WAIVER OF DOCUMENTATION OF CONSENT SCRIPT

Study Introduction
Thank you for your interest in this research study on outcomes of psilocybin use in naturalistic settings. This study will involve filling out a set of up to online 5 surveys over the period of 2 weeks before and up to 3 months after your planned psilocybin experience. The greatest risks of this study include emotional discomfort when answering some questions and loss of confidentiality.

Purpose of This Study
The goal of this survey is to learn more about the positive and/or negative outcomes of using psilocybin in naturalistic settings (meaning outside a research laboratory), and any potential factors that could affect those outcomes. By collecting data from individuals who are already planning to use psilocybin, we aim to investigate variables such as demographics; lifestyle; mindset; and personality traits; as well as characteristics of the experience itself such as dosage, ingestion method, intention, and setting, that could influence psilocybin’s long-term effects.

The researchers conducting this study do not advocate or promote psilocybin or other drug use. The aim of this research is to sample people whose intent to take psilocybin is already established.

This study is designed for individuals who are planning to take psilocybin in a single-dose session and is not designed for a recurring microdosing regimen. You are invited to participate if you are planning to use psilocybin outside a research laboratory in the next 6 months, regardless of the intended purpose.

This study will involve filling out a set of up to 5 surveys, and you can opt out or reschedule at anytime. Email reminders will be provided for each survey at the email address you provide on the following schedule. After completing this initial informed consent process and agree to enroll in the study, you will be asked to complete the first survey up to 2 weeks before a planned psilocybin experience. You will be asked to complete the next survey on the day you take psilocybin, sometime before actually taking any substance. The next survey will be completed between 1 and 3 days after psilocybin use. Finally, follow-up surveys will be completed between 2 and 4 weeks, and between 2 and 3 months after the psilocybin session.

Inclusion Criteria
You are invited to participate in this survey if you fulfill all of the four criteria listed below.
1) You are at least 18 years old.
2) You read and write English fluently.
3) You are planning a psilocybin journey within the next 6 months.
4) You are willing to complete baseline, pre-session, post-session, and follow-up surveys, and share an email address where you will receive reminders with links to survey assessments.
What the Study Entails
Participation in this study involves filling out a sequence of online surveys (as outlined above) that will take between 10 and 30 minutes each. You will be required to complete each survey in one sitting. If you meet study inclusion criteria and agree to participate, you will be asked to provide basic information today including an email address and date of anticipated psilocybin use. Afterwards, you will receive email notifications with reminders to complete additional surveys up to 2 weeks before a planned psilocybin experience, on the day you take psilocybin (before actually taking any substance), between 1 and 3 days after psilocybin use, between 2 and 4 weeks after psilocybin use, and between 2 and 3 months after psilocybin use.

What kind of information will I be providing?
In the initial survey, you will be asked questions about your demographics (e.g., age, sex), as well as your lifestyle and wellbeing. Psychological questionnaires are also included to assess personality traits, and overall health. Immediately prior to and after the session you will be asked about your level of rest and recent nutrition, the specifics of the session setting and dosage, and the psychological and physiological aspects of your experience. Finally, we will be collecting similar data to the initial survey (e.g., lifestyle, wellbeing, health) in the weeks after your session to understand any changes that may take place over time.

Risks/Discomforts
You may get tired or bored when you are completing surveys. You do not have to answer any question you do not want to answer.

There is the risk that information about you may become known to people outside this study.

Is my participation confidential?
Your personally-identifying information will only be collected for the purposes of sending you each of the surveys in this study. Your personal information (e.g., email address) will be destroyed soon after the final follow-up has been completed, or within 6 months of the date of intended psilocybin use. During and after this period, your anonymous responses will be seen and analyzed by Johns Hopkins staff or representatives. The study data will be hosted on a secure website (www.Qualtrics.com). Qualtrics is a reputable and secure platform for conducting survey research online that is approved for use by Johns Hopkins. To further protect the confidentiality of participants, the results of this study will be presented in aggregate. We may quote from your textual responses. However, if you provide specific identifying information, we will edit your responses to protect your confidentiality.

Benefits
There is no direct benefit to you from being in this study. Responses from many different people and your input could materially evolve our collective scientific understanding of psilocybin’s effects on the human mind.
Compensation
Coupon codes are available for participating in this study. You will automatically be emailed an anonymous coupon code when you complete Survey 3, between 1 and 3 days after psilocybin use. Additional coupon codes will be delivered by email upon completion of the final survey, between 2 and 3 months after taking psilocybin. These coupon codes will be redeemable directly at a range of sponsor companies for a variety of items including resources, gear, and event tickets, valued at up to $50.

What will become of the results from this study?
The researchers intend to publish the results from this study in the scientific literature and to present results at scientific meetings. We will also make the results publicly available by posting a notice of any scholarly publications on the website of Unlimited Sciences (unlimitedsciences.org).

Your responses to each survey will only be used if you complete the survey.
Your participation in this study is voluntary. Reviewing this information and completing this initial screening form will serve as your consent to be in the overall study. Even after you complete this screening form, you may stop participating at any time. If you stop early, only your responses up to that point will be used in analysis. At any time during the study you will be able to contact the study team to request that your data be removed from the study and end your participation by clicking a study opt-out link included in each of our communications.

Identifiable information in future research
We may use the information collected through this study for future research including research with external collaborators. Generally, when sharing information for future research we will take precautions to remove any information that could identify you (like your name or medical record number) before sharing.

HIPAA DISCLOSURE
We will collect information about you in this study. People at Johns Hopkins who are involved in the study or who need to make sure the study is being done correctly will see the information. People at Johns Hopkins may need to send your information to people outside of Johns Hopkins (for example, government groups like the Food and Drug Administration) who need to make sure the study is being done correctly. These people will use your information for the purpose of the study.

Your Authorization for the collection, use, and sharing of your information does not expire. We will continue to collect information about you until the end of the study unless you tell us that you have changed your mind. If you change your mind and do not want your information to be used for the study, you must contact the Principal Investigator by using the contact information provided in this document. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

We try to make sure that everyone who needs to see your information uses it only for the study and keeps it confidential - but, we cannot guarantee this.
Contact Information
If you have any questions about this study, please feel free to contact the Principal Investigator Albert Garcia-Romeu at (410) 550-1972 or agarci33@jhmi.edu.

The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu.

How do I start?
You can begin the study by clicking 'Begin study at the bottom of this page. This initial questionnaire will take approximately 5-7 minutes and must be completed in one sitting.

It is important that you answer each question honestly and seriously. If you are not ready to complete the survey now, please return to this page at a time that is convenient for you.

You can exit the survey at any time by clicking the link in the upper right corner of your screen. If you exit the survey early, your responses will not be used.

During the survey, **please do not hit the "back" button** on your internet browser as it may erase your answers or prematurely terminate your session.

By clicking 'Begin survey' below, you affirm that:

1. You have read the information above;
2. You voluntarily agree to participate;
3. You are at least 18 years old;
4. You read and write English fluently;
5. You are planning to use psilocybin outside a research laboratory within the next 6 months, and;
6. You are willing to complete baseline, pre-session, post-session, and follow-up surveys, and share an email address where you will receive reminders with links to surveys.

Please click below to begin or exit the study.
- Begin study
- Exit study