INFORMED CONSENT FORM
AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**University of Minnesota / "Visual Surround Suppression and Perceptual Expectation under Psilocybin"**
Protocol Number:	**28235**
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Supported By: This research is supported by the Department of Psychiatry and Behavioral Sciences and Institute for Health Informatics funding, as well as donations made to the Psychedelic Assisted Therapy (PATH) fund through the University of Minnesota Foundation, and the Young Investigator Program from the Heffter Research Institute.

Financial Interest Disclosure: The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study:

- Dr. Jessica Nielson is the Executive Director of the Psychedelic Society of Minnesota, a 501(c)(3) non-profit organization focused on building community and providing education and harm reduction content about psychedelics. She is also owner of Psychonauts of Minnesota, LLC, a for-profit organization aimed at creating educational and harm reduction content about psychedelics.
- Dr. Ranji Varghese is a co-owner of the Institute for Integrative Therapies, a Mental Health Clinic that offers ketamine assisted psychotherapy.

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?

Doctors and investigators are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Study investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you have identified yourself as being healthy, between 25 to 65 years old, have taken psilocybin or "magic mushrooms", and you and your immediate family members have no current or past history of major mental illness.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

During the COVID-19 pandemic, some research appointments may be held remotely using a video teleconferencing software called Zoom or through a phone call.

Why is this research being done?

Psilocybin is the perception-altering drug found in 'magic mushrooms' and we want to learn more about visual perception in people taking psilocybin and how these relate to brain functions.

Psilocybin is not approved by the U.S. Food and Drug Administration (FDA) for any use at this time, however, it is being studied for its use for depression. It is also a drug that has been abused (people sometimes take it to get "high").

How long will the research last?

We expect that you will be in this research study for 12 weeks over the course of 7 different visits.

What will I need to do to participate?

You will be given an investigational study drug during 2 visits and asked to come in for a total of 7 study visits. During the visits you will have a physical exam (including height and weight), may be asked to take a pregnancy test, take a breathalyzer, give a total of 7 blood samples, fill out questionnaires (including questions that will ask about how you feel), 7 MRI's, and 4 EEG's. We will be audio and video recording you during some of your visits. You will also be required to refrain from using recreational drugs while enrolled in the study, including, but not limited to, hallucinogens, ketamine, and marijuana.

To safeguard against the spread of COVID-19, we will adopt current institutional guidelines regarding COVID safety requirements.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way that being in this study could be bad for me?

There is a slight risk you may feel uncomfortable or upset answering some sensitive questions asked in the questionnaires or forms. These questions are important for the study, but you can also skip any questions you feel uncomfortable or upset answering. Please make sure that you tell the study staff if you feel uncomfortable or upset while answering questions or completing tasks. You can choose to stop participating at any time.

There are risks associated with taking the study drug, and with some of the study procedures.

More detailed information about the risks of this study can be found under ***"What are the risks of this study? Is there any way being in this study could be bad for me? (Detailed Risks)" and in the "What happens to the information collected for the research?" section***

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research.

What happens if I do not want to be in this research?

There are no known alternatives, other than deciding not to participate in this research study.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

We expect about 46 people here will be in this research study.

What happens if I say "*Yes, I want to be in this research*"?

One group of participants will be given the psilocybin 25mg dose first, then the placebo and another group will receive the placebo dose first then the psilocybin 25mg dose.

The order in which you receive the experimental study treatment will be chosen by chance, like flipping a coin. Neither you nor the study investigator will choose which order the experimental study treatment is given to you. You will have an equal chance of being assigned to either group.

Neither you nor the study investigator will know which study treatment group you will be placed in.

Visit 1 Consent and Baseline:

Consent and Baseline visit will be conducted over 1 week and will last 8-10 hours total.

- You will be asked to sign and date this consent form if you would like to participate.
- You will be asked to answer some questions from the study team about your age, gender, race, medical history and medications (past and present).
- You will have a physical exam (including height/weight, pulse, and blood pressure). You will need to come in for an additional blood pressure check (within a week of this visit). If your blood pressure reading average is 140/90mmHg or higher you won't be able to participate in this

study.

