UNIVERSITY OF WASHINGTON
CONSENT FORM

A randomized, placebo-controlled trial of psychedelic-assisted psychotherapy with single dose psilocybin for frontline clinicians experiencing COVID-related symptoms of depression and burnout

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We are asking you to be in a research study. This form gives you information to help you decide whether or not to be in the study. Being in the study is voluntary. Please read this carefully. You may ask any questions about the study. Then you can decide whether or not you want to be in the study.

KEY INFORMATION ABOUT THIS STUDY

Purpose: The purpose of this study is to evaluate the effect of psychotherapy combined with a session of supervised psilocybin on symptoms of depression, burnout, and post-traumatic stress in physicians, advance practice providers, and nurses who have had these symptoms associated with frontline clinical work during the COVID pandemic.

Study duration: Participation in this study will last for a total of 7 months, from the time of the first pre-psilocybin psychotherapy session ('preparation') to the last questionnaires (6 months after the psilocybin or placebo medication dosing session. During that time, the preparation psychotherapy will involve about 2 weeks, the psilocybin or placebo medication dosing session will take one full day, and the follow-up integration psychotherapy will occur about once a week for 3 weeks. The second and third integration psychotherapy sessions and all the follow-up questionnaires can be completed online.

Types of activities you will do in this study: The study intervention includes 2 preparation psychotherapy sessions, which will involve discussing your experiences and the symptoms and feelings associated with them. Next will be a medication dosing session which will take place in a comfortable space that is more like a living room than a clinic room and will take 8 hours total. Starting the following day will be 3 integration psychotherapy sessions, which will involve discussing your experiences with the medication dosing session and the feeling and insights that may have arisen. In addition to these study intervention activities, you will have screening blood tests, urine pregnancy testing for women of reproductive potential, one urine test on the medication dosing day, questionnaires to fill out online, and brief symptom interviews.

Reasons why you might want to be in this study: You may want to be in this study to contribute to scientific knowledge about the use of psilocybin-assisted therapy for clinicians with psychological symptoms related to frontline work in the COVID pandemic. Psilocybin is a drug

that is not currently approved by the Food and Drug Administration, and its benefit in this setting is unknown.

Reasons why you might not want to be in this study: You may wish to wait until further knowledge has been gathered about the efficacy of this treatment, or you may wish to pursue alternative treatments for psychological symptoms. You may be concerned of confidentiality and other risks related to participation in this study. You may want to avoid any in-person therapy during the COVID-19 pandemic. Women may not want to commit to avoid pregnancy from the time of enrollment through the dosing session.

Appropriate alternative treatments: Alternative treatments would include psychotherapy, use of antidepressant medications, or possibly other medications that are used for post-traumatic stress. You would need to be evaluated by a psychologist and/or psychiatrist to determine the range of options appropriate for you.

PURPOSE OF THE STUDY

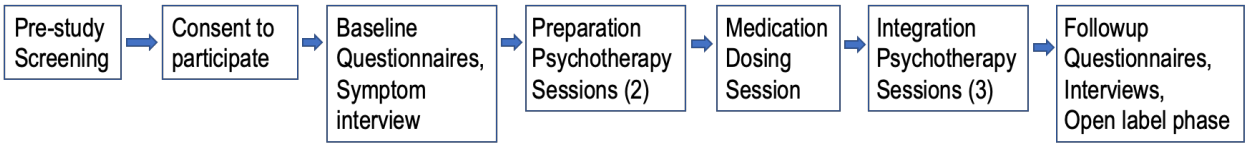
Physicians and nurses who have frontline clinical experience during the COVID-19 pandemic can have psychological issues as a result of their work, including symptoms of depression, burnout, and post-traumatic stress. This clinician COVID psychological syndrome has not been completely characterized but can be moderate to severe for some people. As yet, there are no 'gold standard' treatments for this clinician COVID psychological syndrome.

Psilocybin is a medication that is not currently approved by the Federal Drug Administration (FDA). Psilocybin occurs naturally in some varieties of mushrooms, but study will use synthesized psilocybin as part of a therapeutic process that involves 'preparation' psychotherapy for 2 sessions, a 'medication dosing day' when the psilocybin or placebo is given, and follow-up 'integration' psychotherapy for 3 sessions. Psilocybin acts on serotonin receptors in the brain to produce changes in how people perceive themselves and their problems that can lead to new insights. Psilocybin can also produce changes in blood pressure, heart rate, and symptoms of psychological distress such as anxiety or mood changes, although these changes are transient and generally gone in about six hours.

