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Fred Hutchinson Cancer Center
University of Washington

Consent to take part in a research study:

A Phase 2a Study of Group Retreat Psilocybin Therapy for Cancer-Related Anxiety and Depression

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Emergency number (24 hours): 206-619-4367

Important things to know about this study.

You are invited to participate in a research study. The purpose of this research is to evaluate the safety, feasibility, and efficacy of a refined psilocybin dosing regimen for group retreat psilocybin therapy as a potential treatment for the anxiety, distress, and fear experienced by people living with metastatic cancer. You are being invited because you are living with metastatic cancer and are having symptoms of anxiety and/or depression.

People who agree to join the study will be asked to attend 10 visits over a total of 7 months. The study involves 3 pre-psilocybin psychotherapy group sessions ('preparation') and 1 individual session taking about 2 weeks. The psilocybin medication dosing session will take one full day. The follow-up integration psychotherapy sessions will occur about once a week for 4 weeks. These will have 2 individual and 4 group sessions. The 2nd, 3rd, and 4th integration psychotherapy sessions and all the follow-up questionnaires (6 months after the psilocybin medication dosing session) can be completed online.

The types of activities you will do in this study are as follows: The study intervention includes 3 preparation group psychotherapy sessions and 1 individual therapy session, which will involve discussing your experiences living with cancer and the symptoms and feelings associated with them. Next will be a medication dosing session which will take place at a rustic retreat center and will take about 8 hours total. Starting the following day will be the first of 4 integration psychotherapy sessions, which will involve discussing your experiences with the medication dosing session and the feeling and insights that may have arisen. The second, third, and fourth integration sessions will take place by secure videoconference (Zoom). The first and second sessions will have both a group and individual session. In addition to these study intervention activities, you will have screening blood tests, urine

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pregnancy testing for women of reproductive potential, questionnaires to fill out online, and an interview to discuss your experience in the study.

Although we have promising results from our prior work developing group retreat psilocybin therapy, we do not know for certain if psilocybin-assisted therapy will help treat depression, anxiety and existential concerns for you, and it could even make your condition/disease worse. Psilocybin-assisted therapy could cause side effects that are most likely during the psilocybin session that could even include strong feelings of fear, feelings that your body is dissolving, changes in visual perceptions, and feelings that you are communicating with people who are not present in the room, as described below in this form.

You do not have to join this study. You can choose to receive standard methods to treat cancer-related anxiety instead of participating in this study. We will give you details about the purposes, procedures, risks and possible benefits related to this study. We will explain other choices that you have. We will also give you any other information that you need in order to make an informed decision about joining this study.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

We invite you to join this research study.

We invite you to join this research study because you have metastatic cancer and have moderate or worse symptoms of anxiety and/or depression. Up to 18 people will join this study, and our experience is that not everyone who joins the study completes all the activities—sometimes medical issues make some study activities impossible.

Research is not the same as treatment or medical care. The purpose of a research study is to answer scientific questions.

You do not have to be in the study. You are free to say “yes” or “no”, or to drop out after joining. If you say “no,” you would have no penalty or loss of benefits. Whatever you decide, your regular medical care would not change.

Why are we doing this study?

We are doing this study to examine the side effects and benefits of a group retreat with psilocybin-assisted therapy. We want to find out if the psilocybin dosing regimen we think is best, based on two prior studies, is safe and feasible.

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We are studying psilocybin-assisted therapy. Psilocybin is a medication that is not currently approved by the Federal Drug Administration (FDA). Psilocybin occurs naturally in some varieties of mushrooms, but this study will use purified pharmaceutical grade psilocybin as part of a therapeutic process that involves 'preparation' psychotherapy for 4 sessions, a 'psilocybin session day' when the psilocybin is given, and follow-up 'integration' psychotherapy for 4 sessions.

How psilocybin works. Psilocybin acts on serotonin receptors in the brain to produce changes in perception and congnition. Psilocybin can also produce changes in blood pressure, heart rate, and symptoms of psychological distress such as anxiety or mood changes, although these changes are transient and generally gone in about six hours. Recent research suggests that psilocybin-assisted therapy requires active participation by the person receiving the therapy in ways similar to psychotherapy that does not involve psychedelics.

