Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

You are invited to participate in a research study designed to learn more about the safety, tolerability, and potential clinical benefit of Psilocybin-Assisted Therapy for the treatment of PTSD in US Veterans.

H-50300- THE STARLIGHT PROTOCOL (STATE-FUNDED TRIAL ASSESSING RECOVERY AND LONG-TERM IMPACT OF GUIDED PSILOCYBIN FOR HEALING TRAUMA)

Concise and Focused Presentation

Some information exists about the safety and effectiveness of psilocybin, a hallucinogenic psychedelic drug, in therapy for mental health issues, like depression and anxiety, yet we need more research to better understand its potential. Specifically, we want to understand if it's safe and effective for Veterans with posttraumatic stress disorder (PTSD). This new kind of treatment might not only lessen the challenges of PTSD among Veterans but also has the potential to lower suicide risk. The person leading this study wants to expand on what other psilocybin research has taught us by conducting a trial where Veterans will have two sessions of psilocybin combined with talk therapy. The goal is to check if this approach is safe, well-tolerated, and effective for treating PTSD in Veterans.

Design: This research lasts about 8 months in total, and involves about two months of study treatment with 6 months of follow-up visits. At the start, there's a detailed screening visit. If you decide to continue, you'll have preparation therapy sessions before taking any psilocybin. These sessions help you get ready, meet the therapy team who will be working closely with you throughout the trial, discuss your goals and expectations, talk about what you might experience with psilocybin, and address any worries you might have. After the preparation sessions, you'll have a psilocybin dosing day. The first dose is a lower one (15 mg). During the dosing day, the therapy team will be with you and help to keep you comfortable and help you to explore and process things as they come up. Following the dosing day, there will be integration sessions. These sessions help you go over and make sense of anything that happened during the dosing day. After the first dose, there are two integration sessions before the second (and last) psilocybin dose, which is 25 mg. Following that, there are two more integration sessions. We'll stay in touch, checking in at 1, 3, and 6 months after the second dose to see how you are feeling. While it's not a required part of this plan, you might be asked to join MRI scanning sessions at certain times. If you're eligible and decide to take part, it would be under a different study protocol and you'd be asked to sign a separate consent.

Voluntary: Participating in this study is entirely up to you. You can decide to leave at any time and can choose not to participate in certain aspects. If you say yes now but change your mind later, we won't use any information that can identify you. Leaving the study won't impact your payment for what you've already done, and it won't affect your relationship with us or any of your healthcare providers.

Risks: This study has some risks that include taking psilocybin, participating in therapy, and completing assessments. Psilocybin is a powerful drug that might affect your thinking, cause anxiety or panic, and briefly change your heart rate and blood pressure. It's possible you might have challenging memories or hallucinations during the psilocybin dosing, and these could be linked to your past traumatic experiences. Talking about your mental health may be tiring or uncomfortable, but it's crucial to be truthful so we can ensure your safety. Completing assessments can be time consuming, boring, and/or distressing as they will ask about mental health symptoms, substance use, suicidal thoughts and behaviors and experiences with psilocybin.

Benefits: Being in this study might not directly improve your situation, but some individuals have noticed

improvements and gained insights after using psilocybin. Your involvement could also contribute to helping other Veterans by giving us more knowledge about how psilocybin might be beneficial. Engaging in conversations during the study might boost mood, and the information you provide could be valuable for future research.

Alternatives: You can choose not to participate.

Background

We've seen some hopeful early signs that using psilocybin in therapy might be safe and effective for various mental health issues. But we still need more research to be sure it's safe and works well for Veterans with posttraumatic stress disorder (PTSD). If this new treatment works, it could help ease the challenges of PTSD in Veterans, possibly lowering the risk of suicide. This, in turn, could lessen the heavy impact of this mental health crisis on families and communities across the United States. So, the leader of this study plans to build on what's been learned in past research by doing a new trial. This one involves two sessions of psilocybin combined with talking therapy to see if it's safe, well-tolerated, and effective for treating PTSD in US Veterans.

