UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Comparison of the effects of oral psilocin, sublingual psilocin, and oral psilocybin in healthy adults

Research Project Director:	Joshua Woolley, M.D., Ph.D., Associate Professor, Department of Psychiatry and Behavioral Science 401 Parnassus Ave, Medical Student Education LP 146 Box MSE0984 San Francisco, CA 94143

Study Coordinator:	Michelle Matvey psilocybinstudies@ucsf.edu 415-221-4810 x24117

This is a clinical research study about the effects of psilocin versus psilocybin. The study team leader is Josh Woolley M.D., Ph.D.**,** from the UCSF Department of Psychiatry & Behavioral Sciences. A trained member of the study team will explain the study and discuss it with you. You can ask the team member questions at any time.

STUDY SUMMARY

Introduction: We are asking you to consider taking part in a research study being done by a team of doctors and scientists led by Dr. Josh Woolley, M.D., Ph.D., at UCSF.

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

Purpose of the study: The purpose of this study is to compare the effects of hallucinogenic mushrooms (psilocybin) to the effects of the substance that psilocybin is broken down into after ingestion. This substance is called psilocin. Psilocin is the active component of ingested psilocybin and is believed to be responsible for its effects, including alterations in perception, mood, consciousness, cognition, or behavior. Administration of psilocin may lead to more consistent beneficial effects and have fewer negative effects compared to psilocybin. We will evaluate the effects of psilocin using oral and under the tongue (sublingual) administration. We will test this hypothesis in healthy adults.

You are being asked to participate because you are a healthy volunteer.

Study Procedures: If you choose to be in this study, you will complete several screening procedures to confirm your eligibility. This process may take up to 30 days. After eligibility is confirmed, you will complete self-report questionnaires, behavioral assessments, blood draw, and neuroimaging measures then proceed through four drug dosing sessions, including

administration of 1) oral psilocin, 2) sublingual psilocin, 3) a second sublingual psilocin dose, and 4) oral Psilocybin. Each dosing session will be 8 hours.

You will undergo two preparatory informational sessions (1.5 hours each) before beginning drug dosing sessions, each of which will be followed by an integration session (1.5 hours). A preparatory session is where you meet with a facilitator (trained therapist) to prepare for the drug experience, by discussing expectations, practicing therapeutic touch, and listening to music. An integration session is where you meet with the same facilitator the morning after your drug experience to discuss how the session went for you and any side effects you experienced after or are currently experiencing. The day after each dosing session, you will return to the study site for a blood draw, questionnaire, and brief behavioral assessment. After completion of your final dosing and integration session, you will complete another neuroimaging session then follow-up phone call, including several questionnaires. Follow-up will occur 30 days after completion of each dosing session and before proceeding to the next dosing session. There will also be a brief online survey follow-up six months following your final dosing session. In total, you will be in the study for 12 months and visit the research site approximately 13 times.

Possible Risks: There are risks to taking part in a research study. The most likely risks of psilocin and/or psilocybin in the hours after you take it include:

- Nausea
- Blurred vision and dilated pupils
- Headache
- Mild to moderate increase in heart rate and blood pressure
- Anxiety and fear

We will tell you more about these risks and other risks of taking part in the study later in this consent form. There may also be risks that we do not know about.

Possible Benefits:
There will be no direct benefit to you from participating in this study. However, you may enjoy the feeling of contribution to knowledge in the health or social sciences field.

Your Other Options: You do not have to participate in this study. Your other choices may include:

- Taking part in another study.
- Not taking part in a study.

Feel free to talk to your doctor about your choices before agreeing to participate in this study.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

DETAILED STUDY INFORMATION

This part of the consent form gives you more detailed information about what the study involves.

Research studies include only people who choose to take part. Please take your time to make your decision about participating and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to take part in this study as a healthy volunteer.

Why is this study being done?

The purpose of this study is to compare the effects of ingested psilocybin to the substance that it is broken down into, called psilocin. Psilocin is the active substance of psilocybin, which goes into effect once psilocybin is digested. While oral psilocybin has been studied in many clinical trials, directly administered psilocin taken by mouth (orally) or under the tongue (sublingual) has not. The study team is investigating whether psilocin may lead to more consistent beneficial effects and have fewer negative effects compared to psilocybin. Psilocin is a controlled substance without an approved use.

Who pays for this study?