You are invited to participate in a research study designed to look at the use of psilocybin-assisted psychotherapy in physicians, advance practice providers, and nurses associated with frontline clinical work during the COVID pandemic who experience symptoms of depression that may be associated with clinician burnout, and post-traumatic stress. 30 subjects will be enrolled to participate in this study at the University of Washington. The participants will be randomly assigned to receive psilocybin or an active placebo, and after the 1 month evaluations are complete, the participants who received placebo will have the opportunity to receive open label psilocybin.

STUDY PROCEDURES

This section outlines the study procedures that you will experience if you decide to participate in this study. Participation in this study, including follow-up, will occur over ~ 6 months. Study visits will take place at Harborview Medical Center (HMC) in a specially outfitted clinic room, and some follow-up and self- reported questionnaires/interviews may take place remote.



Screening:

1. Screening Visit: Will take place at the research clinic at HMC and will take up to 90 minutes.

   You will be asked to come to an initial screening visit and sign the study consent form. At the screening visit, vital signs, an and a brief physical exam will be performed, and mental health exam You will also be asked to complete a set of self-reported questionnaires, and you will be asked a series of questions by a study clinician. You will have a blood draw (of about 4 tablespoons) that includes standard laboratory tests to screen for liver, kidney, or blood abnormalities that could affect your safety while taking psilocybin. You will also provide a urine sample for toxicology screen at or prior to your dosing session. For women of childbearing age, a urine pregnancy test will be performed. If you live out of state and it is not feasible for you to come to Harborview Medical Center for an in-person screening visit, or if COVID precautions make it difficult to come for an in-person visit, you have the option of utilizing a secure video communication platform such as Zoom or Skype. We will ask you to send us your most recent physical exam, and bloodwork by fax or secure electronic records transfer. The research team will review this screening information collected from this visit to determine if you are eligible. If you are eligible, you may be invited to participate in this study.

For participants who are confirmed eligible:

1. Baseline questionnaires and interview: Following the screening visit, if it is determined that you are a good fit for the study, you will first complete a series of questionnaires that will ask questions about your experiences, your mood, and your physical and psychological symptoms. For example, the most sensitive questions include “In the last month, how much were you bothered by repeated, disturbing, and unwanted memories of the stressful experience?” and “In the past 2 weeks, I have felt a sense of dread when I think about work I have to do.”

   You will also have an interview with a study clinician who will ask you questions about your psychological symptoms. In this interview, the most sensitive questions include “In the past week, do you think you have looked sad or depressed to other people? And “Have you felt tense or edgy in the past week? What about feeling fearful that something bad is about to happen?”

We will reassess eligibility after the screening appointment. If you are no longer eligible, we will withdraw you from the study. You will complete the questionnaires using a secure web-based platform and the interview by phone or video conference.

2. Drug randomization
   If you continue to be eligible for the study, you will be randomly assigned using a method called randomization. Randomization means that the group you are in is assigned by chance, like the flip of a coin. Your chance of receiving the study drug, psilocybin or the active placebo, niacin, is equal.

3. Preparation sessions (Visits 1 and 2) for the medication dosing session (psilocybin or control) consists of 2 meetings for a total of 5-6 hours. This will take place in clinic room outfitted for psychotherapy at the research clinic space and will take 60-90 minutes at two different times. The first preparation session will occur 1-2 weeks before and the second session will occur 1-2 days before the medication dosing session.

   The purpose of these meetings is to discuss the drug sessions, minimize concerns, and for the study therapists to get to know individual participants. Each of the preparation psychotherapy sessions will be conducted with you and 2 study therapists who will follow you throughout the study. These preparation sessions will inform you about what to expect with the medication dosing session (which may include psilocybin or the active placebo) and will be an opportunity for you to review the experiences that you had as a physician or nurse during the COVID pandemic.

