COMPOUND CONSENT AND AUTHORIZATION FOR PARTICIPATION IN A RESEARCH PROJECT

YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL
CONNECTICUT MENTAL HEALTH CENTER - CLINICAL NEUROSCIENCE RESEARCH UNIT

Study Title: Neural correlates of the effects of psilocybin in obsessive-compulsive disorder: a double-blind, placebo-controlled study.

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Invitation to Participate and Description of Project

You are invited to participate in a research study designed to look at the use of psilocybin in individuals who have been diagnosed with Obsessive Compulsive Disorder (OCD), and if you accept, then to also allow some of your samples (called specimens) and related information to be stored (banked) for future research about the use of Psilocybin in OCD and other conditions. This may help researchers in the future learn more about how to prevent, find and treat OCD.

This study will look at the effect of psilocybin on symptoms of depression, quality of life, beliefs about spirituality and self-boundaries, changes in patient behavior and attitudes, mystical experiences, and personality and perception changes. Psilocybin is not a medication approved by the Federal Drug Administration. Psilocybin is a naturally occurring hallucinogenic ingredient found in some varieties of mushrooms that can be produced synthetically. It is considered to be a serotonergic psychedelic. Psilocybin can produce changes in blood pressure, heart rate, mood, including anxiety, thought, and perception, although these physiological and psychological effects are transient and generally gone in about six hours. Psilocybin can produce some unpleasant side effects related to psychological distress and to increased anxiety, but investigators will take steps to reduce or prevent their occurrence.

In order to decide whether or not you wish to be a part of this research study and whether or not you wish to donate your specimens for future research, you should know enough about its risks and benefits to make an informed decision. This consent form gives you detailed information about the research study, and how the specimens may be used, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures and possible benefits. Once you understand the study, the specimen donation and banking process, you will be asked if you wish to participate; if so, you will be asked to sign this form.

You will be asked to a screening visit at the Yale OCD Research Clinic at Connecticut Mental Health Center (CMHC) /Clinical Neuroscience Research Unit (CNRU) and to register as a patient with the CNRU/CMHC as a part of your study procedures. Some information about your participation may become part of your CMHC medical record that identifies you. If you do not already have a medical record at CMHC, one may be made for your visit and for your participation in this study, including information about your laboratory results, blood draws and the urine tests. You will learn about what is involved in research participation so that you may decide if you wish to do so. If you do not wish to have your information recorded, you have the right to decline the research.

This initial clinic process will last about 3 to 4 hours, depending on how well you can answer questions, understand this consenting process, and help fill out forms.

If you decide to participate, then at a study visit, our nursing staff will gather vital signs, do an electrocardiogram (ecg) that looks at your heart's electrical signals and have a medical doctor review these. A physician will give you a brief physical exam. You will be asked to complete a set of self-report measures. Individuals of childbearing age will be questioned about the possibility of pregnancy and will have a pregnancy test at screening, upon admission to the CNRU, and before study drug administration. If your pregnancy test result is positive, or if you are breast feeding, you will not be able to participate in this study.

The clinical-research team will review this screening information to check your health status, your diagnosis, the severity of your symptoms, and any reasons that participating in this study might not be the appropriate choice for you. This review will be before you may be scheduled for the inpatient stay and study medication administration, and it will determine if you are eligible.

Screening for Out of State Participants:

If you live in another state and it is not feasible for you to come to the CMHC for an in-person screening you have the option of partaking in the screening utilizing a secure video communication platform (i.e. Zoom, Skype, etc.). We will ask you to send us your last physical exam, EKG, and bloodwork that was done by your PCP. This can be faxed to the Kelmendi Clinic and will be reviewed by the principal investigator and the research team.

Due to the COVID-19 pandemic if you live in Connecticut you also have the option to do your screening via a secure video communication (i.e. Zoom, Skype, etc.).

Then you may be invited to consider participation in this study to test the effects of the study medication, either Psilocybin, or niacin (as the active-placebo-control agent), on your symptoms. The dose of psilocybin will be 0.25mg/kg and the dose of niacin will be 250mg. The study will utilize some standard research techniques and procedures which you should understand. These techniques include: The use of **randomized, double-blind, active-placebo-controlled** trials. This means that you will be **randomly assigned** (an experimental technique for

assigning participants to different treatment conditions using randomization) to one of two procedures. In order to determine the effectiveness of study medication, we also use a common research method in which you may receive an "**active-placebo**" intervention. This means that you would not receive the actual study medication and procedure in a given session but instead will receive an alternative active-control agent called niacin and procedure. For either medication, you will experience some effects. But to avoid influencing the results, you will not be told whether or not a session is an active-placebo session (you are **blinded**), nor will the researchers working with you to do your assessments know if your session is an active-placebo or an active treatment (they are **blinded**). At the end of the study if you are in the active-placebo condition, you will have a choice about whether to participate in an open-label trial of Psilocybin.

