University of Colorado **Anschutz Medical Campus**

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SEEKS PARTICIPANTS FOR STUDY:
INDIVIDUALS SUFFERING FROM ANXIETY, DEPRESSION, OR EXISTENTIAL DISTRESS RELATED TO AN ADVANCED CANCER DIAGNOSIS

Principal Investigator: Stacy Fischer, MD

The purpose of this trial is to study the effects of psilocybin-assisted psychotherapy to treat anxiety, depression, existential distress, and quality of life for individuals with late stage or advanced cancer, as compared to an active placebo plus psychotherapy.

This multi-center trial will enroll 200 participants across two sites. During the randomized, controlled phase of the study, participants will receive either a single 25mg oral 'high' dose of psilocybin or an active placebo (100mg niacin), alongside psychotherapy. During the open-label phase, participants will have the opportunity to receive a single 25mg oral 'high' dose of psilocybin, alongside psychotherapy.

Total study participation will be approximately 43 hours across 7 months; the extended open-label phase is approximately 27 hours across 6 months. A participant will be required to do the following:

- Attend in-person visits for Screening, Baseline, medication administration, and final follow-up (two additional visits if participating in open-label).Visits will consist of:
  - Medical history and physical
  - Electrocardiogram (ECG)
  - Safety and laboratory assessments (including blood and urine testing)
  - Psychological assessments
- Attend study visits, consisting of psychological assessments or preparatory and integration sessions with study therapists (option to be virtual)
- Must have a support person to accompany them following the dosing session

For more information, please contact:

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