedicine health. You should talk to your study doctor about any side effects or other problems that you have while taking part in the study.

Risks related to Cannabidiol (Epidiolex®):
Likely but Not Serious (expected to occur in less than 20 out of 100 participants):

- Fatigue
- Drowsiness
- Feeling weak
- Malaise
- Loss of appetite
- Diarrhea
- Skin rash
- Insomnia
- Viral/fungal infections

Rare, but Serious Risks (expected to occur in less than 5 out of 100 participants):

- Liver problems
- Sedation (e.g., elevated somnolence, loss of coordination, and difficulty with concentration)
- Severe allergic reaction (skin rash, itchiness, flushed skin, angioedema, difficulty breathing)
- Suicidal thoughts or behavior (< 1%)

Risks related to Prolonged Exposure Therapy and Psychological Assessments:
Likely but Not Serious (expected to occur in less than 20 out of 100 participants):

- Emotional distress including experiencing an initial increase of PTSD symptoms due to the discussion of traumatic events.

Rare, but Serious Risks (expected to occur in less than 5 out of 100 participants):

- A temporary or occasional increase in symptoms of depression, anxiety, or other pre-existing psychiatric symptoms.

Risks related to the Blood Draw:
Likely Risks, but Not Serious (expected to occur in more than 20 subjects out of 100):

- You may experience discomfort, bruising or both, at the site of the needle puncture during blood sample collection.

Less Likely, and Not Serious (expected to occur in 5-20 subjects or less out of 100)

- Some people experience fainting, the formation of a small blood clot or swelling of the vein and surrounding tissue, or bleeding from the puncture site.

Rare, but Serious Risks (expected to occur in <5 subjects out of 100):

- There could be infection at the site where the blood was drawn, but this risk is reduced because the trained staff drawing your blood will use procedures to reduce this risk.

Risks to Confidentiality

- Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.
- If you use of online conferencing systems there is a possibility for someone to overhear your discussions or our conferencing systems to be accessed, your privacy and confidentiality is not guaranteed.

Reproductive Risks

Concerns for sexually active men and women: Women should not become pregnant and men should not father a baby while taking part in this study because we do not know how the study drugs/procedures could affect a man's sperm (for some drugs/procedures, the concern may be that the sperm might be affected and in some cases, drugs could being carried by the semen into the vagina and cause harm) or a fetus, if a woman becomes pregnant during the study. It is important that you talk to your study doctor about avoiding pregnancy during this study. If you think you might have become pregnant or if you believe your female partner has become pregnant while you are in this study, you must tell one of the study doctors right away so that management of the pregnancy and the possibility of stopping the study can be discussed.

If you are a woman who is pregnant or could be pregnant, you cannot take part in this study because we do not know how CBD might affect a developing fetus. We will do a pregnancy test before you start treatment to make sure you are not pregnant.

Risks to babies who are being breastfed: Women who are breastfeeding cannot take part in this study because we do not know what effect CBD might have on their breast milk and the baby.

Risks whether you participate in this research or not:
Individuals with PTSD may have suicidal thoughts or attempt suicide. This is a risk to you whether you are being treated for PTSD or not. Therefore, the risk of suicide is not any higher in the study than it would be if you were not in this study. Your treatment may require you to talk about some things that might be painful or uncomfortable for you, which could cause increased emotional distress and the possibility of increased suicide risk, which can result in death. In the event that you are thinking about hurting yourself, please tell your therapist. Your therapist will work with you to develop a plan of specific steps for you to follow when in crisis. If we believe that you are at high risk for hurting yourself, we might also decide to include your family and social support network in your care to maintain your safety.

If at any time you are feeling significant distress or if you are having thoughts of hurting yourself or someone else, please notify your therapist or come into the clinic as soon as possible. You can also be seen in a Hospital Emergency Room after business hours and on weekends and holidays at any time.

We will tell you about any significant new findings which develop during the course of this research which may influence your willingness to continue to take part. For more information about risks and side effects, ask one of the researchers or study staff.

