

Who should Volunteer?

ELIGIBILITY REQUIREMENTS

Patients are eligible if they have a potentially life-threatening cancer diagnosis without CSN involvement and they seem to be experiencing anxiety or depressed mood as a result of their illness. Patients with and without disease progression are eligible, but patients with no disease progression are only eligible if at least 1 year has elapsed since their diagnosis. Patients who have decided not to undergo cancer therapy are also eligible. Our physician and screening staff will determine whether volunteers meet inclusion and exclusion criteria.

For individuals who are consented and screened, we will notify the referring physician: 1) whether the individual enrolled in the study or not, and 2) if disqualified, the reason for the disqualification.

Abbreviated inclusion and exclusion criteria -- these will be evaluated by the study investigators:

Inclusion criteria

Volunteers must:

- Be 21 to 70 years old
- Has or has had a cancer diagnosis that is potentially life-threatening. Patients with an active cancer (e.g. stage III or IV with a poor prognosis) or disease progression or recurrence are eligible. Patients who do not have an active cancer or disease progression or disease recurrence are only eligible if at least 1 year has elapsed since their diagnosis.
- Patients receiving chemotherapy, hormonal therapy, radiation therapy, biologic therapies may participate while receiving those therapies. Continuing hormonal therapy, chemotherapy, or radiation treatment is acceptable if the patient is tolerating the therapy or treatment in a sufficient fashion to allow administration of oral psilocybin.
- Have an ECOG performance status of 0, 1, or 2.
- Have anxiety or depressed mood -- Psychiatric diagnosis will be determined by BPRU staff.

Exclusion criteria

General Medical Exclusion Criteria

- Cancer with known CNS involvement, or other major CNS disease. In addition to diagnostic results provided by the referring physician, patients will undergo a neurological exam performed by our BPRU physician. Any patient with evidence of a focal deficit will be excluded.
- Patients will be excluded if they are in treatment in another clinical trial involving an investigational product or device.
- Hepatic dysfunction (GGT, AST, or ALT > 3 x upper limit of normal; Tot Bili > 2.0 mg/dl)
- Known paraneoplastic syndrome or “ectopic” hormone production by the primary tumor such as the patient could have or be at risk for hypercalcemia, Cushing’s syndrome, hypoglycemia, syndrome of inappropriate antidiuretic hormone secretion, or carcinoid syndrome
- Cardiovascular conditions: uncontrolled hypertension, angina, a clinically significant ECG abnormality (e.g. atrial fibrillation), TIA in the last 6 months, stroke, peripheral or pulmonary vascular disease (no active claudication)
- Blood pressure >140 systolic, >90 diastolic
- Epilepsy with history of seizures
- Renal disease (creatinine clearance < 60 ml/min using the Cockcroft and Gault equation)
- Insulin-dependent diabetes; if taking oral hypoglycemic agent, then no history of hypoglycemia
- Females who are pregnant, nursing, or are not practicing an effective means of birth control
- Currently taking on a regular (e.g., daily) basis: investigational agents, psychoactive prescription medications e.g., benzodiazepines), medications having a primary pharmacological effect on serotonin neurons (e.g., odansetron), or medications that are MAO inhibitors. Long-acting opioid pain medications (e.g. oxycodone sustained release, morphine sustained release -- which are usually taken at 12 hour intervals) will be allowed if the last dose occurred at least 6 hours before psilocybin administration; such medication will not be taken again until at least 6 hours after psilocybin administration.

Psychiatric Exclusion Criteria

- Current or past history of meeting DSM-IV criteria for Schizophrenia, Psychotic Disorder (unless substance-induced or due to a medical condition), or Bipolar I or II Disorder.

Psychiatric Exclusion Criteria

- Current or past history of meeting DSM-IV criteria for Schizophrenia, Psychotic Disorder (unless substance- induced or due to a medical condition), or Bipolar I or II Disorder.
- Current or past history within the last 5 year of meeting DSM-IV criteria for alcohol or drug dependence.
- Have a first or second degree relative with schizophrenia, psychotic disorder (unless substance induced or due to a medical condition), or bipolar I or II disorder.
- Currently meets DSM-IV criteria for other psychiatric conditions judged to be incompatible with establishment of rapport or safe exposure to psilocybin.

PSILOCYBIN MUSHROOM



COMFORTABLE STUDY ROOM



5510 NATHAN SHOCK DRIVE
BALTIMORE, MD 21224
USA
T: 410.550.5590