Description of Procedures - Randomized Phase:

If you agree to participate in this study, you will have a choice about whether or not to take a medication called psilocybin and to learn about how that might impact you and your emotions. In this study, you will be asked to come in for a series of at least 12 study appointments, including answering an extensive series of study questions; having a single blood draw; having 3 screening visits (from 4 to 6 hours), 2 sets of Magnetic Resonance scans (about 2 hours each in the days before and after receiving the study medication), video/audio-taping of some sessions (if you are willing) as an aid and future tool, a 3 - 4 night inpatient stay on the CNRU with one day in which you will be randomized to an assignment and another day when you will receive a study drug, be monitored and have your vital signs taken. Your blood pressure, pulse, and temperature will be checked regularly on the day of study drug administration (30 minutes before, 15 and 30 minutes after, every 30 minutes for the next 1.5 hours, every hour thereafter) and with each shift during your overnight stay. You will be asked to commit to completing a series of follow-ups (1 to 2.5 hours) over a 3-month period. You will also be asked to provide the names and contact phone numbers for 2 to 3 family members, coworkers, or friends who might act as community observers of you and informers on your attitudes and behaviors following your overnight inpatient hospitalization. These community observers may be contacted twice (at week one and at week 12) to obtain objective information about how you seem to be doing. Our research staff will guide you through the study and will help you with reminders about what will be done next.

Out of State Participants:

If you live in another state and it is not feasible for you to come to the CMHC for an in-person follow-up visit, we can conduct the follow-up visits via telephone or a secure video communication platform (i.e. Zoom, Skype, etc.)

Due to the COVID-19 pandemic if you live in Connecticut you also have the option to do your follow-up visits via a secure video communication (i.e. Zoom, Skype, etc.).

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More specifically, you will be asked to commit to completing the following:

1. Come in for a set of screening visits at the Yale OCD Research Clinic to determine if you are eligible for the study, including having a psychiatric evaluation and completing numerous questionnaires and assessments. You will have a physical exam, an ecg to look at your heart for areas of concern, and have vital signs taken. The screening takes place at three visits.
2. You must be willing to be registered (have a research medical record created) and to be admitted as an inpatient to the CMHC/ CNRU overnight for 3 nights /4 days, or possibly longer depending on travel distances and health considerations.
3. You must be willing to abstain from alcohol, street drugs and tobacco products while in the study.
4. You must be willing to take drug screening tests to provide proof that you are not taking street drugs. You will have admission bloodwork done for standard screening labs to check your health, and if female, for pregnancy testing. You will have a physical exam and ECG to be sure that you are healthy and that there are no reasons why you should not participate.
5. You must be willing to be randomly assigned to a medication group (either active-placebo or Psilocybin), to receive a one-time dose of the study drug, and to complete all assessments, follow-up assessments and visits.
6. You must complete magnetic resonance safety sheets, along with two sets of Magnetic Resonance Imaging (sMRI / fMRI) scans: one the day prior to the study drug administration and one the day after. These MR scans will take place at The Anlyan Center, 300 Cedar St, New Haven, CT in Magnetic Resonance Research Center (TAC / MRRC).

   Note: If you have been exposed to metal work or shop work that might have left fragments of metal in or near your eyes, we will ask you to have pre-fMRI radiography orbit x-rays to rule-out this possibility.
7. You must not be pregnant or become pregnant while on the study.
8. You will be asked to allow the audio-video taping of some of your study sessions: the initial study experience discussions or the drug administration session. These tapings will serve as an aid for you or for the therapists and investigators during your participation, and will also be utilized for further analysis of your experiences, the therapist interventions, and for ongoing educational, research and training purposes.
9. You will be asked to come for at least twelve study visits over 12 weeks. Aside from the screening (2 visits) and the actual day of Psilocybin dosing, the other visits will consist of a series of psychological and physical assessments and questionnaires. The time you spend

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completing these will vary from one to two hours depending on how quickly you are able to understand and answer the questions.