- You will have an electrocardiogram (ECG) to check for any abnormal heart rhythms. If your QTc is longer than 450 milliseconds, you won't be able to participate in this study.
- You will have a blood draw (about 8.5 ml of blood, a little over 2 teaspoons) for health screening and sample storage at baseline.
- You will have a urine pregnancy test, if you are of childbearing potential.
- You will be asked to complete questionnaires. Some of these questions will be sensitive in nature and may make some people uncomfortable. For example, they will ask about trauma you experience, thoughts of self-harm or suicide, and drug and alcohol use.
- You will fill out an MRI safety form.
- You will have a 3T MRI scan. The MRI visit should last approximately 120 minutes. An MRI is a way to take pictures of the brain.
- An electroencephalogram (EEG) will be used to record the electrical activity in your brain. An EEG is where a small metal disc with thin wires are placed on the scalp, and then signals are sent to a computer to record the results.

Visits 2 and 4 (weeks 2 and 4) Dosing Sessions :
Visits 2 and 4 each will be conducted over 5 separate days, with some overlap between baseline testing from visit 1.

Preparation Days: You will be asked to meet with the dosing session monitoring team over 4 separate days for 2 hour visits, which will be held mostly on Zoom, and once in the dosing room to prepare for the dosing session. The first set of preparatory sessions will take 8 hours prior to the first dosing session. The second preparatory session will be a single session for 1 hour prior to the second dosing session

Dosing Day: Visits will take about 8 hours each.

- You will be asked to answer some questions about any substance use since the last visit.
- You will be asked to complete questionnaires. Some of these questions will be sensitive in nature and may make some people uncomfortable. For example, they will ask about trauma you experience, thoughts of self-harm or suicide, and drug and alcohol use.
- You will have a physical exam (including height/weight, pulse, and blood pressure).
- You will be asked to take a breathalyzer to test if alcohol is present in your system.
- You will have a urine pregnancy test, if you are of childbearing potential.
- You will be assigned to one of the study treatment groups and start receiving the study drug at this visit. It is important that you tell the study team if you start feeling uncomfortable anytime during the study treatment.
- An electroencephalogram (EEG) will be used to record the electrical activity in your brain. This will be done once during the visit and you will also complete visual behavioral tasks on a computer by looking at a simple pictures and make decisions based off of those pictures.
- You will have an electrocardiogram (ECG) to check for any abnormal heart rhythms before being discharged. An ECG is an exam that records electrical impulses of your heart; patches are placed on the outside of your chest. If your QTc is longer than 450 milliseconds, you will need to be evaluated further and possibly admitted to the hospital, and you won't be able to participate further in this study.
- You will not be able to drive yourself home after this visit; you will need to arrange someone to pick you up after this scheduled visit.

Study Visits 3 and 5 (weeks 3 and 5) Follow-up:
Visits 3 and 5 each will be conducted over 3 separate days, totaling 10 hours for each visit.

These visits will last about 3-4 hours for each day and the following will be completed during those 3 days:

- You will meet with the study team for a debrief (or integration) session the day after each dosing session.
- The study team will review your health status and medication usage since the previous visit (past and present).
- You will have a physical exam (including height/weight, pulse, and blood pressure)
- You will have a blood draw (about 8.5 ml of blood, a little over 2 teaspoons) for health screening and sample storage
- You will be asked to complete questionnaires. Some of these questions will be sensitive in nature and may make some people uncomfortable. For example, they will ask about trauma you experience, thoughts of self-harm or suicide, and drug and alcohol use.
- You will have a urine pregnancy test, if you are of childbearing potential prior to each MRI.
- You will fill out an MRI safety form.
- You will have a 3T MRI scan. The MRI visit should last approximately 120 minutes.
- Digital Journal: Within 1 week after these visits, you will be asked to write for 30-60 minutes to describe your experience. You will receive this journal via email or text.

Study Visit 6 (week 6) Follow-up:
This visit will last about 5 hours.

- The study team will review your health status and medication usage since the previous visit (past and present).
- You will have a physical exam (including height/weight, pulse, and blood pressure).
- You will be asked to complete questionnaires. Some of these questions will be sensitive in nature and may make some people uncomfortable. For example, they will ask about trauma you experience, thoughts of self-harm or suicide, and drug and alcohol use.
- An electroencephalogram (EEG) will be used to record the electrical activity in your brain, and you will also complete visual behavioral tasks on a computer by looking at a simple pictures and make decisions based off of those pictures.

Study Visit 7 (week 12) Follow-up/ Last-Visit:
This visit will last about 5 hours.

- The study team will review your health status and medication usage since the previous visit (past and present).
- You will have a physical exam (including height/weight, pulse, and blood pressure)
- You will be asked to complete questionnaires. Some of these questions will be sensitive in nature and may make some people uncomfortable. For example, they will ask about trauma you experience, thoughts of self-harm or suicide, and drug and alcohol use.
- Digital Journal: You will be asked to write for 30-60 minutes to describe your experience in the study. You will receive this journal via email or text.