Are there Risks related to withdrawing from the study?
If you decide to withdraw from this study early, please discuss your decision with the research team. If you decided to withdraw, we may ask you if you are willing to participate in a brief assessment with a study clinician either in-person or by phone just to assess your condition and make appropriate referrals if necessary. We are also interested in following up with you at the times you would have been assessed if you had completed all of the sessions to answer some questionnaires. However, your participation in the follow-up assessments is completely your choice. There is no risk to you if you do not complete the final withdrawal procedures, and you can choose not to participate in them.

Are there risks if you also participate in other research studies?
Being in more than one research study at the same time may affect the results of the studies. You should not take part in more than one study without discussing it with the researchers of both studies.

What if a research-related injury occurs?
The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you experience an adverse reaction, please immediately contact your study doctor. See the section "Contact Information" for phone numbers and additional information. You may also need to tell your regular doctors.

If you are injured or made sick from taking part in this research study, medical care will be provided. This care may be billed to you or your insurance. Depending on the circumstances, this care may be provided at no cost to you. We have no plans to give you money if you are injured. The investigator can provide you with more information.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Benefits – "How could you or others benefit from your taking part in this study?"
The possible benefit of your participating in this study is a potential reduction in your symptoms associated with PTSD, which may positively affect your overall health and well-being. There is no guarantee or promise that you will receive any benefit from this study. We hope the information learned from this study will benefit other people with similar conditions in the future.

Alternative procedures or course of treatment – "What other options are there to participation in this study?"
There are other options available to you. Your other choices may include:

- Not participating in the study.
- Receiving another form of psychotherapy (talk therapy) from another therapist.
- Other medications, such as antidepressants.
- A community physician may be willing to prescribe you CBD (Epidiolex®), but this is not their usual practice for PTSD.
- There may be other research studies involving experimental treatments that could be helpful for your conditions.

Payments – Will there be any payments for participation?
Participants will be paid for each blood draw as follows for a total of up to $100:

- $10 pre-treatment medication appointment
- $20 Interim Assessment 1
- $30 Interim Assessment 2
- $40 Interim Assessment 3

The researchers will provide you with a ClinCard MasterCard®. Compensation will be automatically credited after completion of each blood draw. Your name, address, date of birth, and social security number will be shared with a third-party solely for the purposes of compensation processing. This information will only be used for the administration of the compensation (ClinCard MasterCard®) and will be kept strictly confidential.

In addition to the compensation on the card, you may also elect to receive messages (text and/or email) that money has been loaded onto your card. Please indicate your willingness to receive study-related messages:

- □ **Yes,** I would like to participate (please select the best method(s) for communication)
  - Cell Phone (text messages)
  - Email
- □ **No,** I choose not to participate

Costs – Will taking part in this study cost anything?

CBD (Epidiolex®) will be provided to you free of charge during this study.

You will be required to complete a blood test for liver function tests (LFTs) or provide a copy of LFT lab results completed within the last 90 days. A study team member will work with you to obtain and pay for your LFTs, if necessary. We do not guarantee that there will be no additional costs for LFTs, but if there are additional costs we will work with you to cover those costs.

Confidentiality – How will your records be kept confidential?

Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

Research policies require that private information about you be protected and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

What is Protected Health Information (PHI)?
Protected Health Information is information about a person's health that includes information that would make it possible to figure out who it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include: name, address, phone numbers, and email address to be able to contact you and make follow-up appointments; social security number for medical history to be sure we understand your medical and treatment history as well as any ongoing care that you receive while participating in this study; and questionnaire answers that you provide us as part of this study. We will get this information by asking you.

How will your PHI be shared?
Because this is a research study, we will be unable keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- Members of the STRONG STAR research team at UT Health San Antonio
- The STRONG STAR Data & Safety Monitoring Board, which is a committee that checks the study data on an ongoing basis, to determine if the study should be stopped for any reason.
- Oakdell Pharmacy, responsible for distributing the CBD (Epidiolex®) and compounding the placebo.
- The Institutional Review Board and the Compliance Office of the University of Texas Health Science Center at San Antonio, and other groups that oversee how research studies are carried out.
- The Food and Drug Administration (FDA) and other U.S. State and Federal Government agencies when required by law.

If you decide to participate in this study, you will be giving your permission for the groups named above to collect, use and share your health information within the limits of the law. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax. You need to be aware that some parties receiving your protected health information may not have the same obligations to protect your protected health information and may re-disclose your

protected health information to parties not named here. If your protected health information is re-disclosed, it may no longer be protected by state or federal privacy laws.

How will your PHI be protected?
In an effort to protect your privacy, the study staff will use code numbers instead of your name to identify your health information. These code numbers will be used on any copy of our study records and other study materials containing health information. If the results of the study are reported in medical journals or meetings, you will not be identified.

STRONG STAR strictly controls access to study data only allowing researchers associated with this study to review your data. However, complete confidentiality cannot be promised because information regarding your health may be required to be reported to appropriate medical authorities. For example, if you indicate you have thoughts of harming yourself of others the research team will want to immediately work with you to get you help.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to:

Dr. Casey Straud
University of Texas Health Science Center at San Antonio
Department of Psychiatry and Behavioral Sciences – Mail Code 7747
7550 IH10 West, Suite 1325, San Antonio, Texas 78229

How long will your PHI be used?
By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends and all required study monitoring is over. If you also decide to participate in the STRONG STAR Repository with a separate consent, you will agree to let us use and disclose your health information in accordance with the Repository's authorization.

Contact Information – Who can you contact if you have questions, concerns, comments or complaints?
If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints later or you wish to report a problem which may be related to this study please contact:

Primary contact:
Principal Investigator: Casey Straud, PsyD, ABPP who can be reached at 210-562-6742.

If primary is not available, you can contact:
Partnering Senior Investigator: Alan Peterson, PhD, ABPP who can be reached at 210-562-6700.

The University of Texas Health Science Center committee that reviews research on human subjects (Institutional Review Board) will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the IRB by calling 210-567-8250, or by mail to IRB, UTHSCSA, Mail Code 7830, 7703 Floyd Curl Drive, San Antonio, TX 78229-3900.

Title of Study: Enhancing Prolonged Exposure with Cannabidiol to Treat Posttraumatic Stress Disorder: A Pilot Study

Research Consent & Authorization Signature Section

The lawyers at the UT Health San Antonio require patients participating in research studies who are receiving part of their research by phone or a video platform to read and sign this form voluntarily requesting UT Health San Antonio and such research associates, residents, research assistants and other research health care providers as needed ("UT Health San Antonio Telemedicine/Telebehavioral Providers") to participate in your research care through the use of telemedicine. You understand that UT Health San Antonio (i) may practice in a different location than where you present for medical care, (ii) may not have the opportunity to perform an in-person interview, and (iii) will rely on information provided by you. You acknowledge that UT Health San Antonio research Telemedicine/Telebehavioral Providers' will not provide advice, recommendations about your routine health care. No decisions or recommendations for your care outside of this research project will be made. You acknowledge that it is your responsibility to provide information about your medical history, condition and care that is complete and accurate to the best of your ability, you understand that the practice of medicine is not an exact science and that no warranties or guarantees are made to you as to result or cure. If UT Health San Antonio Telemedicine/Telebehavioral Providers determine that the telemedicine services do not adequately address your medical needs, they may require an in-person psychological evaluation. In the event the telemedicine session is interrupted due to technological problem or equipment failure, alternative means of communication may be implemented, or an in-person psychological evaluation may be necessary. If you experience an urgent matter, such as a bad reaction to any treatment after a telemedicine session, you should alert your primary care provider and, in case of emergencies dial 911 or go to the nearest hospital emergency department.

If you agree to participate in this research and agree to the use of your protected health information in this research sign this section. You will be given a copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE

- You have read the above information.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.

Adult Signature Section

- You have voluntarily decided to take part in this research study.
- You authorize the collection, use and sharing of your protected health information as described in this form.

Printed Name of Subject	Signature of Subject	Date	Time AM PM
Printed Name of Person Obtaining Consent and Authorization	Signature of Person Obtaining Consent and Authorization	Date	Time AM PM

☐ Consent and authorization was obtained from this individual who is unable to read and/or write but can otherwise communicate and/or comprehend English. The method used for communication with the subject was: _____.
The specific means by which the subject communicated agreement to participate was:
_____