10. You must be willing to stay overnight for part of the study and when you leave you must be medically cleared to drive home or you can arrange to be driven home the day after the experimental sessions or for the day of the 48-hour post session assessments, either by a driver arranged by you or by the site personnel or taxi.
11. If you are currently seeing a psychotherapist you may continue to do so.
12. You must avoid starting a new psychiatric medication during the study. You especially must avoid starting any new medication for at least 48 hours after the drug administration. However, should your doctor recommend starting a new psychiatric medication, you will be required to notify the study team.
13. You must be willing to sign a medical release for the investigators to communicate directly with your therapist and/or doctors.
14. You must be medically cleared by the study physician before you can be discharged from the overnight stay at CMHC. If you wish to leave but have not been cleared by our doctor, then you may be involuntarily held overnight in the interest of safety.

Open label phase (option): If you are assigned to the active-placebo and after your unblinding, then you may be offered an opportunity to try the study medication, psilocybin, in a single dose inpatient trial: three days - two nights. You will be asked to do a similar set of procedures to those already described, including a screening, a battery of assessments, an optional MRI before and after drug administration, an overnight stay on the CNRU with study drug administration, and a series of follow-ups.

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.

You will be told of any significant new findings that are developed during the course of your participation in this study that may affect your willingness to continue to participate.

Risks and Inconveniences

The risks involved with this study include those associated with delay in treatment, blood drawing, EEG, psychiatric evaluations, clinical assessments, taking the study medication - Psilocybin or Niacin, experiencing an emotional response during the study, neuropsychological-cognitive assessments including MRI / fMRI, X-Ray, and clinical tests.

Delay in Treatment: In order to participate in this study you may have to delay starting or changing treatment due to the thorough diagnostic evaluation, and the scheduling of the study procedures. During this period, it is possible that your condition could worsen. In order to minimize the chance of this happening, you will be seen in the clinic at regular intervals, and you will be able to contact clinic personnel 24 hours a day should any problems arise. You will refrain from starting a new medication that acts on the serotonin system for at least 48 hours after taking the study drug. Every effort will be made to complete the entire protocol quickly, especially if you or our psychiatrists are concerned that this delay in treatment may be a problem for you. Your participation in the study will be terminated immediately if your condition significantly worsens, especially if you feel suicidal. If necessary, you may be hospitalized free of charge on our inpatient psychiatric research unit.

Risks of Screening, evaluations, possible emotional response

The risks and discomforts of the screening and evaluations are minimal. No discomfort is expected to be associated with the physical examination or the intake interview with the study clinician, other than the possible stress of answering personal questions and the risk of loss of privacy and confidentiality, while revealing personal information. You will be asked questions about your symptoms when filling out questionnaires. You may find this process to be inconvenient, uncomfortable or upsetting. The psychological interviews may include personal questions about previous experiences. The questions will be asked in a private room. You do not have to answer any questions that make you uncomfortable. You will also have the option to discuss concerns with someone on the research staff. One or more trained individuals will be available to talk to you should you become distressed during an interview or while filling out questionnaires.

Risks of Psychiatric Evaluation, Clinical Assessments and Neurocognitive assessments: The major disadvantages of these tests are the time it takes to complete them, and the fact that the researchers may ask personal questions about your feelings or your past, which may feel unpleasant at times. We have asked these questions many times in the past for other studies without difficulty or side effects, so we believe you will probably find them acceptable; however, you do not have to answer any questions that you do not want to answer. You may find the online assessments and surveys to be tedious. You will be offered short breaks if you need them.

Risks of ECG

Sometimes the adhesive pads used to attach the leads for recording the electrical activity of the heart can cause skin irritation. Such irritation usually clears without treatment. Should you develop a skin reaction, study staff will assist you in finding the necessary treatment. The ECG is a standard routine to check your heart's electrical activity and health prior to a clinical study. The research staff is well trained in the application and removal of electrodes, which will be removed as soon as you have completed the study.

Risks of Pre-MRI plain radiography (x-ray) rule-out for metallic objects: If needed and if you are willing, the pre-MRI X-ray will be considered, to rule out the possibility that you have metallic fragments or objects in your body and to ensure that it is safe for you to have an MRI. This X-ray will expose you to a low level of radiation. This radiation exposure is not necessary for your medical care and is for research purposes only. The total radiation exposure amount of one film skull x-ray is the same as the exposure your body normally gets from natural background radiation in a 12-day period.

MRI / fMRI Risks:

Magnetic resonance imaging (MRI) uses magnetic fields and radio waves to take pictures of the body. Millions of people have had MRI scans with no known safety issues. MRI uses a strong magnet, which can pull strongly on some metals. These metals must not be brought into the scan room. They could be pulled towards the magnet and cause serious injuries if they hit you. People entering the scan room must remove all metal from their body, clothing and pockets. This includes jewelry, hearing aids, watches, cell phones, keys, coins, and wallets. Some metal objects could also heat up during the MRI, burning you. Electrical devices such as pacemakers could go wrong or stop working. You must also tell us if you are wearing anything that could contain metal. For example, some medication patches have a metal backing. Some clothing can contain metal fibers that could also heat up during the MRI. We will therefore ask you to fill out an MRI safety form to check if you have anything in your body which might be dangerous in the MRI. It is very important that you fill out this form accurately and ask if you are unsure about anything.

During the MRI scan, you may feel uncomfortable or worried. When the MRI scanner is making pictures, it makes loud tapping, buzzing, and beeping noises. Without protection, this could damage your hearing. We will give you with earplugs and/or headphones to reduce the

sound to a safe level. While the scanner is making noises, we will not be able to hear you. We will give you a squeeze bulb for you to contact us.

We want you to read and answer very carefully the questions on the MR Safety Questionnaire related to your personal safety. Take a moment now to be sure that you have read the MR Safety Questionnaire and be sure to tell us any information you think might be important.

This MR study is for research purposes only and is not in any way a healthcare examination of the brain. The scans performed in this study are not designed to find abnormalities. The principal investigator, the lab, the MR technologist, and the Magnetic Resonance Research Center are not qualified to interpret the MR scans and are not responsible for providing a healthcare evaluation of the images. If a worrisome finding is seen on your scan, a radiologist or another physician will be asked to review the relevant images. Based on his or her recommendation (if any), the principal investigator or consulting physician will contact you, inform you of the finding, and recommend that you seek medical advice as a precautionary measure. The decision for additional examination or treatment would lie only with you and your physician. The investigators, the consulting physician, the Magnetic Resonance Research Center, and Yale University are not responsible for any examination or treatment that you receive based on these findings. The images collected in this study are not a healthcare MR exam and for that reason, they will not be made available for healthcare purposes.

Risks of receiving Psilocybin

The Psilocybin used in this study is manufactured at a central facility which guarantees its purity. You will be given one tablet of either Psilocybin or the active-placebo. The dose of psilocybin you will be receiving in this study is 0.25mg/kg or 0.25mg/2.2 lbs.

Common side effects: 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 (feeling as if the world is unreal or as if one is “in a dream”), dizziness, fatigue, 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 paranoid ideation or temporarily lost insight into the experimental situation.

Physiological effects include pupillary dilation and detectable but moderate increases in blood pressure or heart rate. Researchers sometimes detected changes in blood pressure and heart rate only at one point in time, as sixty minutes after drug administration. These effects are

transient and are generally gone approximately six hours after drug administration. People in previous human studies have tolerated doses of psilocybin equal to or greater than the doses employed in this study.

Acute side effects: The most likely potential adverse effect of psilocybin is anxiety, or possibly panic, delusion, and cognitive impairments, particularly at higher doses (> 25 mg) during the period of acute drug action. In addition to fear, panic, and paranoia during the drug session, there is the possibility of prolonged adverse psychological reactions, such as psychosis and depression. Nevertheless, although the risk is believed to be minimal, it is possible that some participants may develop a brief psychotic reaction while under the influence of psilocybin. Researchers studying the effects of 30 mg psilocybin took precautions similar to the ones we will use in this study and no reactions requiring pharmacological intervention occurred.

These effects are generally gone approximately six hours after drug administration.

Insomnia

Although rare, insomnia following psilocybin administration has been reported in the literature; it has been described as self-limiting and responded well to reassurance from the study team. In the event that you will experience difficulty sleeping and/or anxiety following study drug administration, a study physician may prescribe a sleep aid such as benadryl or hydroxyzine, medications available over the counter. If these medications prove unsuccessful, a one-time dose of lorazepam will be considered. Lorazapem is a medication used to treat anxiety and insomnia and it belongs to a class of drugs called benzodiazepine. This class of medications is associated with several notable risks and side-effects, which include sedation, dizziness, drowsiness, unsteadiness, and prolonged use can lead to substance abuse. Zolpidem is another medication that could be considered should you have difficulty falling asleep following study drug administration, it is associated with several side-effects including headache, drowsiness, dizziness, lethargy, and prolonged use has been associated with substance abuse.