   The study therapists will ask questions, listen carefully, and guide you towards developing an intention for your medication dosing session, and for your recovery. At each of these preparation sessions you will be asked a short series of questions about whether you are suicidal, as a safety precaution, and if you are suicidal, you will be directed to appropriate evaluation and treatment.

4. The medication dosing session (Visit 3) will take place in a clinic room not near inpatient areas, at Harborview Medical 1-2 days after the last preparation session. The investigator will review this session with you in detail. The medication dosing session will take one full-day, 7-10 hours in duration. The following will take place at this visit: a urine pregnancy test will be conducted in all females of childbearing potential , plus a rapid COVID test will be taken by participant and study staff. Should anyone test positive we will reschedule the medication session and participants will be encouraged to follow-up with their primary health care provider for a PCR test to confirm Then, you will be interviewed. If the investigator believes the session should not proceed, the session will be cancelled or postponed.

   If the session proceeds, you will be given the randomly assigned study drug (psilocybin or niacin as the active placebo). If you are randomized to receive psilocybin, you will receive 25 mg. If you are randomized to receive niacin, you will receive 250 mg. During this visit, you will be in a comfortable treatment room with your 2 study therapists for the entire duration of the effects of the medication. During this session, at least one therapist will be present at all times, and both therapists will be present for most of the time. The

therapists will take your blood pressure and pulse every hour. You can listen to the music provided by the study, or simply have silence.

Most people do not talk that much during the medication dosing session, but you may talk as much or as little as you wish, and the therapists will follow your lead. During the session, you will lie on a couch, wear eyeshades, and listen to a program of music through headphones, and be asked to focus your attention inward. The participant will be encouraged to focus her or his attention inward. The eyeshades and music are intended to encourage this inward reflection.

When the medication has worn off, you will be asked to complete 2 brief questionnaires that ask about your medication dosing experience. When the study therapists feel that it is safe for you to leave, you will be discharged. You will need to arrange someone else to drive you home or to where you are staying who can provide continuous contact. You will need to agree to wait for 48 hours after your release from the medication dosing session before returning to work.

5. Integration sessions (Visits 4, 5, and 6) are post medication sessions that will take place at the research clinic space in the same room as before. You will have three integration sessions over the course of 2-3 weeks. Each integration session will last 60-90 minutes in duration. The first integration session will occur on the day following the medication dosing session and you will have two additional integration sessions approximately every week after that.

   These sessions will be conducted by your two study therapists. The study therapists will ask you about your experience during the medication dosing session and will provide guidance designed to enable you to interpret what the experience might mean for you. The therapists will refrain from telling you what your experiences mean—the interpretation is ultimately up to you. After each integration session, you will be asked to fill out questionnaires to assess your psychological symptoms, some of which will be identical to the questionnaires you completed in the baseline set.

   The third integration session will take place about four weeks after your medication dosing day. At this visit, you will complete another set of questionnaires, and have another 30 minute interview with a study clinician that will assess your psychological symptoms. This information will be very similar to the baseline symptom questionnaires and interview.

6. Disclosure of drug group and optional open label phase
   Four weeks after you complete the drug session, you will receive information about whether you received psilocybin or placebo during your medication dosing session. If you are assigned to the active placebo and after your unblinding, then you may have the opportunity of receiving the study drug, psilocybin.

   To receive psilocybin in an open label phase, you would complete a new set of questionnaires, symptom interview, preparation sessions, medication dosing session, and

integration sessions similar to those described above. Information will be collected, and study procedures performed for subjects who select this option, and as above for the study.

7. Follow-up procedures will take place remotely a 2, 3, and 6 months after your medication dosing session, and will be performed by a study therapist who conducted your sessions This follow-up will be conducted by phone or video-conference and will take about 30 minutes to complete each time.
   If you receive psilocybin, whether initially or in the open label phase, you will be asked to complete a set of study questionnaires and a symptom interview. Examples of the most sensitive options in the questions you will be asked include: "I cry more than I used to" and "I feel more worthless as compared to others."

8. Recordings. We will ask for your permission to video- or audio-record all of the study sessions. A separate signature line for this is included at the end of this consent form. The purpose of this recording is to enable you (because you will receive a copy) and the investigators to review your experience and how the therapist interacts with you. These recordings will be kept in our locked offices in locked file cabinets or in encrypted, password-protected formats accessible only by research staff. You may choose to give permission for recording, or decline to give permission for recording, and your decision will not affect your ability to remain in the study.