Filament Ventures, a for-profit psychedelic science organization, is funding this study. The study leader, Josh Woolley, MD, PhD, is a doctor and faculty member employed by UCSF. Dr. Woolley will not receive any compensation from Filament Ventures beyond his regular salary from UCSF and the San Francisco Medical Center (SFVA). The drugs being tested in this study, psilocin and psilocybin, will be provided by researchers at Filament Ventures. Filament Ventures has patents pending related to the formulations used in the current study. MRI scan costs are funded through philanthropic support for the Psychedelics Division of Neuroscape, UCSF.

Disclosure of financial or proprietary interests:

The investigators have the following disclosures related to this study:

Josh Woolley:

- Compensated consultant on the Scientific Advisory Board of Alvarius Pharmaceuticals.
- Previous paid consultant for Silo Pharma. Silo Pharma is a for-profit company interested in developing psilocybin as an available therapy. They fund clinical trials designed to study psilocybin's effects in different patient populations. Dr. Woolley consults on the development of new studies for Silo Pharma.
- Previous paid consultant for Filament Ventures. In the past, Dr. Woolley consulted on the development of new studies for Filament Ventures.

Robin Carhart-Harris: Compensated consultant for Entheon Biomedical and Beckley Psytech, for-profit pharmaceutical companies interested in bring psychedelic therapy to market.

How many people will take part in this study?

20 healthy volunteers will participate in this study.

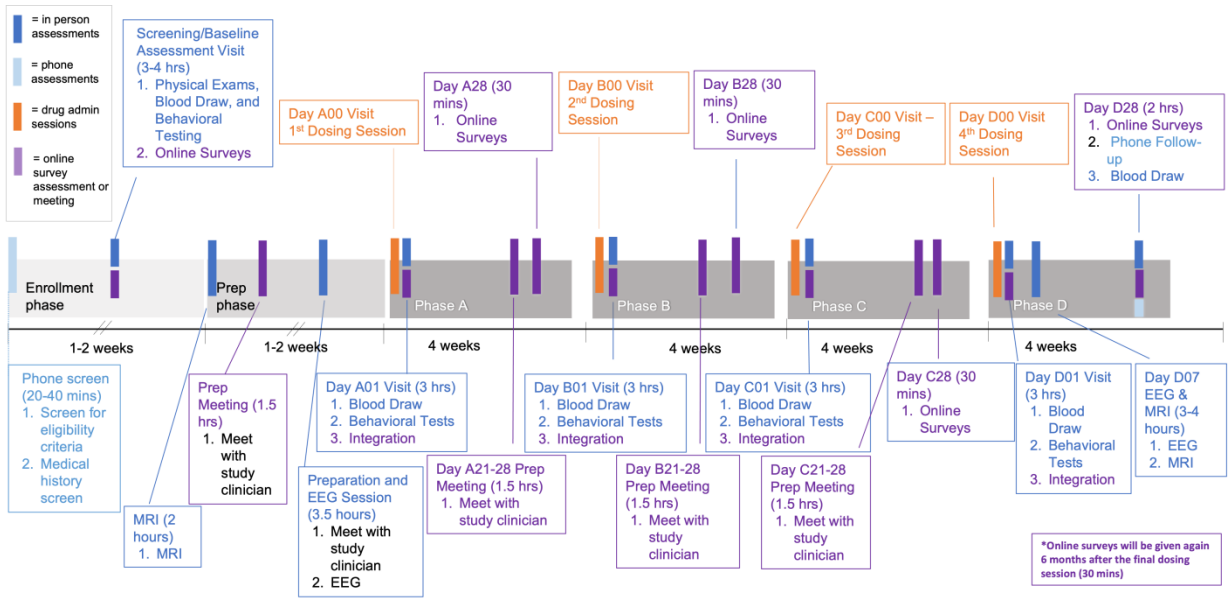
What will happen if I take part in this research study?

First, you will provide informed consent by reviewing this document with the study team and providing your signature. Consent will either be obtained remotely using DocuSign, or in-person