If you are having suicidal thoughts call the principle investigator at the telephone number listed on the first page of this form. If you feel in crisis, you can call 911 and/or a Nationwide Suicide Hotline that is answered 24 hours a day with a skilled, trained counselor. One example is the National Suicide

Prevention Lifeline at 1-800-273-TALK (8255).

COVID-19 Infection Risk: Just like any in-person interaction, attending in-person research appointments comes with a risk of becoming infected with COVID-19. Some procedures will require close contact between you and our study staff. To lower the risk of spreading COVID-19, we will follow current guidelines set forth by the University of Minnesota and MHealth/Fairview regarding best practices for reducing the spread of COVID-19.

If you test positive for or experience symptoms of COVID-19 during the course of the study, please notify study staff immediately so proper precautions can be taken to reduce spread. If we learn that you may have been exposed to COVID-19 during a study visit, we will contact you as soon as possible.

Please INITIAL HERE to confirm you have reviewed the above information: _____

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for attending all study visits and following instructions given to you by study staff.

What happens if I say "Yes", but I change my mind later?

Your decision to participate in this study is voluntary. If you take part in this research study, and want to leave, you should tell us. Your choice not to be in this study will not negatively affect your right to any present or future medical care.

We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

If you stop being in the research, information about you that has already been collected may not be removed from the study database.

Can I be removed from the research?

It's possible that we will have to ask you to leave the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

What are the risks of being in this study? Is there any way being in this study could be bad for me? (Detailed Risks)

<u>Psilocybin side effects</u>:
The most common side effects are moderate increase in pulse and blood pressure, and headaches.

Other possible side effects, but not as likely: An adverse psychological reaction also known as a "bad trip", it would create fear, panic, anxiety, disturbing feelings and troubling thoughts. The study team has been trained on how to minimize the chance that this will happen and what to do if this were to happen during the study treatment.

Very rarely, even after taking psilocybin only once, people may experience brief recurrent changes in perception (for example, changes in vision). These episodes are generally not experienced as troublesome.

Even more rare, and reported more commonly with LSD, is Hallucinogen Persisting Perceptual Disorder (HPPD). In HPPD, the significant changes in perception (for example, changes in vision) that occur while the drug is in the body persist for an unusually long time after the drug is no longer present.
Abuse potential: There is a low risk, of wanting the study drug after exposure and seeking to use it repeatedly to get high.

You will be closely monitored during the study for these possible side effects, or others which may not be known at this time.

Blood Draw:
May cause discomfort, bruising, bleeding, lightheadedness, fainting, infection at the blood draw site, nausea, anxiety and swelling at the puncture site.

EEG:
Some minor skin irritation is a possible reaction to the electrode cap application. Reddening of the skin from the pressure of the electrodes usually resolves within 24 hours.

MRI:
MRI machines use a strong magnet and radiofrequency magnetic fields to take images of your body. The scanning process is similar to an x-ray or CT scan, but MRI does not use ionizing radiation (high-energy radiation that can potentially cause damage to DNA) like x-rays or CT scans. The risks associated with MRI scans are:

Projectiles: Objects with magnetic properties can be pulled into the magnet and turn into projectiles. To minimize this risk we ask that subjects remove all metallic items (watches, cell phones, hair pins, etc.) prior to entering the scanner and by controlling access to the scanner.

Claustrophobia: The scanner is a long narrow tube that may cause some people to feel claustrophobic.

Hearing Damage: The noise generated by the operation of the scanner during a study is loud enough to cause hearing damage if you do not wear hearing protection. Hearing protection is required and is provided by the study investigator.

Nerve Stimulation: Some people experience localized tingling, twitching, or muscle contractions during MRI scans. This is expected, but if it is uncomfortable please notify the study investigator.

Disruption of Devices: Some devices can be damaged by magnetic fields and should not be brought into the scanner room. This includes some implanted devices such as pacemakers, cochlear implants, insulin pumps, nerve stimulators, etc. If you have any implanted device notify the study investigator.

Heating of Devices: The radiofrequency waves used in MRI can heat conductive materials such as metal implants (screws, plates, rods, wires, artificial joints, etc.), certain tattoo inks, certain clothing fabrics, jewelry, medication patches, wigs, etc. You will be asked to remove these items if possible. If they cannot be removed you will be asked to provide more information to allow MRI staff to be able to make determination on the safety of proceeding with the scan.