9. Option for remote procedures: Some of the study procedures can take place remotely, and not in-person. This may be useful if you live outside of the Seattle area.

   The **screening visit** can occur remotely if you are out of the area and have recent screening labs to provide to the study team (in the last 30 days) as defined above. A urine pregnancy test will need to be ordered remotely for females of childbearing age.

   The **baseline questionnaires and interview** will always take place remotely.

   The **first preparation visit** (Visit 1) can take place by video-conference. The second preparation visit will always occur in-person.

   The **2nd and 3rd integration visits** (Visits 5 and 6) can take place by video-conference. The first integration visit (Visit 4) will always occur in-person.

   The follow-up procedures at 2, 3, and 6 months after your medication visit will always take place remotely, by phone or video-conference.

RISKS, STRESS, OR DISCOMFORT

We will take care to collect all of the information we need to ensure that you can safely participate in this study before initiating any of these procedures. You will not be able to participate in this study if you have an unstable medical or neurological condition, or if your psychiatric condition is sufficiently concerning that the psychiatrists associated with our clinic think it would be unsafe or unwise for you to participate in this study.

Interruptions in existing treatments or delay in seeking other treatments
In order to participate in this study, you may have to change any treatments you are currently receiving for your symptoms. In particular, if you are taking any antidepressant medication, you will need to be tapered off that medication prior to entering the study, and you may experience worsening of symptoms during that period. In order to minimize this risk, you will be able to contact a study physician 24 hours a day should any problems arise through Day 28 after the medication session, and during business hours after that through the end of the study.

In addition, you will need to refrain from starting any new antidepressant medications that act on the serotonin system in the body during the entire study period, until you have completed the questionnaires and symptom interview that occur four weeks after the medication dosing session. The study physicians will make exceptions for worsening symptoms or emergencies. If you participate in this study, you will be off your pre-study medication for at least 10 weeks—4 weeks prior to entering the study, 2 weeks of screening and preparation sessions, and 4 weeks post-medication measurements, until you complete the Study Day 28 questionnaires. At that point if you are randomized to the psilocybin group, you will be able to resume your medications, if you and your provider agree that would be best. If you are randomized to the placebo group, you could either opt to have an open-label psilocybin session, which would take 1-3 additional weeks to complete, or opt to be followed, which would mean that you could resume your medications if you and your provider agree that would be best.
You should realize that if you are randomized to the placebo group and opt to receive open-label psilocybin following drug unblinding, you will be off your medication and without the possible benefit of active study drug for a slightly longer period of time (1-3 weeks) than participant randomized to the psilocybin group. We recognize that this longer time may represent an additional risk, so we will monitor your well-being closely with at least weekly contact during the time period from study enrollment to Day 28 post-psilocybin. The reason for randomization is to increase the scientific value of the data we collect from your experiences.
Your participation in the study will be terminated immediately if your condition significantly worsens, especially if you feel suicidal.

Safety Plan for Suicidality: During all study visits a Masters or Doctoral level clinician will assess your well-being – responses, intent, plan, etc. while administering the C-SSRS (Columbia Suicidality Severity Response Scale, which all clinicians have received training on) and if there is a serious concern they will either ask you to meet with or call the PI, or report to the clinic (if the study visit is being done remotely), or go to the nearest ER, or call 911. If necessary, we will also call your treating clinician and/or your emergency contact. As part of the consent, you are required to designate an emergency contact person and provide your treating clinician's contact information. We will coordinate with your treating clinician, in regard to local plan for such emergencies so our study team can follow this plan should an emergency situation arise. The study investigators will take steps to reduce and manage any physical or psychological changes that could be unpleasant or harmful.

Risks of screening visit and baseline questionnaires, and symptom interviews
The risks of screening include any stress or discomfort associated with a brief physical examination or answering questions that may be sensitive in the questionnaires or the symptom interview. You may find answering these questions to be inconvenient, uncomfortable, or upsetting. The symptom interviews may include some personal questions about previous experiences. You will be able to complete these activities in a private room, and you may decline

to answer any questions that make you uncomfortable. You can discuss any concerns with someone on the research staff, and you will have access to clinicians trained to address these issues. You may take short breaks if you need them.

Risks of having a blood draw

We will need to draw blood for routine laboratory testing. The baseline labs are necessary to review your current health prior to participation. The risks or side effects associated with taking blood from a vein are bruises, local irritation (swelling) with itching, slight bleeding, and inflammation. In rare cases, it may result in thrombosis (blood clots) or an infection. Insertion of the needle can cause localized pain or pain at the needle puncture site. Subjects may feel slightly weak or lightheaded, or faint. Occasionally, in rare cases, inserting the needle can result in injury to a nerve. We minimize this risk by having skilled nurses and phlebotomists do our blood drawing. In the very rare event of a puncture-site infection, the study staff will aid you in treating the site.

Risks of preparation sessions

The risks of the preparation sessions are that the study therapists may ask personal questions that evoke personal feelings from your past, or feelings that may still be present, and this may be uncomfortable or unpleasant. These sessions will take place in a private room, or over a secure video connection, and you may decline to answer any questions or stop the sessions and/or recordings at any time.

Risks of medication dosing sessions, including psilocybin

The psilocybin used in this study is manufactured at the Usona Institute, which provides researchers with pharmaceutical grade synthesized psilocybin. You will be given one tablet of either Psilocybin or the active placebo, niacin. The dose of psilocybin you will be receiving in this study is 25 mg.

Common acute side effects of psilocybin are almost all psychological, and include anxiety, changes in thought (experiencing thinking speeding up or slowing down), changes in motion perception, changes in time perception (time slowing down or speeding up), depersonalization (feeling as if one is "outside oneself"), derealization (feelingas if the world is unreal or as if one is "in a dream"), dizziness, fatigue, slowed heart rate, headache, impaired concentration, inattention, mood lability (rapid and sometimes profound changes in mood), nausea, nervousness, parasthesias (strange bodily sensations or feelings), perceptual alterations (general), altered time perception, alteration in visual perception (distortions, illusions and imagery seen with eyes open or closed), and unusual thought or feelings about the self or the world. Most of these effects are acute and last no longer than six hours. For the most part, people receiving psilocybin maintained insight concerning the nature and source of their experience. However, some participants occasionally exhibited reactions including paranoid ideation or temporarily lost insight into the experimental situation. In recent studies, these reactions have been managed with reassurance and breathing directed by the study therapist. However, if medication is required to treat any uncontrollable anxiety or agitation, the study physician may perform an assessment and prescribe a small dose of lorazepam, a benzodiazepine medication.

The physiological effects of psilocybin include pupillary dilation and detectable but moderate increases in blood pressure or heart rate. In other studies, changes in blood pressure and heart

rate have sometimes occurred at only at one point in time. These effects are transient and are generally gone approximately six hours after drug administration.

The most likely potential adverse effect of psilocybin is anxiety, which is usually handled by the study therapists. Uncommon but more serious side effects of psilocybin include panic, delusion, and cognitive impairments, which have mostly occurred with doses of psilocybin higher than used in this study. If these side effects occur, clinical evaluation will be given with the potential for medication to be given if needed.

A rare risk reported in anecdotal literature but not in a research study with psilocybin in the past 5 years is that a participant could have a brief psychotic reaction. If this were to happen, clinical evaluation and treatment will be given. Another rare risk is you may have visual disturbances that you first notice during the medication dosing day that reoccur at lower intensity long after the medication has left your body, including halos, distorted colors, or bright lights. This condition is called Hallucinogen Persisting Perception Disorder, and is not a sign or precursor of psychosis, but you should see your physician and contact Dr Back, the PI for this study, if you experience these symptoms.

All the acute side effects of psilocybin explained in this consent form are transient and generally gone approximately six hours after drug administration.

A subacute side effect of psilocybin that has been reported in the literature is mild insomnia for the first night or two after the medication dosing session. This side effect has been described as self-limiting. If needed you may take over the counter sleeping aids if this occurs. In the unusual case where insomnia persists, study staff can direct you to a clinician for further evaluation.

At the end of the medication dosing session, you must be medically cleared to be discharged, and you must be driven home, either by a driver arranged by you or by the site personnel, which could include a ride-sharing service or a taxi. You may return to work not earlier than 48 hours after the medication dosing session is over.

If you have a mental health emergency, we will involve hospital staff who will enact procedures to keep you safe.

Adverse events will be reviewed with subjects weekly from the time of preparation visit 1 through week 4 and repeated during the open-label study.

After administration of Psilocybin/placebo, participants will be checked regularly. A research team member will accompany the participants and be available at all times tocall for medical assistance if required. Procedures will be immediately stopped if you request to stop or exhibit any sign of significant distress. The study therapists will have immediate access to the PI or a designated physician to assess any problems, or to clear you for discharge from the research facility.

Study therapists are trained on the protocol and are in communication with the Principal Investigator, who is available to assess participants during the medication session. This study is being monitored by a Medical Monitor and the Principal Investigator, Dr. Back.

Both have the ability to stop this study at any time if it is deemed necessary.
Because this treatment is considered investigational and has not received FDA approval, there may be risks that we do not know about at this time.

Risks of receiving niacin (active placebo)
The single administration and dosage of niacin being used in this study, 250 mg, is often associated with mild, expected physiological side effects which is why it is used as an "active placebo". These acute side effects include flushing, tingling, itching, and redness of the face, arms, and chest. Other minor symptoms include upset stomach, intestinal gas, mild transient headache, and mild dizziness, which are transient and resolve on their own.

Pregnancy risks

WOMEN PLEASE NOTE: You should not participate in this study if you are pregnant or might become pregnant during the period of this study or are breast-feeding. If you are pre-menopausal, you will take a pregnancy test as part of the study tests (at screening and at the beginning of the drug session). If your test result is positive, you will not be included in this study. If your test result is negative, we will discuss with you the need to avoid becoming pregnant during this study and what precautions you plan to take. If you change your mind about becoming pregnant or your method of avoiding pregnancy, we will ask you to notify us immediately. You will be asked to take a urine pregnancy with your screening labs and immediately before drug administration.
Risks of integration sessions
The risks of the integration sessions are that the study therapists may ask questions that evoke uncomfortable or unpleasant memories from your medication dosing session or your past experiences prior to the medication dosing session. These sessions will take place in a private room, or over a secure video connection, and you may decline to answer any questions or stop the sessions or recordings at any time.

Risks of confidentiality and privacy
There are risks related to a breach in confidentiality. Some states require clinicians to report any mental health condition that may affect their performance to the state licensing board. If despite our efforts, a participant's identity as a study participant were to become known, their reputation could be damaged and possibly their employability could be affected. The same state requirement is rarely mandated for advance practice providers or nurses, but those clinicians could still face reputational damage if their participation in this study were made public. To mitigate this risk, we have an FDA Certificate of Confidentiality, we will try to use the most secure forms of communication exclusively, and all data will be entered using a study code rather than identifying information. We will follow high standards for ensuring confidentiality and use all known methods of data security handling to reduce risks to your confidentiality.

ALTERNATIVES TO TAKING PART IN THIS STUDY

If you choose not to part in this study, alternatives to treat symptoms of depression, burnout, and post-traumatic stress include psychotherapy and medication treatment with FDA approved

antidepressants. You would need to have an evaluation by a psychologist and/or a psychiatrist to determine the best options for you.

BENEFITS OF THE STUDY

You may experience reduced symptoms of burnout and depression as a result of psilocybin-assisted psychotherapy, or placebo-assisted psychotherapy, but because this is the first study of this therapy for this condition, it is unclear how effective psilocybin-assisted psychotherapy will be. You may not experience direct benefits from this study. Your participation may benefit others in the future. We hope that the knowledge gained from this study will lead to better treatments for physicians and nurses with this condition.

SOURCE OF FUNDING

The University of Washington is receiving the study drugs (psilocybin and niacin) from the Usona Institute, and funding to conduct the study from the Steven and Alexandra Cohen Foundation and the Rita and Alex Hillman Foundation.

CONFIDENTIALITY OF RESEARCH INFORMATION

All identifiable information that is obtained in connection with this research study will remain confidential as described for the study here. Information about the study visit, including information about your laboratory results, blood draws, and urine test will be stored as research records and will not be stored in a medical record. Your medical record will not identify you as a participant in this study. Your identifiable information and study records will be kept separate. The link between your identifiers and the research data will be destroyed after the records retention period required by state and/or federal law. Information about you will be kept in locked offices, on password-protected computers, or in secure clinic files on a University of Washington secure server, or in locked cabinets on a locked unit. This includes audio or video-recordings, as applicable. During the course of this study, it is possible that information about your health and safety will need to be shared with others to keep you safe. As a part of the safety plan for this study, you will designate an emergency contact person and provide your treating clinicians' contact information. We will coordinate with them about any local plan for an emergency.
If we learn that you intend to harm yourself or others, we must report that to the authorities.

The U.S. Food and Drug Administration (FDA) reserves the right to review study data that may contain identifying information.

The Usona Institute, a nonprofit research drug company that is providing the psilocybin, reserves the right to review study data that may contain identifying information.

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.

We have a Certificate of Confidentiality from the Food and Drug Administration (FDA). This helps us protect your privacy. The Certificate means that we do not have to give out

information, documents, or samples that could identify you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the institution(s) conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- individuals who want to conduct secondary research if allowed by federal regulations and according to your consent for future research use as described in this form;
- authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

USE OF INFORMATION AND SPECIMENS

Returning Results to You

You will have the opportunity to receive any results from research tests that are clinically relevant, which would include abnormal results of blood draws, or urine test.

Using Your Data in Future Research

The information that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information. If we do so, that information may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

OTHER INFORMATION

You may refuse to participate, and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. If you wish to withdraw, please contact the researcher listed on page 1 of this consent form. You may be withdrawn from the study if there is evidence of suicidal ideation and will be referred to appropriate psychiatric care. You may also be withdrawn at the beginning of the study, if after the baseline interview and questionnaires, it is determined your symptoms have improved between the screening visit and baseline.

All costs of study-related procedures will be billed to the research team. The study will pay for visits that require onsite procedures at HMC.

RESEARCH-RELATED INJURY

If you think you have a medical problem or illness related to this research, contact Anthony Back MD (206-619-4367) right away. He will treat you or refer you for treatment.

For a life-threatening problem, call 911 right away or seek help immediately. Contact Anthony Back MD (206-619-4367) when the medical emergency is over or as soon as you can.

If you are injured as a result of being in this study, necessary medical treatment will be offered at a UW Medicine facility.

The costs of the treatment may be billed to you or your health insurance just like other medical costs, or it may be covered by the UW's discretionary Human Subjects Assistance Program (HSAP), depending on a number of factors. The researcher may request HSAP coverage by following established procedures. If you wish to request HSAP coverage yourself, contact the researcher or the UW Human Subjects Division at hsdinfo@uw.edu or 206-543-0098. You may also call collect to the UW Human Subjects Division at 206-221-5940 if you do not otherwise have access to a telephone. Ask the researcher if you would like information about the limits and conditions of the HSAP. The UW does not normally provide any other form of compensation for injury. However, the law may allow you to seek payment for injury-related expenses if they are caused by malpractice or the fault of the researchers. You do not waive any right to seek payment by signing this consent form.

Printed name of study staff obtaining consent Signature Date

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940. I will receive a copy of this consent form.

Printed name of subject Signature of subject Date

Copies to: Researcher
Subject

Video - Audio Recording (option): We are requesting your permission to video/audio record some of your participation as part of this study. If you agree to the record, we will use these recordings of your study sessions for evaluating the quality of the therapists' work, and for improving future interventions. We would like to record the drug administration session in entirety. In addition, we would like your permission to keep these recordings for the purposes of research and our own team training purposes indefinitely. The recording is optional. You may choose to give permission for one or both uses of the recordings or you may decide not to participate in recording at all. Your decision will not affect your ability to remain in the study.

If you agree to participate, we will keep the recordings in our locked offices in locked file cabinets, accessible only by the research staff. To protect your confidentiality, we will date and then code the recordings with a study identification number (rather than your name) and session numbers.
These coded tapes will be kept along with the study records, either indefinitely (with your permission) or for no more than four years after the study ends.

I agree that video/audio recording may be taken of me as part of this study. The recordings may be used for (initial all that apply):

a. _____ any purpose relevant to research, medical evaluation, training
_____ (Initial)

b. _____ purposes of the study only
_____ (Initial)

c. _____ No recordings
_____ (Initial)