In this study, we want to learn what effects, good or bad, psilocybin in a group retreat experience has on people with metastatic cancer and anxiety. If you join this study, we would give you psilocybin and watch carefully for any side effects.

You are invited to consider participating in a research study designed to look at the use of psilocybin-assisted psychotherapy in a small group model for people living with metastatic cancer who have stable disease. The small groups will have up to 9 participants, with a team of up to 5 facilitators, but the most likely number is 8 participants and 4 facilitators. The number of participants might vary because of last minute issues, but there will always be at least 1 facilitator for every 2 participants. You would need to be prepared to participate in the small group discussions which involves some personal sharing about your journey with cancer in a supportive and safe context. All personal sharing will be held confidentially and would involve only as much as you wish to share. All participants in this study will receive psilocybin.

What research tests, procedures, and treatments are done in this study?

This section outlines the study procedures that you will experience if you decide to join this study. Taking part in this study, including follow-up, will occur over ~ 6 months. Study visits will take place in a suitable group room and by Zoom, and all self- reported questionnaires/interviews may take place online.

If you join this study, you will have a screening visit, preparation sessions, a psilocybin day session, and integration sessions. These are explained below.

Screening:

1. <u>Screening Visit: Will take place at a clinic at Harborview Medical Center or online and will take up to 90 minutes.</u>

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You will be asked to come to an initial screening visit and sign the study consent form. At the screening visit, vital signs, and a brief physical exam will be performed, and mental health exam. You will also be asked to complete a set of self-reported questionnaires, and you will be asked a series of questions by a study clinician. We will review a recent ECG, or perform an ECG if you do not have a recent one, to check your heart ,and we will do labs to screen for liver, kidney, or blood abnormalities that could affect your safety while taking psilocybin. A blood draw would be about 4 tablespoons of blood. You will also provide a urine sample for toxicology screen prior to your dosing session. For people of childbearing potential, a urine pregnancy test will be performed.

The screening will include a review of your cancer treatment history and the current status of your cancer. If you are on intravenous or oral cancer therapy, you will need to take a short break to participate in the research session. The exact length of the break needed will depend on your specific treatment. If you are on radiation therapy, you may be able to participate if you have completed your radiation at least one month prior to the psilocybin session and have recovered adequately to participate. We may request that we have a discussion with your oncologist to ensure that your study participation can be combined safely with your cancer therapy.

The screening will also include a review of your mental health history. You must have no pre-cancer history of a mental health diagnosis like depression, and cannot have been on antidepressants prior to your diagnosis of cancer. However, if you started taking antidepressants after your diagnosis of cancer to deal with cancer-related anxiety or depression, you may still be able to participate in this study.

If you live out of state and it is not feasible for you to come to Harborview Medical Center for an in-person screening visit, or if COVID precautions make it difficult to come for an in-person visit, you have the option of utilizing a secure video communication platform such as Zoom. We will ask you to send us your most recent physical exam, and bloodwork by fax or secure electronic records transfer. The research team will review this screening information collected from this visit to determine if you are eligible. If you are eligible, you may be invited to participate in this study. We will reassess eligibility after the screening appointment. If you are no longer eligible, we will withdraw you from the study.

For participants who are confirmed eligible:

1. Baseline questionnaires and interview: Following the screening visit, if it is determined that you are a good fit for the study, you will first complete a series of questionnaires that will ask questions about your experiences, your mood, and your physical and psychological symptoms. For example, the most sensitive questions ask you how to rate how you have been feeling in the past week using statements like “I get a sort of frightened feeling as if something awful is about to happen” (‘Yes, definitely and quite

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badly' to 'Not at all') and "I get a sort of frightened felling like butterflies in the stomach" ('Not at all' to 'Very Often').

You will also have an individual interview with a study clinician who will ask you questions about your psychological symptoms. In this interview, the most sensitive questions include "Are you concerned about the meaning in your life?" and "How much are you concerned about your own mortality?"

You will complete the questionnaires using a secure web-based platform and the interview by phone or video conference.

The study procedures after the screening visit will be small group sessions with 6-8 participants. The study intervention involves either staying at a retreat center near Seattle for 3 days, including 2 nights. The study will pay for all costs associated with the retreat but will not cover travel from your home to the retreat.

