

INFORMED CONSENT TO RECEIVE PSILOCYBIN SERVICES

Introduction:

In the State of Oregon, psilocybin services are delivered during three different sessions: preparatory, administration, and integration. You should receive this informed consent form at the start of your preparatory session. During the session, your facilitator will discuss the form with you. Please ensure that you read and understand every section because you must sign the form before the preparatory session concludes. If you do not understand any part of this document, please ask your facilitator for clarification before signing.

Statement on Data Collection:

While receiving psilocybin services, you may be asked to contribute information regarding your participation in psilocybin services for research purposes. Efforts will be made to protect the security and confidentiality of your information, such as the deidentification of your data, consistent with standards of medical care and research. However, there is a risk the information could be used to identify you and reveal that you have received psilocybin services. If you agree to share your information, then data collected about you by your facilitator may be shared with people and institutions outside the psilocybin service center. If you would prefer that your information not be shared for these purposes, then you should not agree, and your information will only be shared if required by law. Your decision will not affect your ability to receive psilocybin services.

I have been informed of and understand the following:

(Please initial each item below.)

1. ____ I attest that I am 21 years of age or older.
2. ____ I have been provided with a copy of the Psilocybin Services Client Bill of Rights, my facilitator has explained it to me, and I understand my rights as a client.
3. ____ Based on the outcome of Phase 1 and 2 clinical trials, the Food and Drug Administration (FDA) has designated psilocybin a "breakthrough therapy" for major depressive disorder and treatment resistant depression, which means psilocybin may be a significant improvement over current FDA approved therapies. Additionally, randomized controlled clinical trials and peer reviewed medical literature suggest that psilocybin may improve symptoms of depression,

anxiety, end of life distress, various forms of trauma, and problematic substance use. During clinical trials, participants may have received more preparatory, administration, and integration sessions, and clients should use caution when using the results of these trials to predict the nature of their experience when receiving psilocybin services.

4. ____ Preliminary medical and public health research suggests that psilocybin is unlikely to be addictive.
5. ____ However, while existing research has shown promising results, the risks, benefits, and drug interactions of psilocybin are not fully understood, and individual results may vary.
6. ____ *Psilocybin has not been approved by the FDA for marketing as a drug*, and the federal government currently classifies psilocybin as a Schedule I controlled substance.
 - a. According to the Drug Enforcement Administration (DEA), Schedule I controlled substances have (1) a high potential for abuse; and (2) no currently accepted medical use.
 - b. Federal law prohibits the manufacture, distribution, and possession of psilocybin even in cities and states that have modified their laws to allow its possession or use.
7. ____ I understand that some people find psilocybin administration sessions challenging and uncomfortable. Common potential side effects include mild and transient headache, fatigue, anxiety, confusion, increased blood pressure, elevated heart rate, paranoia, perceptual changes, altered thought patterns, reduced inhibitions, unmasking of repressed memories and traumas, and altered perception of time and one's surroundings. If they occur, these side effects are usually mild and temporary. However, because the potential risks and benefits of psilocybin administration are not fully understood, there may be unanticipated side effects of psilocybin administration.
8. ____ I understand that less common, and potentially more serious side effects may include dizziness, fainting, and changes in heart rhythm (arrhythmia) such as QT prolongation. In very rare cases, people have reported experiencing perceptual disturbances that have persisted for months after the administration of psilocybin. However, these rare effects appear to be more commonly associated with the use of lysergic acid diethylamide (LSD) than with psilocybin, or with the use of these substances without supervision.

9. ____ I understand that if I am taking prescription medications or have a chronic medical condition including, but not limited to, heart disease, kidney disease, and liver diseases, I should check with my doctor before being administered psilocybin.
10. ____ I understand that people diagnosed with certain mental health conditions, such as schizophrenia and bipolar disorder, may be at increased risk for serious side effects during and following the administration of psilocybin.
11. ____ I understand that some people are allergic to mushrooms, and psilocybin is sometimes derived from mushrooms. If I have a known mushroom allergy, I should check with my doctor before being administered psilocybin.
12. ____ I attest that I am not pregnant or breastfeeding. The effects of psilocybin during pregnancy are unknown and may harm me or my unborn child.
13. ____ I understand that if I disclose instances of child or sexual abuse to my facilitator, or information that may put me or another person at risk of imminent harm, my facilitator may be required by law to report my statements to police and other authorities.
14. ____ I agree not to drive, operate heavy machinery, or engage in any activities that require alertness or quick responses for at least 24 hours after psilocybin administration.
15. ____ I understand that being administered psilocybin is completely voluntary and I may decide not to receive psilocybin at any time.
16. ____ I understand that if I agree to share my information for research purposes, then data collected by my facilitator may be shared with people and institutions outside the psilocybin service center. Efforts will be made to protect the security and confidentiality of my information, such as the deidentification of my data, consistent with standards of medical care and research. However, there is a risk the information could be used to identify me and reveal that I have received psilocybin services. If I do not want my information to be used for research, then I should decline to share my data. I will still be permitted to receive psilocybin services, and my data will only be shared to the extent required by law.
17. ____ I understand that for my own safety, leaving a psilocybin service center during an administration session once it has begun is not recommended. Doing so could expose me to safety and legal risks.
18. ____ I understand and have been informed of the potential benefits, risks, and complications of psilocybin services with my facilitator to the extent that they are known.

19. ____ I have had the opportunity to ask questions regarding anything I may not understand or that I believe needs to be clarified.

Name (Print)

Signature

Date

DRAFT