A thorough pre-scan questionnaire will allow us to minimize the risk of device disruption and heating. You will be in constant contact with the investigator and should notify the study investigator

immediately, via the squeeze ball, if you notice anything unusual, become claustrophobic, think that your hearing protection is not adequate, or if you experience nerve stimulation that is uncomfortable.

In addition, there is a risk of unknown effects related to participation in MRI research. Long-term effects of exposure to high magnetic fields are unknown. Most people experience no short-term ill effects from the strong magnetic field, but some people report dizziness, mild nausea, headache, a metallic taste in their mouth, or sensations of flashing lights. These symptoms, if present, subside shortly after leaving the magnet. There is a risk that the MRI scan could exacerbate an underlying, and possibly unknown, condition that could result in the known side effects lingering into the hours and possibly days after the scan. If any sensations experienced during participation cause discomfort or pain, notify the researcher right away and your participation will stop and you will be taken out of the magnetic field.

The risks of exposure to high magnetic fields are unknown for fetuses. It is also unknown if there are any risks of psilocybin to someone who is pregnant. Therefore, if you are a female who is capable of becoming pregnant, and you have any reason to believe that you might be pregnant, you should not participate in this study.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

Will I receive any imaging results after an MRI?

The pictures created during this study are for research purposes only and are not intended to provide health care to you. You will be offered a copy of your scan, if you would like a copy. We will not be sharing your results with your primary physician.

Will I know about any new information about the effects of MRIs on human health? Notification of Significant New Findings

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services are performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

What happens to the information collected for the research, including my health information?

We try to limit the use and sharing of your information, including research study records, any medical records and any other information about you, to people who have a need for this information. But we cannot promise complete confidentiality.

Overview

If you participate in this study, your information, including your health information, will be used and

shared for purposes of conducting this research. As described later in this authorization, your information may also be used and shared for publishing and presenting the research results, future research, and any optional elements of the research you agree to in this Consent Form, which may include creating audio and video recordings of you. If you sign and date this authorization, you are giving us permission to use and share your health information for these purposes, and if we are using your medical records, you are giving permission to any health care providers who are treating you to share your medical records with us.

The University of Minnesota and representatives of this institution and its affiliates, including those that have responsibilities for monitoring or ensuring compliance, such as the Quality Assurance Program of the Human Research Protection Program.

What health information will be made available?

Health information about you to be used and shared for the research includes those items checked by the research team below:

☐ Your medical records, which may include records from hospital and clinic visits, emergency room visits, immunizations, medical history and physical exams, medications, images and imaging reports, progress notes, psychological tests, EEG/EKG/ECHO reports, lab and pathology reports, dental records and/or financial records. These records may be used and shared for as long as this research continues.

☒ Information collected as part of this research study, including research procedures, research visits, and any optional elements of the research you agree to, all as described in this consent form and authorization. This information might not be part of your medical record, and may include things like responses to surveys and questionnaires, and information collected during research visits described in this authorization.

Who will access and use my health information?

If you agree to participate in this study, your information will be shared with:

- The study investigator and study staff may share your information with representatives of the University of Minnesota and M Health. These people may use your information to provide oversight and administrative support for the research, conduct evaluations and reviews, and perform other activities related to the conduct of the research.
- Others at the University of Minnesota and M Health/Fairview who provide support for the research or who oversee research (such as the Institutional Review Board or IRB which is the committee that provides ethical and regulatory oversight of research at the University, systems administrators and other technical and/or administrative support personnel, compliance and audit professionals (Such as the Quality Assurance Program of the Human Research Protection Program (HRPP)) , individuals involved in processing any compensation you may receive for your participation, and others);
- The research sponsor(s), any affiliates, partners or agents of the sponsor(s) involved in the research, organizations funding the research, and any affiliates, partners or agents of the funding organization(s) involved in the research;
- Organizations who provide accreditation and oversight for research and the research team, and others authorized by law to review the quality and safety of the research (such as U.S. government agencies like the Food and Drug Administration, the Office of Human Research Protections, the Office of Research Integrity, or government agencies in other countries); and
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).

- Organizations that process any payments that may be made to you for participating in this study, and any other individuals or organizations specifically identified in this Consent Form.
- Your data will be shared with OpenNEURO and Usona Institute, Inc., which will include MRI and EEG data to OpenNeuro, and medication, pregnancy, and any side effects you have experienced to Usona Institute, Inc.
- Video recordings of your sessions will be used for internal monitoring of protocol adherence, qualitative analysis of video content during visits where you are taking the study drug, and for training and educating study staff and students on procedures used during this research.