2. Preparation sessions (Visits 1, 2, 3, and 4) prior to the psilocybin dosing session will consist of virtual or in-person group meetings for a total of 5-6 hours. Visits 1, 2, and 3 will take place on a secure video platform like Zoom and will take 75-90 minutes per meeting. Preparation visit 4 will be in-person and is an individual session. These sessions will take place in clinic room outfitted for psychotherapy at the research clinic space or at a non-hospital retreat site.

   The purpose of these meetings is to discuss the drug sessions, understand your concerns, and for the study therapists to get to know individual participants and for the small group members to get to know each other. Each of the group preparation psychotherapy sessions will be conducted with you, the other participants in your small group, and the 2 lead study therapists who will follow you throughout the study (including the psilocybin session). One of the main study therapists will conduct your individual preparation session. These preparation sessions will inform you about what to expect with the medication dosing session (which will involve psilocybin) and will be an opportunity for you to review the experiences that you had as a person living with cancer.

   The study therapists will ask questions, listen carefully, and guide you towards developing an intention for your psilocybin dosing session, and for what to expect in the time after your psilocybin session and the integration sessions. All participants will be invited to share some aspect of why they wanted to participate in this study with the other participants. At all these sessions, the study therapists will remind participants that they should share only as much as they are comfortable sharing. The study therapists will be structuring the group in a way that maximizes psychological safety for every participant, but you will be hearing about other people's

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experiences with their cancer, and what they discuss could make you uncomfortable or remind you about your own situation.

After each of these preparation sessions you will be asked privately a short series of questions about whether you are suicidal, as a safety precaution, and if you are suicidal, you will be directed to appropriate evaluation and treatment.

In addition, each study participant will have one individual preparation session of 45 minutes with one of the study therapists before the psilocybin dosing session. During these individual sessions, you can discuss any issues that you did not wish to bring up in front of the entire group, and study therapists will not disclose anything you bring up to other members of the small group.

Study participants will be responsible for up to 2 hours of homework doing individual activities such as journaling, listening to music, and reflecting with a partner.

3. The psilocybin dosing session (Visit 5) will take place in a non-hospital site that will be a retreat center near Seattle. The investigators will review this session with you in detail. The psilocybin dosing session will take one full-day, 7-10 hours in duration. The following will take place at this visit: a urine pregnancy test will be conducted in all females of childbearing potential, blood pressure check before and after taking psilocybin. Should anyone test positive we will reschedule the medication session and participants will be encouraged to follow-up with their primary health care provider. Then, you will be interviewed. If the investigator believes the session should not proceed, the session will be cancelled or postponed.

   Initial dose of psilocybin. You will be given the psilocybin study drug at a dose that depends on whether you are taking antidepressant medication, such as an SSRI like sertraline or escitalopram. If you are taking an antidepressant, you will receive an initial dose of psilocybin 35 mg, by mouth. If you are *not* taking antidepressant medication, you will receive an initial dose of psilocybin 25 mg by mouth. During psilocybin dosing session, you will be in a comfortable room with other members of your small group and your 4-person therapist facilitation team for the entire duration of the effects of the medication. During this session, all therapists will be present, and there will be 2 backup therapists available if more assistance of any kind is needed. The therapists will take your blood pressure and pulse before the session starts and at least once during the session. There will be specially curated music playing, although you could wear earplugs if you wish to minimize the music.

   If during the psilocybin session, you do not feel much effect of the psilocybin, you may be able to have an additional ‘booster’ dose of 10 mg from 60-90 minutes after you take the initial dose of psilocybin. If you want

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to have a booster dose, which is not required, you will have to have a safety check by Dr Back that includes a brief physical exam with a blood pressure check. This would be done in a separate room from the main room where the session is taking place. You must pass the safety check to be able to take the booster dose.

Most people do not talk that much during the medication dosing session, but you may talk as much or as little as you wish, and the therapist team will be available if you wish to talk or would like individual support. During the session, you will lie on a mattress on the floor, wear eyeshades, and listen to a program of music through speakers, and be asked to focus your attention inward. All study participants will be encouraged to focus their attention inward. The eyeshades and music are intended to encourage this inward reflection.