before you begin any study procedures, depending on the state of the COVID-19 pandemic. If remote, this will occur over a Zoom call. If in person, you will be consented in our research unit at Langley Porter Psychiatric Institute.
After consenting, you will complete a series of assessments in-person and by video to confirm your eligibility for this study. This may take 2-3 hours in total.
If you are eligible, you will meet with a facilitator one-on-one and complete two in-person, informational preparatory session, one online and another at our research unit located in UCSF Langley Porter Psychiatric Institute (LPPI; 401 Parnassus Ave, San Francisco, CA). Each meeting with the facilitator will last 1.5 hours.
After preparation, you will complete your first in-person dosing session at our research unit. For each dosing session, your dose will be assigned in a random order. Before your dosing session, you will be asked to provide the name and contact information for your designated support person, who will escort you home on the evening of your dosing session. This session will last approximately 8 hours. Your facilitator and an assistant will be present all day, and one of our study physicians will be available at all times.
The morning after your dosing session, you will complete an integration session with your facilitator, in person or by Zoom call, lasting 1-2 hours. The day after each dosing session, you will also return to the study site for a blood draw, questionnaire, and for a brief behavioral assessment. There will be a baseline neuroimaging visit 1-7 days prior to your first dosing session and your follow-up neuroimaging visit will be 1-7 days after your final dosing session, each lasting approximately 4 hours. For the duration of the COVID-19 pandemic, integration sessions will be conducted remotely over Zoom, unless an in-person session is necessary for your safety. As the pandemic recedes, sessions may be conducted in person. The study team will communicate with you about these changes and take into account your level of comfort with in-person activity. Integration sessions will be audio and video recorded. 4 weeks after your first dosing session, and before additional dosing, you will complete a follow-up survey by phone. You will complete this survey 4 weeks after every dosing session, and before moving onto additional dosing. This can be completed in-person or remotely and will take approximately 1 hour. You will also be asked to wear an Oura ring throughout the study period; this ring tracks basic physiological measures related to heart rate and body temperature. Study personnel will orient you on how to setup and use the ring.
A minimum of 4 weeks after your first dosing session, you will return to our research unit for a second dosing session (in-person, 8 hours), followed by a second integration session (remote or in-person, 1-2 hours). A minimum of 4 weeks later, you will return for your third dosing session (in-person, 8 hours), followed by a third integration session the day after (remote or in-person, 1-2 hours). Finally, at a minimum of 4 weeks after your third dosing session and upon PI's confirmation of safety and tolerability, you will return to our research unit for a fourth dosing session (in-person, 8 hours), followed by a final, fourth integration session the day after (remote or in-person, 1-2 hours). You will only complete a fourth dosing session if the PI determines it is safe to do so. 30 days after your last integration session, you'll be contacted by phone to check for any negative effects you might have noticed since your last study visit and complete several

questionnaires. This will take 20-30 minutes. There will also be a brief online survey follow-up six months following your final dosing session.

FLOWCHART OF STUDY PROCEDURES:



If you agree, the following procedures will occur:

Screening / Baseline Sessions (*Combination of remote and in-person activity):
You will need to complete the following exams, tests or procedures to confirm you are eligible for this study. These exams, tests or procedures are part of regular medical care and may be done even if you do not decide to join the study. If you have had some of them recently, you may not need to repeat them. This will be up to your study doctor. These can be broken into multiple visits if necessary.

Procedures that can be conducted remotely, such as clinical interviews, questionnaires, and medical history, will be performed remotely via Zoom during the COVID-19 pandemic. Certain procedures require in-person activity, including the physical exam, blood draws, and urine tests. As the pandemic recedes, all session procedures may be conducted entirely in-person. The study team will communicate with you about these changes.

- Questions about your general health and medical history, including your mental health
    - You will be asked sensitive questions, such as about past substance use, recent illnesses, and medications
- Physical exam and vital signs
- Electrocardiogram (ECG) where stickers will be placed on your body to detect the electric activity in your heart

- Blood draw where a needle will be inserted into a vein in your arm. A total of about 8 tablespoons of blood will be drawn for tests.
- Urine tests, including a urine drug screen for recent drug use and pregnancy test (if you can become pregnant).
    - The following substances will be tested in the urine drug screen: amphetamines, benzodiazepines, cocaine, cannabis, MDMA, and opioids (including methadone and buprenorphine)
- You will be asked to provide the name and contact information for your designated support person who will take you home after your dosing session.
- You will be asked to complete a series of simple behavioral tests on an iPad.
- Study staff will obtain your mailing address and mail you an Oura ring sizing kit so that the participant can ascertain which size ring they will need for the study.

Before the first psilocybin session:

If the exams, tests and procedures show that you can continue to be in the study and you choose to take part, then you will complete the following in-person / video sessions and procedures:

Baseline MRI session

- Magnetic resonance imaging (MRI) measures will be collected in-person. MRI will be collected in the Neurosciences Clinical Research Unit (suite 130) at the Sandler Neuroscience Center. MRI uses noninvasive magnetic imaging to reveal the structure and activity of the brain.