Additional sharing of your information for mandatory reporting

If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

- Current or ongoing child or vulnerable adult abuse or neglect;
- Communicable, infectious or other diseases required to be reported under Minnesota's Reportable Disease Rule;
- Certain wounds or conditions required to be reported under other state or federal law; or
- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

How will my information be used in publications and presentations?
We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify you (such as your name and contact information, SSN and medical records number) will not be part of any publication or presentation. If you have an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

What will be done with my data and specimens when this study is over?
We will use and may share data and/or specimens for future research. They may be shared with researchers/institutions outside of University of Minnesota. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data and/or specimens, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or data.

Do I have to sign and date this authorization and give my permission to make my information, including my health information, available for use and sharing?
No, you do not have to sign and date this authorization. But if you do not sign and date, you will not be able to participate in this research study. Treatment available outside of the study, payment for such treatment, enrollment in health insurance plans and eligibility for benefits will not be impacted by your decision about signing and dating this authorization.

Does my permission for making my health information available for use and sharing ever expire?
No, there is no expiration date.

May I cancel my permission for making my health information available for use and sharing?
Yes. You may cancel your permission at any time by writing to the study investigator at the address on

the first page of this consent form. If you cancel your permission, you will no longer be in the research study. You may also want to ask someone on the study team if canceling will affect any research related medical treatment. If you cancel your permission, any health information about you that was already used and shared may continue to be used and shared for the research study and any optional elements of the study to which you agree in this authorization.

What happens to my health information after it is shared with others?
When we share your information with others as described in this authorization, privacy laws may no longer protect your information and there may be further sharing of your information.

Will I be able to look at my records?
It is possible that the research team may not allow you to see the information collected for this study. However, you may access any information placed in your medical records after the study is complete.

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.

Certificate of Confidentiality

To help protect your privacy, the Food and Drug Administration (FDA) has granted a Certificate of Confidentiality. The researchers can use this Certificate legally to 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 does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children/vulnerable adults, or information to the FDA when required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.

You also 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, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

Will anyone besides the study team be at my consent meeting?

You may be asked by the study team for your permission for an auditor to observe your consent meeting. Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (for example, name, date of birth) or confidential information about you. The auditor will not observe your consent meeting without your permission ahead of time.

Whom do I contact if I have questions, concerns or feedback about my experience?

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Ste. 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00045074.

To share feedback privately with the University of Minnesota Human Research Protection Program (HRPP) about your research experience, call the Research Participants' Advocate Line at 612-625-1650 or go to https://research.umn.edu/units/hrpp/research-participants/questions-concerns . You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

The University of Minnesota HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous. If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the University of Minnesota HRPP.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury let the study investigator know right away. By signing and dating this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

Will I be compensated for my participation?

If you agree to take part in this research study, we will pay you up to $1540 for your time and effort.

- You will receive $30 per hour on the 2 visits you are scheduled to receive treatment of psilocybin or control (8-10 hours sessions) up to a total of $600.
- You will receive $20 per hour for the following assessments and study visits: baseline testing, 7 MRIs, and 4 follow up visits (47 hours total) up to a total of $940.

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 3 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, will be given your name and social security number. They will use this information only as part of the payment system. Your information will not be used for any other purposes and will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

Additionally, you will have the option to receive updates related to appointment reminders and payment reminders and updates via text message and email message (standard text messaging rates will apply). You will have the opportunity to opt-in to receive these messages, you are not required to provide your cell phone or email address to be enrolled in the study or use a ClinCard. If you choose to receive messages and decide at a later date that you want to stop these messages, you will have the ability to opt-out.

Any demographic information collected and provided to Greenphire is stored in a secure fashion and will be kept confidential, except as required by law.

Payment you receive as compensation for participation in research is considered taxable income. If payment to an individual equals or exceeds $600 in any one calendar year, the University of Minnesota is required to report this information to the Internal Revenue Service (IRS). Research payments to study participants that equal or exceed $600 during any calendar year will result in a FORM 1099 (Miscellaneous Income) being issued to you and a copy sent to the IRS.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

Yes, I agree	**No, I disagree**	
_____	_____	The study investigator may contact me in the future to see whether I am interested in participating in other research studies by this study investigator
_____	_____	I would like to receive reminders using Greenphire.

Signature Block for Capable Adult:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed and dated document.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent