

How the Study Works

Screening:

After signing this consent form you will have two or more screening sessions to find out if you are able to participate in the study. You will be asked to do the following:

- Complete questionnaires and interviews about your personal and family medical and psychiatric history.
- Complete questionnaires that assess your psychological functioning and general life adjustment.
- Have a physical examination.
- Have your heart function assessed by taking blood pressure and an electrocardiogram (ECG).
- A blood sample (about 4 teaspoons of blood) will be taken for general medical screening. If you pass screening and participate in the study, this blood sample will also be used to assess blood markers of stress and immunological function.
- A urine sample will be taken to test for the presence of various drugs and, if you are female, to confirm that you are not pregnant.

If you successfully complete the screening procedures and are able to take part in the study, your participation will last about 8 to 10 weeks, with an additional follow up visit at about 6 months.

After completing the screening procedures, you will be asked to provide the names and contact information of three friends or family members for the purpose of telephone interviews about possible variations in your attitudes and behaviors during the course of the study. Before providing names, you will have the chance to find out if the friend and family member is willing to be called for these interviews. When we contact the people you select, we will tell them that you are taking part in the “States of Consciousness Research Project” at Johns Hopkins University School of Medicine and we will describe the questionnaire they will answer. It is your decision about what additional information about the study you would like to tell your friends, family members, or coworkers/colleagues at work.



We will notify your referring physician as to: 1) whether you enrolled in the study or not, and 2) if disqualified, why. Your referring physician will also be told if disqualification was based on severe depression or anxiety (for example suicidal thoughts).

Study Visits:

Preparation Sessions:

Over a period of about 2 weeks following screening, you will have 2 or more meetings with a trained and experienced “guide”. In this study, a guide is a study team member who will help you prepare before the day-long psilocybin sessions, and will teach you meditative and mental imagery procedures.

Psilocybin Sessions:

You will be asked to come to the Johns Hopkins Behavioral Pharmacology Research Unit (BPRU) for two day-long sessions.

On the morning of each day-long session you should eat only a light low-fat breakfast. Each session will last between 8 to 10 hours. When you come to BPRU, you will be asked for a urine sample to test for the presence of various drugs and, if you are female, to confirm that you are not pregnant.

You will then be given capsules containing psilocybin to swallow with water. During the session, you will spend your time in a room furnished with comfortable living room furniture including a large couch. One or more guides will be with you in this room throughout the session. For much of the time during the session, you will be invited to lie down on the couch with eye-shades and headphones through which you can listen to a pre-selected musical program. You will be encouraged to focus your attention inward to your inner experience. You may use a nearby restroom when needed.

At intervals throughout the day-long session your blood pressure and heart rate will be measured. Toward the end of the session you will complete various questionnaires to assess your mood and psychological state.

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For research purposes, an audio/video recording will be made of the day-long session. For the day-long sessions you must agree to remain at BPRU until the research team says you are ready to leave. At the end of the session you will be driven home by a trusted friend or relative, or a member of the BPRU staff. However, if the BPRU staff believes it is necessary for safety reasons, you will stay overnight. If you stay overnight, the BPRU staff will interview you before you return home.

The two psilocybin day-long sessions will take place about one month apart. The doses of psilocybin received in the two sessions will range anywhere from low to high. The doses of psilocybin in the two day-long sessions may or may not be the same. Neither you, your guide, nor the research staff will know what dose you received. However, the staff will have access to this information in case it is needed. The purpose of not telling you what dose you get is to keep you from being biased as to the possible effects you may experience.

Follow-Up Sessions:

You will meet with the guide and BPRU research staff for at least 1 to 2 hours within 1 or 2 days after each day-long psilocybin session to discuss any insights or issues that may arise during or after the sessions.

You will also be asked to return to the BPRU for a follow-up visit within about 1 month after each psilocybin session in order to complete some assessments.

During some of these meetings you will be interviewed and asked to complete various questionnaires and tests to assess your mood and psychological state. Audio recordings may be made of interviews in which you describe your day-long session experiences. You will be asked to provide brief written descriptions of your life, of your day-long session experiences, and of how these experiences affect your life.

A third follow-up assessment session will take place about 6 months after the second psilocybin. A blood sample (about 2 teaspoons) will be taken during each of the three follow-up sessions.

Requirements for continued participation: Please understand that you are expected to report to the research unit or to an office where preparatory or follow-up sessions may be held every time you are scheduled. You may be dropped from the study if you miss a scheduled session or appointment or if you are late. Your participation in the study may be stopped if one of the investigators feels that it is in your best interest to stop. You will not forfeit any rights or privileges if your participation is stopped for medical reasons. While you are in the study you must follow our regulations.

PSILOCYBIN MUSHROOM**COMFORTABLE STUDY ROOM**

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