Preparation and baseline EEG session

- One preparation session with your facilitator. This will be in person. We will familiarize you with what to expect during your psilocybin session including the physical space where you will take psilocybin.
- Electroencephalography (EEG) will be collected in the dosing room at Langley Porter Psychiatric Institute (LPA310). EEG measures the electrical activity of the brain while doing certain tasks. We can do this by measuring the very small amount of electrical activity produced by your brain that is normally present on the surface of your scalp.

First dosing session (*In-person required):

- You will arrive at our research unit around 8:00 am.
- Before taking psilocybin and/or psilocin, study staff will put your belongings (e.g. phone, wallet, keys) in a secure location. This is to ensure your safety while you are on psilocybin. Items will be returned to you once the effects of psilocybin have worn off, after about 6 hours.
- You will be asked to complete urine tests, including a urine drug screen for recent drug use and pregnancy test (if you can become pregnant), and a breathalyzer test.
- During this visit, you will be randomly assigned to receive oral psilocin 17.5 mg, sublingual psilocin 2.18 mg, or oral psilocybin 25 mg.
- You will take both an oral capsule and a tablet under your tongue. One of these substances will be placebo (an inactive substance), and the other will be active drug. The purpose of this procedure is so that neither you nor the research team knows which substance is the active drug.
- While you are on study drug, your facilitator will monitor your heart, blood pressure, temperature, and how you are feeling. EEG measures will also be collected during the first hour and a half of each dosing session. A study physician will be available at all times.
- After drug effects have worn off, you will complete several self-report questionnaires.
- Following completion of questionnaires, study staff will confirm that you are ready to safely leave the research unit.
- Your designated support person will meet you at our research unit and escort you home. This is for your safety, because you should avoid operating heavy machinery, driving home, etc.
- The following morning, the study team will check in with you about any side effects you might have experienced.

First integration session (*Remote for the duration of the COVID-19 pandemic; can be in-person if the study team determines this is necessary for your safety. As the pandemic recedes, this visit may be conducted in-person. The study team will communicate with you about these changes):

- The morning after your first dosing session, you will complete your first integration session with the study facilitator.
- You will be asked to report any dosing-related side effects.
- Next, you will be asked and encouraged to share about their dosing session experience with the facilitator.
- All integration sessions will be audio and video recorded to ensure treatment fidelity and for subsequent behavioral analyses.

- On this day, you will be asked to return to the study site to complete a series of behavioral tests on an iPad, complete a questionnaire and have another blood draw where about 3 tablespoons will be taken.

28 Day Post- First Dose Follow-up Surveys (*Remote):

- One month after your first dosing session, and before moving onto additional dosing sessions, you will complete several questionnaires.
- Surveys can be completed in-person or remotely.

Second dosing session (*In-person required):

- At a minimum of 4 weeks following your first dosing session, you will return to the UCSF facility for a second dosing session. The procedure will be the same as in the first dosing session.
- You will be randomly assigned to receive oral psilocin 17.5 mg, sublingual psilocin 2.18 mg, or oral psilocybin 25 mg.
- You will take both an oral capsule and a tablet under your tongue. One of these substances will be placebo (an inactive substance), and the other will be active drug. The purpose of this procedure is so that neither you nor the research team knows which substance is the active drug.
- Your designated support person will meet you at our research unit and escort you home. This is for your safety, because you should avoid operating heavy machinery, driving home, etc.

Second integration session (*Remote for the duration of the COVID-19 pandemic; can be in-person if the study team determines this is necessary for your safety. As the pandemic recedes, this visit may be conducted in-person. The study team will communicate with you about these changes):

- The morning after the second dosing session, you will complete the second integration session with the study facilitator. The procedure will be the same as in the first integration session.
- Session will be audio and video recorded.
- On this day, you will be asked to return to the study site to complete a series of behavioral tests on an iPad, complete a questionnaire, and have another blood draw where about 3 tablespoons of blood will be taken.

28 Day Post-Second Dose Follow-up Surveys (*Remote):

- One month after your second dosing session, and before moving onto additional dosing sessions, you will complete several questionnaires.
- Surveys can be completed in-person or remotely.