If any person in the small group needs extra support, one of the study therapists will be assigned to be with that person 1:1 for as long as is needed; if this happens it is typically from 15 min to an hour. There will be a private space available for any study participant who needs privacy during the psilocybin session. The core facilitation team consists of 4 people. If there are any times when more than 4 people in the small group need individual support, there will be backup facilitators to provide extra assistance. The use of a backup facilitator is the main indicator we will use to determine whether this small group model is safe and feasible.

When the medication has worn off, you will be evaluated by one of the study therapists. When the study therapists feel that it is safe for you to leave, the session will be concluded with a short closing circle. A set of questionnaires to complete on paper will be given. If you are at the retreat center, dinner will be available and you will be staying overnight. If you are at a city location, you will need to arrange for someone else to drive you home or to where you are staying who can provide continuous contact. You will need to agree to wait for 48 hours after your release from the medication dosing session before returning to work.

4. Integration sessions (Visits 6, 7, 8, and 9) are post medication sessions that will take place after the psilocybin dosing session. The integration sessions will begin on the day following the medication dosing session, which will be in person. There will be one group and one individual session. The following integration sessions will start online about 1 week after leaving the retreat, and you will have three online integration sessions at 1 week intervals. The first of these sessions will have one group and one individual session. Each integration session will last 60-90 minutes in duration.
   These sessions will be conducted by your therapist facilitation team. The study therapists will ask you about your experience during the medication dosing session and will provide guidance designed to enable you to

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interpret what the experience might mean for you. The therapists will refrain from telling you what your experiences mean—the interpretation is ultimately up to you. After each integration session, you will be asked to fill out questionnaires to assess your psychological symptoms, some of which will be identical to the questionnaires you completed in the baseline set.

At four weeks after your medication dosing day, you will complete another set of questionnaires, including questions about suicidality. This information will be very similar to the baseline symptom questionnaires.

5. Follow-up procedures will take place remotely up to 6 months after your medication dosing session. You will have online questionnaires to complete and a brief individual interview by phone or videoconference with one of your study facilitators and this will take about 30 minutes to complete each time.

6. Recordings. All the small group sessions in this study will be video- and audio-recorded. If you prefer not to have your face shown in the video recordings, we can point the camera so that your face is not visible. However, participating in this study does require that you agree to the small group video- and audiorecordings. We will ask your permission to record your individual sessions, and you may decline to have those sessions recorded.

7. Remote procedures: Some of the study procedures will take place remotely, and the screening visit could occur remotely.

   The **screening visit** can occur remotely if you are out of the area and have recent screening labs to provide to the study team (in the last 2 months) as defined above. A urine pregnancy test will need to be ordered remotely for females of childbearing age.

   The **baseline questionnaires and interviews** will always take place remotely.

   Preparation Visits: (Visit 1, 2, 3, and 4). Visit 1,2, and 3 will be online and Visit 4 will be in person.

   Integration visits (Visits 6, 7, 8, and 9): Visit 6 will be in-person, and Visits 7, 8, and 9 will be by video-conference.

   The follow-up questionnaires at 2, 3, and 6 months after your psilocybin day can be done on a mobile device (phone or laptop) or by talking to study staff on the phone. There will be a 30 minute interview that can be done by video-conference.

   Dr Back will check your electronic medical records after the 6 month followup so that we can track how you are doing as long term follow-up.

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How long would you stay in this study?

If you join this study, you would stay in this study for about 6 months.

You would attend prep group sessions each week for 2 weeks prior to receiving psilocybin on the the medication dosing date. At the retreat you will have group sessions (the third prep session) and an individual session, followed by the psilocybin session. After the psilocybin session, you would have one integration group session at the retreat, and three more integration visits over the next 6 weeks, with the last questionnaires at 6 months after the psilocybin session.

Doctors could take you out of this study at any time. This would happen if:

- They think it is in your best interest not to continue in the study.
- You are not able or willing to follow study procedures.
- The whole study is stopped.

If you withdraw from the study for any reason, previously collected information would remain in the study records and would be included in the analysis of results. This information could not be removed from the study records.

Long-term follow-up means keeping track of someone's medical condition after the 6 month questionnaires. We would like to consult your electronic medical record every 6 months to see how you are doing. We will not need to contact your oncology team directly. This information will help us learn about whether psilocybin therapy might affect the long-term experience of living with cancer.