The study doctors and staff will, whenever possible, take the steps below to further reduce or prevent their occurrence.

- You will be closely monitored for any unusual symptoms or anything that would place you at risk.
- Randomized experimental phase - Inpatient CNRU stay will be for 4 days and 3 nights (up to 4 nights, if conditions warrant longer, e.g. if your health or symptoms need monitoring then we will keep you and continue your evaluation; or if due to travel distances / other considerations, it is more convenient to stay over, then you may do so). If you are given the option to try the open label phase and choose to do so, you will be required to be an inpatient on CNRU for 3 days / 2 nights.
- You will be given medications to correct any unusual symptoms if the study staff and doctors decide that you are at risk of worsening symptoms or danger.

- In case of insomnia or an overly anxious reaction, you may be prescribed a benzodiazepine or zolpidem as a "rescue medication" for the day or night after drug administration.
- You must be medically cleared to drive yourself home or you can be driven home after the inpatient experimental stay (v 3 to 6), and / or after the 48-hour post session assessments (v 7), either by a driver arranged by you or by the site personnel or taxi.

Risks of receiving niacin (active-placebo)

The risks of receiving niacin are minimal and the dosage being used has been well tolerated in previous studies. Niacin has some expected physiological side effects which is why it is used as an "active placebo". These include flushing, tingling, itching, and redness of the face, arms, and chest, as well as headaches. Other minor but expected side effects include upset stomach, intestinal gas, and dizziness. It is important to note that these side effects do not pose a serious risk to your health.

Risk of involuntary hospitalization for patient safety

Your safety is important to us. As part of enrollment in this study, you must agree to staying overnight at the CNRU for 3 to 4 nights. It is important for you to be monitored after receiving psilocybin (even if you think you received placebo). If you are not compliant with the requirement, there is possibility for you to be involuntarily hospitalized against your will.

Also, if there is concern about you being a risk to yourself or others during the study there is potential for you to be hospitalized against your will. You will be monitored and discharged only after study doctor believes that it is safe to do so.

Risks of 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 total amount of blood drawn in this study would be up to 50 ml which is equivalent to roughly 10 teaspoons. This blood draw carries the same amount of risk as a blood draw in your doctor's office does. 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.

PROCEDURES TO ENSURE SAFETY

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.

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 CMHC 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 regards to local plan for such emergencies so our study team can follow this plan should an emergency situation arise.

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INDIVIDUALS OF CHILDBEARING POTENTIAL 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. You will take a pregnancy test as part of the study tests. If your test result is positive, you will not be included in this study. 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 test the day of the drug administration.

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.

Benefits

There is probably no benefit to you from your participation in this study. You may learn more about your OCD diagnosis through talking to the study doctors and staff who are screening you for participation in this study. Your participation in this study may benefit others in the future who have been diagnosed with OCD in that we may learn more about how Psilocybin works in the brain of people with OCD. Using your specimens for research will probably not help you. We do hope the research results will help people in the future. We hope that the information we learn in future research studies will increase our knowledge of human health and that this information will lead to better prevention, diagnoses and treatments in the future.

Economic Considerations

You will not be charged for any of the study procedures that are related to this study, including any assessments with the study doctor or study team, cost of the Psilocybin or the cost of the fMRI scans.

There is a possibility that tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed, or lead to development of products that will be commercialized. If this happens, there is no plan to share any financial gain with you.

You will be paid up to $350 for the Randomized Phase (and up to $150 for Open-label phase). This means that you will be paid according to the following schedule for the visits you are eligible to complete:

Screening	$50
fMRI scan (2 scans)	$30 each scan
4-Days, 3-nights inpatient stay with 1 medication day dosing	$100 for inpatient stay
Six follow up visits	$20 each visit
Bonus for completing all visits:	$20
	$350. total

If you received the active-placebo control agent during the first part of the study, you may be eligible to choose to receive a dose of the Psilocybin and to be paid according to the completion of these open-label phase visits:

2 Days inpatient with 1 medication day dosing	$120.00 for inpatient stay
Six Follow up visits	$70.00
fMRI Scan (2 scans)	$30 each scan
	$250. total

If you leave the study early, you will receive payment based on the study visits you completed.

This payment for study participation may be made by a Bank of America pre-paid debit card. Please note that your name, address, and telephone number will be shared with Bank of America. You will receive the Bank of America card in the mail which you will need to activate over the phone in order to use the funds. This card can be used anywhere that a credit card is accepted. At the PI's discretion, subject payment may be through a petty cash system, by Yale check request, or an E-gift card.

At the principle investigator's discretion on a case by case basis and when arranged in advance, additional subject payment may be offered for travel, parking, lodging, food or transportation to ease participation expenses.

According to the rules of the Internal Revenue Service (IRS), payments that are made to you as a result of participation in a study may be considered taxable income

Treatment Alternatives

Participation in this study is not intended to treat your OCD. There are many treatments for OCD, some of which work better than others, depending on the person and their experiences. The study team can help you find treatment for OCD if you ask for a referral or information.

Confidentiality

If you decide to take part in this research study, you will be required to give us information about your substance use or possibly criminal behavior. To help us protect your privacy, we have obtained a Certificate of Confidentiality from the Food and Drug Administration. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, *except as explained below:*

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member

of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, 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. The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of the abuse of a child or elderly person, or a participant's threats of violence to self or others. If any member of the research team is given such information, he or she will make a report to the appropriate authorities.

All identifiable information that is obtained in connection with this research study will remain confidential. Information about you will be kept in locked offices, on password-protected computers, or in secure clinic files on Yale secure server; or in locked cabinets on a locked unit. Only the members of the research bank staff and researchers who have received the approval of the HIC to use your specimens and data will know your identity. Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as required by U.S. or State law. Examples of information that we are legally required to disclose include abuse of a child or an elderly person.

Representatives from the NIH, the FDA, the study sponsor, the Yale Human Research Protection Program, the Yale Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects) may inspect study records during internal auditing procedures. However, these individuals are required to keep all information confidential.

All study information about you will be assigned a code so that no one, except for the study doctor and his staff, will know your name. The code linking names and numbers will be kept in a locked cabinet in a locked office or in a database log on password protected servers.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained.

Privacy Rights:

We understand that information about you obtained in connection with your health is personal, and we are committed to protecting the privacy of that information. The researchers are required by law to protect the privacy of information known as protected health information (PHI). All reasonable efforts will be made to protect the confidentiality of your PHI, which may be shared with others to support this research, to conduct public health reporting, and to comply with the law as required. Despite these protections, there is a possibility that information about you could be used or disclosed in a way that it will no longer be protected.

By signing this form, you give permission for the researchers to store and use and/or disclose the information in this research database. You have a right to refuse to sign this form. Your health care outside the study, the payment for your health care, and your health care benefits will not be affected if you do not sign this form. Information about you gathered during your clinical care or during this research study will not be placed into the research data bank described in this form or used for future research if you do not sign this form. You do not give up any of your legal rights by signing this form.

If you decide to be in this study, the researcher will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name and medical record number. This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, and this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify you will remain confidential. The research team will only give this coded information to others to carry out this research study. The link to your personal information will be kept for until the study drug is approved for prescription, after which time the link will be destroyed and the data will become anonymous. The data will be kept in this anonymous form indefinitely.

The information about your health that will be collected in this study includes:

- Research study records
- Medical and laboratory records of only those services provided in connection with this Study.
- The entire research record and any medical records held by Yale University and the Connecticut Mental Health Center for the time the study is open or the data is still being analyzed.
- Records about phone calls made as part of this research
- Records about your study visits
- Physical exams
- Psychological Assessments by the study team
- Laboratory, x-ray, and other test results
- Diaries and questionnaires
- Records about any study drug you received

Information about you and your health which might identify you may be used by or given to:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Yale Human Investigation Committee or IRB (the committee that reviews, approves, and monitors research on human subjects), who are responsible for ensuring research safety. These individuals are required to keep all information confidential.
- Those individuals at Yale who are responsible for the financial oversight of research including billings and payments
- The Study Doctor, Benjamin Kelmendi, M.D.
- Study Coordinator and Members of the Research Team
- The U.S. Food and Drug Administration (FDA) This is done so that the FDA can review information about the drug product involved in this research. The information may also be used to meet the reporting requirements of drug regulatory agencies.
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- Health care providers who provide services to you in connection with this study.

- Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan.
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at Connecticut Mental Health Center, the Yale School of Medicine and Yale-New Haven Hospital are required to comply with HIPAA and to ensure the confidentiality of your information. Some of the individuals or agencies listed above may not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

You have the right to review and copy your health information in your medical record in accordance with institutional medical records policies. However, by deciding to take part in this study and by signing this consent form, you will not be allowed to look at or copy your study related information until after the research is completed.

This authorization to use and disclose your health information collected during your participation in this study will never expire.

In Case of Injury

If you are injured while on study, seek treatment and contact the study doctor as soon as you are able.

Yale School of Medicine, Yale-New Haven Hospital and the Connecticut Mental Health Center do not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available.

You do not give up any of your legal rights by signing this form.

Voluntary Participation and Withdrawal

Participating in this study is voluntary. You are free to choose not to take part in this study. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled (such as your health care outside the study, the payment for your health care, and your health care benefits).

Withdrawing from the Study

If you do become a subject, you are free to stop and withdraw from this study at any time during its course, except immediately after receiving the study drug. For your safety, if it is necessary, you may be hospitalized until the doctor believes it is safe to release you.

Otherwise, to withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part. This will cancel any future appointments.

The researchers may withdraw you from participating in the research if necessary. You will be withdrawn if you cannot complete the questionnaires or undergo the MRI or if you become pregnant or use street drugs.

Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. It will not harm your relationship with your own doctors or with the Yale-New Haven Hospital or the Connecticut Mental Health Center. We would still treat you with standard therapy or, at your request, refer you to a clinic or doctor who can offer this treatment.

When you withdraw from the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to insure the integrity of the study and/or study oversight.

Video - Audio Taping (option): We are requesting your permission to videotape/audiotape some of your participation as part of this study. If you agree to the taping, we will use these tapes of your follow-up and drug administration sessions for you and the investigators to review and to aid in the evaluation of your experience and the therapist interventions. We would like to tape the drug administration session in entirety. In addition, we would like your permission to keep these tapes for educational, research, and training purposes indefinitely. The taping is optional. You may choose to give permission for one or both uses of the tapes, or you may decide not to participate in taping at all. Your decision will not affect your ability to remain in the study.

If you agree to participate, we will keep the tapes 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 tapes 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 videotape/audiotape may be taken of me as part of this study. The tapes /films 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)

Seeking permission to retain tapes for future use: You have the choice of how long we may keep your tapes.

a. _____My tapes may be kept permanently for research, educational or training purposes by the OCD Research Clinic.

_____(Initial)

b. _____My tapes must be destroyed after completion of study as outlined.
_____(Initial)

I understand that my consent for this part of the study is optional, and I am free to refuse this request and may still participate in the study. I understand that I may request at any time during the research that the videotapes or films of me be destroyed and the research staff will honor my request promptly. My initials above indicate my decisions and my signature below indicates my consent for the use of these tapes.

Community Observer Ratings (option): We are requesting your permission to provide the **names and telephone numbers of two to three friends or family** who can independently comment on any changes in your mood or behavior after administration of Psilocybin. You may wish to contact these individuals first to ask if it is okay to provide us with the names and numbers.

I agree to provide the names and telephone numbers of two to three friends or family who can independently comment on any changes in my mood or behavior after administration of psilocybin (initial your choice):

_____YES _____NO

_____(Initial) _____(Initial)

Name_____Phone _____

Name_____Phone _____

Name_____Phone _____

We will contact these individuals 1-2 times after the administration of the drug or they may call us to report any changes or concerns.

Emergency Contact:

Please provide the name and phone number of someone who we may contact in the case of an emergency.

Name_____Phone _____

Treating Physician's Contact Information:

Please provide the contact information of your treating physician so we can contact them in case of an emergency.

Name_____Phone _____

Email: _____

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you make a decision.

Authorization

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

By signing this form, I give permission to the researchers to use [and give out] information about me for the purposes described in this form. By refusing to give permission, I understand that I will not be able to be in this research.

Name of Subject: _____

Signature: _____ Date: _____

_____ _____
Signature of Principal Investigator Date

or

_____ _____
Signature of Person Obtaining Consent Date

Whom to contact with questions:

If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at 203-432-5919.

If you have further questions about this project or if you have a research-related problem, you may contact Dr. Benjamin Kelmendi at ben.kelmendi@yale.edu, 203-974-7752; or Dr. Christopher Pittenger at Christopher.pittenger@yale.edu, 203-974-7675.

If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.