Third dosing session (*In-person required):

- At a minimum of 4 weeks following your second dosing session, you will return to the UCSF facility for a third dosing session. The procedure will be the same as in the first dosing session.
- You will be randomly assigned to receive oral psilocin 17.5 mg, sublingual psilocin 2.18 mg, or oral psilocybin 25 mg.
- You will take both an oral capsule and a tablet under your tongue. One of these substances will be placebo (an inactive substance), and the other will be active drug. The purpose of this procedure is so that neither you nor the research team knows which substance is the active drug.
- Your designated support person will meet you at our research unit and escort you home. This is for your safety, because you should avoid operating heavy machinery, driving home, etc.

Third integration session (*Remote for the duration of the COVID-19 pandemic; can be in-person if the study team determines this is necessary for your safety. As the pandemic recedes, this visit may be conducted in-person. The study team will communicate with you about these changes):

- The morning after the third dosing session, you will complete the third integration session with the study facilitator. The procedure will be the same as in the first integration session.
- Session will be audio and video recorded.
- On this day, you will be asked to return to the study site to complete a series of behavioral tests on an iPad, complete a questionnaire, and have another blood draw where about 3mL of blood will be taken.

28 Day Post-Third Dose Follow-up Surveys (*Remote):

- One month after your third dosing session, and before moving onto your final dosing session, you will complete several questionnaires.
- Surveys can be completed in-person or remotely.

Fourth dosing session (*In-person required):

- At a minimum of 4 weeks following your third dosing session, you may return to the UCSF facility for your fourth and final dosing session. The procedure will be the same as in the first dosing session.
- Depending on the PI's assessment of your tolerability of 2.18mg sublingual psilocin, you may receive a second sublingual psilocin dose of 4.36mg.
    - If the PI determines it is unsafe to proceed with a 4.36mg dose, you will not complete a fourth dosing session.
- You will take both an oral capsule and a tablet under your tongue. One of these substances will be placebo (an inactive substance), and the other will be active drug. The purpose of this procedure is so that neither you nor the research team knows which substance is the active drug.
- Your designated support person will meet you at our research unit and escort you home. This is for your safety, because you should avoid operating heavy machinery, driving home, etc.

Fourth integration session (*Remote for the duration of the COVID-19 pandemic; can be in-person if the study team determines this is necessary for your safety. As the pandemic recedes, this visit may be conducted in-person. The study team will communicate with you about these changes):

- The morning after your fourth dosing session, you will complete your final integration session with the study facilitator. The procedure will be the same as in the first integration session.
- Session will be audio and video recorded.
- On this day, you will be asked to return to the study site to complete a series of behavioral tests on an iPad, complete a questionnaire, and have another blood draw where about 3mL of blood will be taken.

1 week Follow-up Neuroimaging Visit

- After your fourth and final dosing session, there will be a follow-up neuroimaging visit. EEG will again be collected in the dosing room at Langley Porter Psychiatric Institute

(LPA310) and MRI will be collected in the Neurosciences Clinical Research Unit (suite 130) at the Sandler Neuroscience Center.

28 Day Post- Final Dose Follow-up Surveys (*Remote and In-Person):

- One month after your final dosing session, you will be contacted by phone to check for any negative effects you may have noticed since your last study visit.
- You will complete several questionnaires remotely.
- You will return to the study site for a final blood draw where about 3mL of blood will be taken.

6 Month Follow-Up (*Remote)

- You will be asked to complete online self-report surveys

Audio-video recording

We will be audio and video recording you during this study. We will use these recordings to make sure our study staff meet quality requirements, and to perform behavioral analyses. We will protect the confidentiality of all recordings by limiting access to them. Only study team members and researchers who are analyzing data from this study will be able to access the recordings. The recordings will be stored on encrypted computer drives that are kept in locked rooms at UCSF. They will be kept permanently and securely by the UCSF Department of Psychiatry and Behavioral Sciences. Audio and video recording is required for participation; if you do not want to be recorded then you will not be able to participate.

We may share recordings with researchers at our university/other universities who are collaborating with us, or companies that are helping with data analysis (for example, we may have a HIPAA-compliant, secure service transcribe audio recordings to text). Any data transferred outside of UCSF will involve a legally binding, signed agreement to make sure that collaborators use appropriate procedures to protect your privacy. We will not share your name or any additional personal information. When possible, we will only share de-identified data. Any data that we share with collaborators will be destroyed when we finish the analysis. Your data, including audiovisual recordings, will never be accessible to the general public.

Specimen Storage for Future Research Including Genetic Research

Your data and specimens will be stored indefinitely by the study team and may be reexamined if new ideas emerge over time. Stored samples may be shared with researchers both within and outside of UCSF. Data stored will consist of questionnaire and task responses, results of bodily response and brain imaging tests, and recordings of your clinical interview. Specimens stored will consist of blood samples. There is a risk of loss of privacy if data or specimen security is compromised during storage. To minimize this risk, we will ensure that your data is stored on a secure server and identified only by a unique study ID number on the computer in the laboratory. Your specimens will also be labeled only by a unique participant ID and not with your name or other identifying details. Specimens will be stored in locked freezers accessible only to trained personnel.

Genetic information (also known as genotype data) and the medical record data (also known as phenotype data) may be shared broadly in a coded form for future genetic research or analysis. We may give certain medical information about you (for example, diagnosis, blood pressure, age if less than 85) to other scientists or companies not at UCSF, including to a government health research database, but we will not give them your name, address, phone number, or any other identifiable information. Research results from these studies will not be returned to you. Donating data may involve a loss of privacy, but information about you will be handled as confidentially as possible. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security. Genetic information that results from this study does not have medical or treatment importance at this time. However, there is a risk that information about taking part in a genetic study may influence insurance companies and/or employers regarding your health. Taking part in a genetic study may also have a negative impact or unintended consequences on family or other relationships. It is possible that future research could one day help people of the same race, ethnicity, or sex as you. However, it is also possible through these kinds of studies that genetic traits might come to be associated with your group. In some cases, this could reinforce harmful stereotypes.

There will be no direct benefit to you from allowing your data to be kept and used for future research. However, we hope we will learn something that will contribute to the advancement of science and understanding of health and disease. If the data or any new products, tests or discoveries that result from this research have potential commercial value, you will not share in any financial benefits. If you decide later that you do not want your information to be used for future research, you can notify the investigator in writing, and any remaining data will be destroyed. However, we cannot retract any data that has been shared with other researchers.

How long will I be in the study?

You will be in the study for up to 12 months. Expected length of participation is 12 months, or approximately 60 hours. This includes:

- Screening/ Baseline: Remote and/or In-Person (3-5 hours; can take up to 30 days)
- Preparatory Sessions (four visits total): Remote and/or In-Person (1.5 hours each)
- Dosing Sessions (four visits total): In-Person (8-10hours each)
- Integration Visit (four visits total): In-Person and/or Remote (4 hours each)
- 28 Day Post-Dose Visit (four visits total): In-Person and/or Remote (2 hours each)
- 6 Month Post Final Dose : Remote (30 minutes)
- MRI and EEG Visit (two visits total): In-Person (1.5-2 hours for each MRI and EEG)

Can I stop being in the study?

Yes. You can decide to stop at any time. If you are thinking about stopping or decide to stop, the study team leader will work with you to make sure that you are able to stop your participation safely.

Important Note: While you are under the effects of psilocybin and/or psilocin (which last about 5-6 hours), you will not be able to stop being in the study. If you tell a study doctor, your

facilitators, or another study staff member that you wish to stop being in the study, you will still have to stay at the research unit until the drug effects have worn off and it is safe for you to leave. This is because we must prioritize your safety while you are under the effects of psilocybin.

It is important to tell a study doctor if you are thinking about stopping so any risks from the psilocybin dose can be monitored.

One of the study doctors may stop you from taking part in this study at any time if they believe it is in your best interest, if you are not able to follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

You may have side effects while on the study. The study staff will monitor you for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects from psilocybin and/or psilocin go away soon after the session ends. In some cases, side effects can be serious, long lasting, or may never go away.

You should talk to a study doctor about any side effects you experience while taking part in the study.

Please note, there are some unknown side effects of sublingual administration, as there are no previously published studies on this method.

Medical risks and side effects related to taking psilocybin and/or psilocin include those which are:

Likely

- Temporary elevations in heart rate and/or blood pressure during the drug session
- Temporary anxiety or confusion during the drug session
- Headache soon after the drug session

Less Likely

- Nausea and/or vomiting during the drug session
- Temporary slower movements or difficulty coordinating movements during the drug session
- Temporary fatigue or difficulty sleeping the night after the drug session

Rare but serious

- Elevated blood pressure during the drug session that require medications to bring back to normal

- Elevated body temperature, muscle stiffness, and confusion during the drug session due to serotonin syndrome (too much serotonin in the body)
- Anxiety, mania (elevated arousal, affect, and energy level), or psychotic symptoms (like hallucinations or paranoia) soon after the drug session that last for >24 hours after the drug wears off
- Anxiety, mania or psychotic symptoms during or after the drug session that are severe and require medications to maintain your safety and/or the safety of study staff
- Unknown Risks: It is important to note that psilocybin and/or psilocin may have side effects that no one knows about yet. The study leaders will let you know if they learn anything that might make you change your mind about participating in the study.

Other risks of participating in this study

- Blood Drawing (Venipuncture): Drawing blood may cause temporary discomfort from the needle stick, bruising, infection, and fainting.
- Reproductive risks: You should not become pregnant or have a baby while on this study because the drugs or procedures in this study may affect a fetus. In addition, you should not breastfeed a baby after taking psilocybin, because we do not know how psilocybin could affect the baby. If you can become pregnant, you must agree to use reliable birth control while you are participating in this study. Check with your study doctor about what kind of birth control methods to use and how long to use them. If you can become pregnant, we will have you complete a pregnancy test before you enter this study and before each psilocybin session. These tests must show that you are not pregnant in order for you to continue in the study. If you think you may be pregnant at any time during the study, tell your study staff right away
- Risk of loss of employment or violation of standard medical care practice: Please note that standard illicit drug testing does not typically test for psilocybin or psilocin. If you are tested for psilocybin or psilocin it may show on a urine / blood toxicology test for 1-3 days and hair toxicology tests for 90 days after ingestion.
- Loss of privacy
- MRI Scans: There are no known risks associated with MRI scans. However, MRI cannot be carried out in people with metal implants, therefore, if you have a metal implant such as a pacemaker. you will not be able to take part in this study. It should be noted his research does not involve MRI medical diagnosis. You should not regard these research scans as a medical screening study. It is important that you realize that these scans will not provide any information that may help in the diagnosis of any medical condition. However, if anything untoward comes to light during scanning, you will be informed. If you do have any health concerns, you should contact a qualified medical practitioner in the normal way.
- *EEG Recordings:* The EEG to be used in this study measures brain electrical activity passively. Thereis a potential for developing a headache from participating in the EEG evaluation, due to wearing the cap on your head. This headache is related to the tightness of the cap and is not related to the measurement of the surface electrical activity on your scalp. You will also have a gel in your hair after the procedure, which will wash out, but will affect your appearance until the gel is removed. Additionally, some participants find the setup procedures to be uncomfortable, as the scalp or skin may feel irritated from the gel. There is also a small possibility that a skin infection may develop. This risk is minimized by using

disposable supplies to scrub the scalp, and by carefully cleaning and disinfecting the sensors after each use. The occurrence of irritation or infection is very rate.

- Questions about sensitive issues (such as alcohol use, illegal drug use, and your mood): questions could make you feel uncomfortable and lead to feelings such as anxiety, distress, sadness, or embarrassment.
- Specimen Storage for Future Research: There is a risk of loss of privacy if data or specimen security is compromised during storage. To minimize this risk we will ensure that your data is stored on a secure server and identified only by a unique study ID number on the computer in the laboratory. Your specimens will also be labeled only by a unique participant ID and not with your name or other identifying details. Specimens will be stored in locked freezers accessible only to trained personnel.
- Future Genetic Research or Analysis: Donating data may involve a loss of privacy, but information about you will be handled as confidentially as possible. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security. Genetic information that results from this study does not have medical or treatment importance at this time. However, there is a risk that information about taking part in a genetic study may influence insurance companies and/or employers regarding your health. Taking part in a genetic study may also have a negative impact or unintended consequences on family or other relationships. It is possible that future research could one day help people of the same race, ethnicity, or sex as you. However, it is also possible through these kinds of studies that genetic traits might come to be associated with your group. In some cases, this could reinforce harmful stereotypes.
- For more information about risks and side effects, please ask the study leaders

Are there benefits to taking part in the study?

There will be no direct benefit to you from participating in this study. However, the information that you provide may help health professionals better understand/learn more about psilocybin and/or psilocin therapy as a treatment for future patients.

What other choices do I have if I do not take part in this study?

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

How will my information be used?

Researchers will use your information to conduct this study. Once the study is done using your information, we may share them with other researchers so they can use them for other studies in the future. When possible, we will only share de-identified data sets. Your data, including audio and video recordings, will never be accessible to the general public. We will not ask you for additional permission to share this de-identified information.

In instances where de-identification of data is not possible (e.g. audio and video recordings), transfers outside of UCSF will involve a legally binding, signed agreement to make sure that collaborators use appropriate procedures to protect your privacy. We will not share your name or any additional personal information. Any data that we share with collaborators will be destroyed when we finish the analysis. Your personal information will never be accessible to the general public.

Research results: There may be times when researchers using your information may learn new information. If this information might impact your health, medical care, and/or personal, this information may be shared with you. If this information is not relevant to your wellbeing, safety, or medical care, the information may not be disclosed.

Will information about me be kept private?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records will be collected and used for this study. If you do not have a UCSF medical record, we will create one for you. Your signed consent form and some of your research tests will be added to your UCSF medical record. Therefore, people involved with your future care and insurance may become aware of your participation and of any information added to your medical record as a result of your participation (e.g., blood draw, lab reports, etc.). Study tests that are performed by research labs, and information gathered directly from you by the researchers will be part of your research records but will not be added to your medical record. Your personal information may be given out if required by law.

Safety concerns may also lead to a loss of privacy. The study team will need to break confidentiality for safety purposes, in case of threat of harm to self or others. Specifically, if the study staff are concerned that you are at risk of harming yourself/suicidal, a study doctor will evaluate you as soon as possible. You may need to stop participating in the study and be hospitalized.

If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Filament Ventures
- University of California
- Food and Drug Administration (FDA)
- Research Advisory Panel of California

Certificate of Confidentiality

This study is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any legal action or suit unless you give approval. They also cannot provide your information, documents, or samples as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things about the Certificate of Confidentiality that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop YOU from willingly releasing information about your involvement in this research. It also does not prevent YOU from having access to your own information.

Are there any costs to me for taking part in this study?

No. The sponsor has agreed to pay for all items associated with this research study; you or your insurer will not be billed. The sponsor will provide study medications and pay for all of the assessments at no cost to you.

Will I be paid for taking part in this study?

In return for your time, effort and travel expenses, you will be paid for completing all parts of this study. We will provide compensation for the Screening/Baseline session (up to 3 hours), Phone Surveys (up to 1 hour), EEG (up to 4 hours), MRI (up to 4 hours), behavioral testing (up to 5 hours) at a rate of $20/hr. You may also receive up to a total of $50 for the entire study for travel and parking for in-person appointments. In total, you can earn up to $390 for participating, which will be paid by check.

What happens if I am injured because I took part in this study?

It is important that you tell the study leader, Dr. Joshua Woolley, if you feel that you have been injured because of taking part in this study. You can tell them in person, call at 415 221-4810 x24117, or email PsilocybinStudies@ucsf.edu

Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California or the study sponsor (Filament Ventures), depending on a number of factors. The University of California and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you can call the office of the Institutional Review Board at 415-476-1814.

What are my rights if I take part in this study?

You can choose either to take part or not to take part in the study. If you decide to take part in this study, you can leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care in any way. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to the study leader about any questions, concerns, or complaints you have about this study. You can reach Dr. Joshua Woolley at 415-221-4810 x24117 or by emailing PsilocybinStudies@ucsf.edu

If you wish to ask questions about the study or your rights as a research participant to someone other than the study leaders or if you wish to voice any problems or concerns you may have about the study, please call the office of the Institutional Review Board at 415-476-1814.

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. Law. This Web site will not include any 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.

CONSENT COMPREHENSION QUESTIONS

1. Participation in this study is voluntary and I may withdraw at any time.	T or F
2. I will complete a series of interviews and questionnaires in order to determine my eligibility.	T or F

3. I will complete four drug dosing sessions, each followed by an integration session.	T or F
4. The purpose of this study is to compare the effects of psilocybin to psilocin.	T or F
5. I can drop out of the study at any time, but it is recommended that I first consult with the study doctor to make sure it is safe.	T or F
6. Possible side effects of psilocybin and/or psilocin include anxiety, nausea, and headache.	T or F
7. How many times will you receive study drug?	_____

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CONSENT

You have been given a copy of this consent form to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

You have read this information, which is printed in English. Please sign below to confirm this is a language that you read and understand.

_____ _____

Date Participant's Signature for Language Verification

If you wish to participate in this study, you should sign below.

_____ _____

Date Participant's Signature for Consent

_____ _____

Date Person Obtaining Consent

OPTIONAL CONSENT ITEMS
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

Please read each sentence below and think about your choice. If you agree with any of the statements below, sign and put today's date.

If you have any questions, please ask the researchers, talk to your doctor, or call our research review board at (415) 476-1814. No matter what you decide to do, it will not affect your care or participation in this study.

Someone may contact me in the future to see if I am interested in other research studies.

_____ _____

Date Participant's Signature for Consent