You do not have to allow us to check your medical records for long term follow up. You could say "yes" or "no". Either way, you could still join this study. If you drop out of the study, you would be asked if we could contact you by phone or email every 6 months to see how you are doing.

If you choose not to join long-term follow-up, you would not be contacted regularly, but we might still need to contact you for some other reason.

What are the side effects (risks)?

In this part of the consent form, we describe the side effects we expect from the tests and treatments in this study. Psilocybin-assisted therapy could cause side effects we do not know about yet. We carefully watch everyone in the study for side effects.

If you join this study, we would tell you if we discover new side effects that could affect you.

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This form lists side effects of *individual* drugs. We will take care to collect all of the information we need to ensure that you can safely participate in this study before initiating any of these procedures. You will not be able to participate in this study if you have an unstable medical or neurological condition, or if your psychiatric condition is sufficiently concerning that the psychiatrists associated with our clinic think it would be unsafe or unwise for you to participate in this study.

Side effects may be mild or very serious. Medicines could be given to help lessen side effects. Many side effects go away soon after you stop taking psilocybin. In some cases, side effects can last a long time or never go away. There also is a risk of death.

The psilocybin used in this study is manufactured by Filament Health, which provides researchers with psilocybin that has been purified from mushrooms and analyzed so that you will be getting an exact dose of 25 mg of psilocybin.

Likely side effects of psilocybin are:

- anxiety.
- changes in thought (experiencing thinking speeding up or slowing down).
- changes in motion perception.
- changes in time perception (time slowing down or speeding up).
- depersonalization (feeling as if one is “outside oneself”).
- derealization (feeling as if the world is unreal, or as if one is “in a dream”).
- dizziness.
- fatigue.
- slowed heart rate.
- headache.
- impaired concentration.
- inattention.
- mood lability (rapid and sometimes profound changes in mood).
- nausea.
- nervousness.
- parasthesias (strange bodily sensations or feelings).
- perceptual alterations (general).
- altered time perception.

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- alteration in visual perception (distortions, illusions and imagery seen with eyes open or closed).
- unusual thought or feelings about the self or the world.
- pupillary dilation.
- moderate increases in blood pressure.
- moderate increases of heart rate.

Less likely side effects of psilocybin are:

- feelings that you are being plotted against, or that others are out to get you.
- losing awareness that you are in a therapeutic situation.
- mild insomnia for the first night or two after medication session.

Rare but serious side effects of psilocybin are:

- panic.
- delusion.
- cognitive impairments.
- severe psychological reaction that is almost like psychosis.
- visual disturbances including halos, distorted colors or bright lights (this is called Hallucinogen Persisting Perception Disorder).

These effects are generally acute and last no longer than six hours, except for very rare prolonged visual disturbances that are noticeable but do not affect daily function.

In recent studies, these reactions have been managed with reassurance and breathing directed by the study therapist. However, if medication is required to treat any uncontrollable anxiety or agitation, the study physician may perform an assessment and prescribe a small dose of lorazepam, a benzodiazepine medication. While your blood pressure may increase, it is extremely rare to require any treatments for high blood pressure during a psilocybin session.

At the end of the medication dosing session, you will be at the retreat center, and you will be accompanied to dinner and then to your room after dinner. On the day following the medication dosing session, you will fill out a number of questionnaires about your experience and about how well you felt supported by the facilitators. You may return to work not earlier than 48 hours after the medication dosing session is over.

If you have a mental health emergency, we will involve hospital staff who will enact procedures to keep you safe.

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Adverse events will be assessed weekly from the time of preparation visit 1 through week 4 and repeated during the open-label study. During the psilocybin medication session, participants will be assessed continuously, and the facilitation team and backup staff will be available at all times to call for support or medical assistance if required. The study therapists will have immediate access to the PI or a designated physician to assess any problems, or to clear you for discharge from the session room. After the psilocybin session, you will be completing online surveys and have brief weekly phone calls with a member of the study team.

Study therapists are trained on the protocol and are in communication with the Principal Investigator, who is available to assess participants during the medication session. This study is being monitored by a Medical Monitor and the Principal Investigator, Dr. Back. Both have the ability to stop this study at any time if it is deemed necessary. Because this treatment is considered investigational and has not received FDA approval, there may be risks that we do not know about at this time.