If you decide to be part of this study by signing this consent document, you'll go through a detailed screening to check if you're eligible. This screening is part of another research study (H-48748) designed to evaluate people interested in research studies connected to our program. You'll be asked to sign a separate consent form for that study, and all screening procedures, their potential risks, and compensation will be described in detail during that separate consent process before you participate in any procedures.

By signing this psilocybin study's consent form, you're agreeing to share your data between the psilocybin and the screening study. During the screening, you'll also have a session with a clinician. This involves interviews and self-report measures asking about your mental health, experiences with trauma, PTSD, thoughts of self-harm, and related topics. You'll also do a medical evaluation, including a physical examination, echocardiogram (ECG), and a blood draw for lab tests. These procedures all help us understand if it's okay for you to be part of the psilocybin study. Additionally, you may be invited to participate in optional MRI brain scans as part of the screening protocol, H-48748. Those procedures will not be documented in this consent form because you will discuss those in detail when consenting into the screening protocol. We mention this here only to let you know what you might expect.

This study involves several steps: screening, preparation therapy sessions where you will be getting ready to take psilocybin, two sessions of taking psilocybin, and sessions afterward each dosing to help integrate the experience. This part takes approximately two months. After that you'll also have follow-up visits with us for 6 more months. Two facilitators will be with you throughout the dosing days. At least one will be a licensed mental health provider (like an MD, PhD, LCSW, APRN), and the other will have some training in mental health. We'll keep a close eye on you on the days you take psilocybin to make sure you're safe.

This research study is funded by Texas Health and Human Services Commission

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.

Purpose
This study has two main goals: (1) to check if using psilocybin in therapy for Veterans with PTSD is safe by looking at any new or worse mental health symptoms and any troubling side effects, and (2) to see if psilocybin could be helpful by examining how PTSD and other feelings related to stress and trauma, like depression, might change after taking it.

Procedures
The research will be conducted at the following location(s):
Baylor College of Medicine, BCM: Jamail Specialty Care Center, and The Menninger Clinic.

Once you finish the screening procedures under protocol H-48748 and are found eligible for this psilocybin study, you'll have two preparation sessions with a study facilitator. We aim to finish these sessions the week before dosing, and at least one can be in-person so you can see the study space and meet the facilitators. The main goal of these prep sessions is to build a relationship and trust, reducing the risk of fear or anxiety during the psilocybin sessions. We'll discuss your expectations, review your goals, and address any questions or concerns. This approach has worked well in past psilocybin studies, including trials with patients dealing with depression and anxiety.

Dosing Day 1: You'll need to come to the study site in the morning (we'll let you know the exact time and provide an address and directions for your driver). On that day, you'll do a urine test for drugs and pregnancy. Positive results for drugs or pregnancy will stop the study visit from proceeding. You'll also go through some clinical assessments, answering questions about any thoughts of self-harm and how severe your PTSD symptoms are. After that, you'll take the first dose of psilocybin. Psilocybin will be manufactured and provided by Usona Institute. It comes in pill form, and you'll swallow it with water. During the early part of the psilocybin session, we'll encourage you to sit or lay comfortably, wear eyeshades, and listen to some music through headphones. We'll ask you to rate how intense your experience is. We'll also check your vital signs (pulse and blood pressure for example) before you take psilocybin, right after, at 60, 90, and 120 minutes, and again before you leave. Once the most intense effects wear off, we'll ask some questions about your psychedelic experience, changes in consciousness, challenging moments, any personal insights, and the like.

For the psilocybin part of the study, we'll follow procedures like what other researchers have done in past studies. After taking psilocybin, you'll be closely watched for about 8 hours by two monitors. They'll be in the room with you the whole time, or at least one will be there while the other will monitor through live video. The lead monitor is a licensed clinician with advanced training and experience in psychotherapy, allowed to practice independently (like MD, PhD, MSW, PCPC, LMFT, Psychiatric NP).

The second monitor has at least a bachelor's degree and a year of clinical experience in mental health care. A medical doctor will also be on call during the 8 hours and can get to the site within 15 minutes if there's an emergency. At the end of each dosing day, you'll talk about your experience with the monitors discussing what happened, any insights you had, and the effects of the drugs. We'll check your medical and psychiatric stability, make sure the psilocybin effects have calmed down, and confirm you have a safe way to get home. If you show any health issues that are worrying, you won't leave until they're better. If they don't get better quickly, we'll get you more advanced care, possibly making sure you get to a medical facility. After taking psilocybin, you must agree not to drive or use heavy machinery for the rest of the day or make any big financial or legal decisions. We ask that you arrange a family member or friend to drive you for your dosing visits. If you cannot arrange for someone to drive you to and from the dosing day appointments, we can help arrange a ride with a service such as uber.

Around 24 hours after taking psilocybin, you'll have the first integration session. This is where you talk about and make sense of your experiencediscussing thoughts, memories, insights, and any challenging moments. Before the second dosing day, you'll have two more integration sessions. At the third of these integration sessions, you will also prepare for the second dosing day as we did before.

Dosing Day 2: This study visit be identical in structure and format to the first dosing day with the exception that you will get a higher dose of psilocybin (25mg) this time. This is the standard dose given in most psilocybin trials. After this dose, you will follow the format and structure noted above for two additional integration sessions.

You will complete some clinical assessments at 1, 3, and 6 months after your second dose of psilocybin, and will be asked about any adverse or distressing effects you may have experienced since the last study visit.

If you're doing the optional MRI brain scans under screening protocol H-48748, you'll may be invited to do them the day before and after each dosing day and/or at the final follow-ups.

If, during the dosing days, you feel anxious and therapeutic support (like grounding skills or deep breathing) doesn't help, the study physician can offer another medication to ease these symptoms. The decision to provide this will be made by the study physician based on your individual situation.

In case of a rare medical or psychiatric emergency that can't be handled safely by the study staff using reassurance or medication, the study physician will decide if you can be safely taken to the nearest emergency department with medical staff, or if 911 should be called for transport.

Clinically Relevant Research Results

The results generated from this research study are not expected to have any clinical relevance to you.

Sharing and Future Research Studies with Identifiable Private Information

Information that identifies you may be removed from your identifiable private information collected as part of this research, and after such removal, your information may be used for future research studies or distributed to another investigator for future research studies without additional consent/authorization from you.

Research related health information

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine, BCM: Jamail Specialty Care Center, and The Menninger Clinic to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Specific information concerning alcohol abuse
- Specific information concerning drug abuse
- Specific information concerning psychiatry notes
- Demographic information (name, D.O.B., age, gender, race, etc.)
- Full Social Security #
- Photographs, videotapes, and/or audiotapes of you

The health information listed above may be used by and or disclosed (released) to researchers, their staff and their collaborators on this research project, the Institutional Review Board, Baylor College of Medicine, BCM: Jamail Specialty Care Center, The Menninger Clinic, AIM YOUTH MENTAL HEALTH and their representatives, and TEXAS DEPARTMENT OF HEALTH and their representatives.

Agents of the U.S. Food and Drug Administration may inspect the research records including your health information. Agents of regulatory agencies such as the U.S. Department of Health and Human Services will be permitted to inspect the research records including your health information.

The data coordinating center will have access to the research records including your health information.

A Data and Safety Monitoring Board will have access to the research records including your health information.

Use or Disclosure Required by Law

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure of child abuse, neglect, or harm to self or others to state or local authorities.

Baylor College of Medicine, BCM: Jamail Specialty Care Center, and The Menninger Clinic are required by law to protect your health information. By signing this document, you authorize Baylor College of Medicine, BCM: Jamail Specialty Care Center, and The Menninger Clinic to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that the research involves treatment. You do not have to sign this Authorization, but if you do not, you may not receive research-related treatment. To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete. However, your health information that is necessary to your care will be provided to you or your physician. At the conclusion of the research and at your request, you generally will have access to your health information that Baylor College of Medicine, BCM: Jamail Specialty Care Center, and The Menninger Clinic maintain in a designated record set, which means a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at Baylor College of Medicine, BCM: Jamail Specialty Care Center, and The Menninger Clinic to make decisions about individuals. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by representatives of the specific institution where you are being enrolled into this research study which are: Baylor College of Medicine, BCM: Jamail Specialty Care Center, and The Menninger Clinic.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research project,

the Institutional Review Board, AIM YOUTH MENTAL HEALTH and their representatives, TEXAS DEPARTMENT OF HEALTH and their representatives, regulatory agencies such as the U.S. Department of Health and Human Services, FDA, Baylor College of Medicine, data coordinating center, Data and Safety Monitoring Board, BCM: Jamail Specialty Care Center, and The Menninger Clinic may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this Authorization, you must write to: Dr. Lynnette A. Averill
Baylor College of Medicine
Department of Psychiatry & Behavioral Sciences
1977 Butler Blvd, E4.187
Houston, TX 77030
801-440-8718
lynnette.averill@bcm.edu

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Potential Risks and Discomforts
Possible psilocybin effects and side effects

Psilocybin is a hallucinogenic drug, similar to LSD and mescaline. It's generally not considered physically harmful, but it hasn't undergone the standard tests used to assess the toxicity of therapeutic drugs in animals and humans. So, there's no scientific data to confirm its toxicity or safety. There is a chance, which we believe to be small, of physical toxicity not yet found in historical religious use, recreational use, or in the past 50 years of experimental and clinical use of this drug.

The primary effects of psilocybin are psychological. A high dose, like you might receive in this study, can lead to a wide range of profound changes in perception and consciousness during the drug's effects. In previous studies, about one-third of people reported feeling moderate to strong fear or anxiety after taking psilocybin. Changes in normal perception might involve seeing or hearing things differently (pseudo-hallucinations) and experiencing unusual smells, tastes, or other bodily sensations.

During the time psilocybin is affecting you, you might feel anxiety, panic, or paranoia (suspiciousness). Your behavior could include intense crying, laughing, or panic that might seem embarrassing later on. You could experience strong emotions, both good and not so good. Your sense of time might change, making it feel like time is passing faster or slower than usual. You might feel a sense of separation

between your body and mind. The effects of psilocybin typically last around 5-7 hours.

Like other powerful experiences, positive or negative, you might have dreams or lasting memories of your psilocybin session. After the session, there could be short-term or even permanent changes in your personality, attitude, or creativity.

During the time psilocybin is affecting you, it may cause dizziness, nausea, vomiting, incontinence, increased pulse and blood pressure, dilated pupils, heightened reflexes, tremors, and muscle twitching. There's also an increased risk of falling or other injuries due to incoordination, misjudgment, or other effects of psilocybin. In an earlier study, a few people experienced increases in blood pressure during psilocybin sessions. Like with any drug, there's a chance of allergic reactions such as itching, rash, or hives. Some participants have reported a temporary headache starting about 7 hours after taking psilocybin, sometimes lasting into the next day. Headaches from psychedelic treatment can usually be successfully treated with over-the-counter pain relievers. Some participants have mentioned leg pain lasting 1-2 days after the session.

Though uncommon, there are additional risks of adverse effects lasting for hours or days after the psilocybin session. These may include mood disorders like depression, psychotic disorder, and anxiety disorder. In rare cases, hallucinogen exposure seems to be linked to the development, acceleration, or triggering of significant or lasting psychiatric conditions such as psychoses and occasional or enduring visual perceptual disorders (known as "flashbacks" or visual disturbances). There aren't extensive well-controlled studies of psilocybin to definitively confirm or disprove the occurrence of such long-term effects. However, it's believed that the likelihood of such lasting effects is very small.

The risks of adverse effects from psilocybin will be minimized through careful volunteer selection and screening processes. Additionally, you'll have extensive preparation with the study team before the psilocybin session and integration sessions after. Throughout the dose days, you'll be in a supportive environment with attentive care to further minimize any potential risks.

You'll be closely monitored throughout the dose days, and if needed, medical care will be provided. This could involve increased medical monitoring and administering medically appropriate drugs. For safety, after psilocybin is given and during its effects, physical support or guidance may be offered if there's a risk of falls or dangerous behavior. If deemed necessary by the study physician, sublingual (under the tongue) nitroglycerin may be given to lower blood pressure. Possible side effects of nitroglycerin include headache, low blood pressure, skin flushing, dizziness, weakness, and other signs of reduced blood flow to the brain. Other potential effects are nausea, vomiting, restlessness, paleness, sweating, collapsing, rash, skin irritation, a tingling or creeping sensation on the skin, nasal inflammation, body swelling, loss of strength, and abdominal pain. If medical intervention is needed, you may be transported to the Emergency Department, and a doctor will conduct a physical examination.

PTSD symptoms
Psilocybin has not been proven to be an effective treatment for PTSD. There's a possibility that your

PTSD symptoms may worsen during the study. If this occurs, it could be linked to the study interventions, including psilocybin, or it might be the natural progression of your PTSD. Worsening symptoms may include, but are not limited to, increased anxiety and depressive symptoms.

Depressive symptoms
If you suffer from depression, there is a possibility that your depressive symptoms may worsen during the study. An increase in depressive symptoms could be associated with the study interventions, including psilocybin, or it could be part of the natural course of your depression. Worsening symptoms may include, but are not limited to, suicidal thoughts, low mood, feelings of hopelessness or guilt, fatigue, lack of pleasure, poor concentration, and changes in sleep or appetite.

Alcohol restrictions
The effects of psilocybin may interact with alcohol. If you consume alcohol while the drug is in your system, you might experience intensified or unpredictable effects, impairing your ability to perform everyday tasks, like driving. These effects could persist for at least 24 hours after your visit to the research unit. Hence, it's advised not to consume alcohol for at least 24 hours before and 24 hours following the psilocybin session.

Smoking restrictions
While smoking doesn't exclude you from the study, you won't be allowed to smoke on dosing days. You'll need to either abstain or use a patch, depending on your preference for avoiding withdrawal symptoms. Abstaining from smoking can lead to symptoms like agitation, anger, fatigue, anxiety, headache, and others. If you plan to use a patch, it's your responsibility to obtain it. Please inform us if you plan to wear one, and confirm on dose day that you have it on.

Activity restrictions
For safety reasons, you won't be allowed to drive yourself home after a day-long psilocybin session; we'll provide public transportation if necessary. It's possible that the effects of psilocybin may persist after your scheduled departure from the dosing room. We recommend staying with a trusted friend or relative overnight and avoiding the operation of dangerous machinery or a motor vehicle for at least 12 hours after psilocybin administration. The study team may also request that you restrict other activities or stay at the dosing room until the effects of psilocybin lessen. Only agree to participate if you are willing to cooperate with these precautions.

Blood Draw
Drawing blood (which will only occur once, during the eligibility screening under H-48748) might cause some discomfort, bleeding, or bruising at the needle site. In rare cases, it may lead to fainting. The small risk of infection is minimized by using standard sterile procedures. Blood draws will collect approximately 3 teaspoons, less than would be collected for a blood donation.

Questionnaires and Interviews
You may get tired or bored when we are asking you questions, or you are completing questionnaires. You may become uncomfortable or upset when answering questions about your psychiatric history, current symptoms, or by discussing other things with the study team.

Pregnancy related risks
If you are pregnant or become pregnant, you won't be able to participate in this study. If you suspect you might be pregnant, you cannot join the study. The drugs administered in this study could potentially harm an embryo or fetus. A pregnancy test will be conducted before accepting you into the study and again at the beginning of each dosing day before giving you any psilocybin. The impact of this research on an embryo or fetus is uncertain at this time.

Risks Associated with Collection of Potentially Sensitive Information:
Sensitive information may be disclosed during the screening process and/or throughout the study. The identification of diseases during screening could impact the participant's future insurability. Additionally, certain diagnoses may lead to stigmatization or self-stigmatization for the participant. To ensure maximum protection in collecting, storing, and using potentially sensitive information, best practices will be followed at all study stages. All collected data will be securely stored in an electronic database, coded by a study ID number and kept separately from any documents containing personally identifiable information or a key linking such information to study data. All research staff will undergo human subjects training as required by institutional guidelines to ensure the proper conduct of scientific research in humans.

Risks Associated with Psychiatric Questionnaires:
Little to no discomfort is expected during interviews with the study investigators, aside from the possible stress of answering personal questions. Participants will respond to inquiries about their psychiatric symptoms and complete questionnaires. Some may find this process inconvenient, uncomfortable, or upsetting. The psychological testing might involve personal questions about previous experiences, all asked in a private room. Participants will be informed that they are not obliged to answer any question they are uncomfortable with and will have the option to discuss concerns with someone on the research staff. One or more individuals will be available to talk to participants if they become distressed during an interview or while filling out questionnaires.

Unknown risks
There may be side effects and discomforts of this study that are not yet known.

There may be unknown risks or discomforts involved. Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

Potential Benefits

The benefits of participating in this study may be: You may or may not directly benefit from being in this study. There is a chance that participating may help lessen your PTSD severity, anxiety, depression, or suicidal thoughts, but this is not guaranteed, and it's unknown how long any positive effects may last. You might gain insights into your life that you find helpful.

Your participation will contribute to scientific knowledge and a better understanding of the effects of psilocybin in treating PTSD. By taking part, you may contribute to helping others in the future.
. However, you may receive no benefit from participating.

Alternatives

You may choose to not participate in this study.

Investigator Withdrawal of Subject from a Study

The investigator or sponsor may decide to stop you from taking part in this study at any time. You could be removed from the study for reasons related only to you (for example, if you move to another city, if you do not take your study medication, or if you have a serious reaction to your study medication) or because the entire study is stopped. The sponsor, investigator, Food and Drug Administration, or Institutional Review Board may stop the study at any time.

Subject Costs and Payments

Each preparation or integration session will be compensated $50. Each dosing session will be compensated at a rate of $250. Each follow-up visit will be compensated at $20. An additional $200 will be offered to those who complete the entire study as a recognition of their time and investment in the study. If you do not complete the full study, you will be compensated for the procedures you have completed. If you have completed some but not all of a study visit, you will be compensated for the portion of that visit you have completed (for example if you complete only half of the last integration session, you would earn $25 for that session rather than $50).

Note you will be paid separately for any participation in screening procedures and scanning sessions through the associated protocol H-48748.

You will be reimbursed for costs such as parking, necessary dependent care support, and local travel required for study visits.

Payment will be issued via ClinCard.

Research Related Injury

No specific medical treatments for injury are available at the study site. Treatment of injury would take place by emergency first responders or other medical providers or treatment facilities. However, in the case of minor issues or events, the study will have an in-room licensed mental health professional, another study monitor, and a nearby physician to assist as detailed elsewhere in the protocol.

Research personnel will try to reduce, control, and treat any complications from this research. If you are injured because of this study, you will receive medical care that you or your insurance will have to pay for just like any other medical care.

Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, LYNNETTE AVERILL, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: Dr. LYNNETTE AVERILL at 801-440-8718.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

You are invited to participate in a research study designed to learn more about the safety, tolerability, and potential clinical benefit of Psilocybin-Assisted Therapy for the treatment of PTSD in US Veterans.

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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Subject	Date
Investigator or Designee Obtaining Consent	Date
Witness (if applicable)	Date
Translator (if applicable)	Date