Reproductive risks

Taking psilocybin may involve unknown risks to an embryo, fetus (unborn baby) or nursing infant. Therefore, you could not join this study if you are pregnant, if you are planning to become pregnant, or if you are breast-feeding.

If you join this study and are a person of childbearing potential, you would have to use an effective method of birth control from the time this form is signed until at least 1 day after the last dose of psilocybin. You will need to have a negative pregnancy test at the time you enter the study and on the day of the psilocybin administration. You should discuss this with the study doctor or a member of the study staff. In addition, if you are receiving chemotherapy, your oncology team may have additional guidance about birth control.

If you became pregnant after joining this study, you would have to notify the study doctor immediately. Participation in this study would end, and you would receive counseling and follow-up throughout the pregnancy and for about 6 months after the child is born.

If you have a positive pregnancy test, you would not be included in the study.

Non-physical risks

- The risks of screening include any stress or discomfort associated with a brief physical examination or answering questions that may be sensitive in the questionnaires or the symptom interview. You may find answering these questions to be inconvenient, uncomfortable, or upsetting. The symptom interviews may include some personal

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questions about previous experiences. You will be able to complete these activities in a private room, and you may decline to answer any questions that make you uncomfortable. You can discuss any concerns with someone on the research staff, and you will have access to clinicians trained to address these issues. You may take short breaks if you need them.

- The risks of the preparation sessions are that the study therapists may ask personal questions that evoke personal feelings from your experiences living with cancer, including feelings that may still be present, and this may be uncomfortable or unpleasant. You may also hear about other people's experience and this may be uncomfortable or unpleasant. These sessions will be structured by the study therapists, and no one will be expected to talk about sensitive details of their treatment or feelings. At all times you may share as much or as little as you feel comfortable with, and you may decline to answer any questions or even leave the session at any time.
- The risks of the integration sessions are that the study therapists may ask questions that evoke uncomfortable or unpleasant memories from your medication dosing session or your past experiences prior to the medication dosing session. You may decline to answer any questions or stop the sessions or recordings at any time.
- Most procedures will take place in a small group setting with other participants. Others who participate in this study will know that you have metastatic cancer as this is one of the criteria to participate in the study. We will ask all participants to respect others' privacy and confidentiality, but we cannot guarantee this. You may not wish to have anyone know that you are participating in this study. To help protect your confidentiality, we will try to use the most secure forms of communication available, and all data will be entered using a study code rather than identifying information. We will follow high standards for ensuring confidentiality and use all known methods of data security handling to reduce risks to your confidentiality.

Other possible side effects

We will need to draw blood for routine laboratory testing. The baseline labs are necessary to review your current health prior to participation. The risks or side effects associated with taking blood from a vein are:

- bruises.
- local irritation (swelling) with itching.
- slight bleeding.
- inflammation.
- In rare cases, it may result in thrombosis (blood clots) or an infection.

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- Insertion of the needle can cause localized pain or pain at the needle puncture site.
- slightly weak or lightheaded, or faint.
- Occasionally, in rare cases, inserting the needle can result in injury to a nerve.

We minimize this risk by having skilled nurses and phlebotomists do our blood drawing. In the very rare event of a puncture-site infection, the study staff will aid you in treating the site.

Interruptions in existing treatments or delay in seeking other treatments

In order to participate in this study, you may have to change any treatments you are currently receiving for your cancer or your symptoms. If you are receiving oral chemotherapy you will need to take a 2 day break, with the permission of your oncologist. If you are receiving iv chemotherapy, you will need to arrange a schedule that provides at least a week before the retreat and a week after the retreat, 2 weeks total, during your chemotherapy, again with the permission of your oncologist. Dr Back will be available to discuss issues with your oncologist and answer any questions they may have.

You will need to refrain from starting any new antidepressant medications that act on the serotonin system in the body during the entire study period, until you have completed the questionnaires and symptom interview that occur four weeks after the medication dosing session.

Your participation in the study will be terminated at any time if your medical condition significantly worsens, or if your psychological condition changes such that you feel suicidal.

Safety Plan for Suicidality: During all study visits a trained clinician will assess your well-being – responses, intent, plan, etc. while administering the C-SSRS (Columbia Suicidality Severity Response Scale, which all clinicians have received training on) and if there is a serious concern they will either ask you to meet with or call the PI (Dr Back), or go to the nearest ER, or call 911. If necessary, we will also call your treating clinician and/or your emergency contact. As part of the consent, you are required to designate an emergency contact person and provide your treating clinician's contact information. We will coordinate with your treating clinician, in regard to local plan for such emergencies so our study team can follow this plan should an emergency situation arise. The study investigators will take steps to reduce and manage any physical or psychological changes that could be unpleasant or harmful.

What are the benefits?

We are testing a psilocybin group retreat to see its effects on people with depression, anxiety and existential distress during metastatic cancer. We do not

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know if this study would help you. You might get better if you participate, but your condition could stay the same or even get worse. Although the study may not benefit you directly, we hope the information we learn may help people in the future who are living with cancer and have *depression, anxiety and existential distress.*You have other choices besides this study.

You do not have to join this study. You are free to say “yes” or “no”. Your regular medical care would not change if you decide to say “no”.

You have other choices for treatment. Each of these choices has risks and benefits. You should talk to your doctor or healthcare provider about these choices.

Other choices include: psychotherapy and medication treatment with FDA-approved antidepressants.

Protecting Privacy as an Individual and the Confidentiality of Personal Information

If you join this study, some people or organizations might need to look at your medical records and research records for quality assurance or data analysis. They include:

- Researchers involved with this study.
- Healing Hearts Healing Minds Foundation (funding the study) and their agents.
- Filament Health / Psilo Scientific Ltd, providing study drug psilocybin.
- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Center IRB and University of Washington Human IRB. An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- Fred Hutchinson Cancer Center and University of Washington.
- Office for Human Research Protections, Food and Drug Administration, and other regulatory agencies as required.

We will do our best to keep personal information confidential. But we cannot guarantee total confidentiality. Personal information may be disclosed if required by law. For example, we are required to report certain diseases and infections to public health authorities. We are also required to report suspected abuse or neglect of children and vulnerable adults. Workplace safety rules may require health workers to contact you about lab tests. Or a court may order that study information be disclosed. Such cases are rare.

We will not use personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

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At the start of the study, this research is covered by a Certificate of Confidentiality from the U.S. government. This Certificate means that generally we would not have to give out identifying information about you even if we were asked to by a court of law. We would use the Certificate to resist any demands for identifying information. The Certificate may not last the duration of the research. Talk to the study doctor if you have questions about this.

We could not use the Certificate to withhold research information if you give written consent to give it to an insurer, employer, or other person.

This protection has some limits. We would voluntarily provide the information:

- To a member of the federal government who needs it in order to audit or evaluate the research.
- To the funding agency and groups involved in the research, if they need the information to make sure the research is being done correctly.
- To the federal Food and Drug Administration (FDA), if required by the FDA.
- To someone who is accused of a crime, if they believe that our research records could be used for defense.
- To authorities, if we learn of child abuse, elder abuse, or if participants might harm themselves or others.

Data will be confidential to the extent possible as described here. Given the group nature of this research, we cannot ensure confidentiality of your participation. Others who participate in the study will know that patients have metastatic cancer. We ask participants to keep information about the participation of others in this study confidential.

Information about the study visit, including information about your laboratory results, blood draws, and urine test will be stored as research records and will not be stored in a medical record. Your medical record will not identify you as a participant in this study. Your identifiable information and study records will be kept separate. The link between your identifiers and the research data will be destroyed after the records retention period required by state and/or federal law. Information about you will be kept in locked offices, on password-protected computers, or in secure clinic files on a University of Washington secure server, or in locked cabinets on a locked unit. This includes audio or video-recordings, as applicable. During the course of this study, it is possible that information about your health and safety will need to be shared with others to keep you safe.

As a part of the safety plan for this study, you will designate an emergency contact person and provide your treating clinicians' contact information. We will

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coordinate with them about any local plan for an emergency. If we learn that you intend to harm yourself or others, we must report that to medical staff.

To support your care, you can provide permission to have one of the study therapists speak with a member of your clinical care team. A study therapist would provide information learned from study visits, including information about the presenting issues, what happened with the psychedelic treatment, and what remains to be worked on.

Would we pay you if you join this study?

You will not be paid if you join this study.

If you are having issues covering travel expenses please talk to the study team.

Would you have extra costs if you join this study?

There are no extra costs for being in this study.

What if you get sick or hurt after you join this study?

For a life threatening problem, call 911 right away or seek help immediately. Contact your study doctor when the medical emergency is over or as soon as you can.

For all other medical problems or illness related to this research, immediately contact Anthony Back MD (206-619-4367). They will treat you or refer you for treatment. The costs of the treatment may be billed to you or your health insurance just like other medical costs, or it may be covered by the UW's discretionary Human Subjects Assistance Program (HSAP), depending on a number of factors. The researcher may request HSAP coverage by following established procedures. If you wish to request HSAP coverage yourself, contact the researcher or the UW Human Subjects Division at hsdinfo@uw.edu or 206-543-0098. You may also call collect to the UW Human Subjects Division at 206-221-5940 if you do not otherwise have access to a telephone. Ask the researcher if you would like information about the limits and conditions of the HSAP. The UW does not normally provide any other form of compensation for injury. However, the law may allow you to seek payment for injury-related expenses if they are caused by malpractice or the fault of the researchers. You do not waive any right to seek payment by signing this consent form.

You or your insurer will be billed for treatment of problems or complications that result from your condition or from standard clinical care.

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You would not lose any legal right to seek payment for treatment if you sign this form.

What will my information be used for?

During this study, if the researchers learn new information that may be important to your general health or to your disease or condition, they will share that information with you. You will have the opportunity to receive any results from research tests that are clinically relevant, which would include abnormal results of blood draws, or urine test. Your information and tissue samples (such as blood or urine) will be used for the purposes of this study . Your samples will not be shared or used for commercial profit.

Will my information ever be used for future research?

In addition to the planned uses described above, we might remove all identifiers and codes from your information. We could then use or share them with other researchers for future research. If you do not want your anonymous information used for other projects, you should not participate in this study.

If we do share your information with others, we would not be able to stop the future research, even if you asked later. There will be no way to link the information back to you. We will not contact you or otherwise inform you before we share your information for future research.

Your rights

- You do not have to join this study. You are free to say “yes” or “no”.
- If you get sick or hurt in this study, you do not lose any of your legal rights to seek payment by signing this form.
- During the study, we might learn new information that you need to know. For example, some information may affect your health or well-being. Other information might make you change your mind about being in this study. If we learn these kinds of information, we would tell you.
- If you join this study, you would not have to stay in it. You could stop at any time (even before you start). Your regular medical care would not change. You would have no penalty for stopping, but it would be better not to join the study if you think that you would change your mind later.
- If you decide to drop out, we would want you to tell the study doctor. The doctor could tell you about the effects of stopping psilocybin. You and the doctor could talk about the follow-up care and testing that would help the most.

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A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Your responsibilities

If you join this study, you would have some responsibilities.

- Follow the schedule of study visits and procedures.
- Take study medications as directed.
- Prevent pregnancy.
- Tell us about side effects.

For more information

If you have questions or concerns about this study, you can talk to your doctor anytime. Other people you could talk to are listed below.

If you have questions about:	**Call:**
This study (including complaints and requests for information)	206-619-4367 Dr. Anthony Back
If you get sick or hurt in this study	206-619-4367 Dr. Anthony Back
Your rights as a research participant	206-667-5900 or email irodirector@fredhutch.org (Director of Institutional Review Office, Fred Hutchinson Cancer Center) 206-543-0098 (Human Subjects Division, University of Washington)
Your bills and health insurance coverage	206-606-6226 (Fred Hutch Patient Financial Services)

Emergency number (24 hours): 206-619-4367

Do you agree to take part in the long term follow up?

(circle one)

YES **NO**

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Signatures

Please sign below if you:

- have read this form (or had it read to you);
- had the opportunity to ask any questions you have;
- had the opportunity to discuss the research with the person obtaining consent; and
- agree to participate in this study.

Participant:

Printed Name	Signature	Date

Researcher's statement

I have discussed the research study, including procedures and risks, with the person signing above. A copy of the signed consent form will be given to the participant.

Person obtaining consent signature:

Printed Name	Signature	Date

Protocol: BACK007
Current consent version date: 11 Feb 2026
Copies to: