Informed Consent/Authorization for Participation in Research

Title of Research Study: **TRIP** – **TR**eatment to **I**mprove Depression and/or Anxiety using **P**silocybin-Assisted Psychotherapy in Patients with Advanced Cancer on Maintenance Therapy

Study Number: 2022-0170

Principal Investigator: Moran Amit

_____ _____
Participant's Name Medical Record Number or Study ID

Key Information

The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are invited to take part in a research study because you are being treated for advanced cancer and are experiencing challenges with your mood.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The goal of this clinical research study is to learn about the feasibility, safety, and effects of psilocybin-assisted psychotherapy on depression and/or anxiety in patients who are being treated for advanced cancer.

In this study, psilocybin is being compared to a placebo. A placebo is not a drug. It looks like the study drug but is not designed to treat any disease or illness. It is designed to be compared with a study drug to learn if the study drug has any real effect. In this study, Niacin (a B vitamin) is being given as the placebo.

This is an investigational study. Psilocybin is not FDA approved or commercially available. It is currently being used for research purposes only.

Psilocybin belongs to a class of compounds called classic hallucinogens. Hallucinogens can alter moods and thoughts. The study doctor will explain in more detail how psilocybin and psilocybin-assisted psychotherapy works.

How long will the research last and what will I need to do?

You are expected to be in this research study for 6 months. You will be randomly assigned to receive either psilocybin or placebo.

Before your first dose of psilocybin/placebo, you will have 2-3 psychotherapy sessions over 1 to 2 weeks to help prepare you. Then you will receive 1 dose of psilocybin/placebo, followed by 2-3 psychotherapy sessions over 1 week. The second dose of psilocybin/placebo will then be given and again followed by 2-3 psychotherapy sessions over 2 weeks. Follow-up sessions will be done at 2 weeks and at 2 months after completing the treatment.

You will be asked to have tests and procedures during this study (such as EKGs, blood draws, and imaging scans) and to answer questionnaires about your quality of life, levels of depression and anxiety, and experience receiving psilocybin/placebo.

More detailed information about the study procedures can be found under ***"What happens if I agree to be in this research?"***

Is there any way being in this study could be bad for me?

Single doses of psilocybin have been used in controlled settings without serious side effects. The most common side effects include confusion, fear, hallucinations, headache, high blood pressure, nausea, and paranoia. These side effects tend to go away after the session. Despite being a controlled substance in the US, the risk for abuse is low. Previous studies show that a carefully monitored administration of psilocybin to healthy volunteers within an experimental setting does not increase the risk for subsequent abuse of psilocybin or other illicit drugs.

Among the most often reported long-term side effects of hallucinogenic drug use is a sudden and unexpected reoccurrence of all or certain aspects of the hallucinogenic effects. Previous reports support the view that troubling perceptual abnormalities rarely occur in a therapeutic or research context, where subjects are carefully screened and

monitored, and appropriate doses of pharmaceutical quality drugs are given.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

Psilocybin-assisted psychotherapy may help to improve your depression and/or anxiety. Future patients may benefit from what is learned. However, it cannot be promised that there will be any benefits to you or others from your taking part in this research.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate, not participate, or discontinue participation at any time without penalty or loss of your regular benefits.

Instead of being in this research study, you may choose to receive psychotherapy alone or receive FDA approved anti-depressant drugs such has SSRI's. Other integrative medicine options such as psychologic treatment are also available. You may receive other investigational treatment, if available. These alternative treatments have risks and benefits that may be the same or different than those in this research study. The study doctor can discuss these alternative treatments, including their risks and benefits, with you.

Another alternative is not participating in the study.

Detailed Information

The following is more detailed information about this study in addition to the information listed above.

Who can I talk to if I have questions or concerns?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the study chair, Dr. Moran Amit, at 713-794-5304.

This research has been reviewed and approved by an Institutional Review Board ("IRB" - an ethics committee that reviews research studies). You may talk to them at (713) 792-6477 or IRB_Help@mdanderson.org if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.

- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be in this study?

It is expected that about 30 people at MD Anderson will be enrolled in this research study.

What happens if I agree to be in this research?

Screening Tests

Signing this consent form does not mean that you will be able to take part in this study. The following screening tests will help the doctor decide if you are eligible:

- Blood (about 5 tablespoons) will be drawn for routine and immune system tests.
- Urine will be collected for drug screening.
- You will answer a questionnaire about your risk of suicide. It will take about 5 minutes to complete and will ask you about your current thoughts of self-harm and your history of suicide attempts or self-injurious behavior. If needed, you will be referred to psychiatry and psychology resources.
- You will have a psychiatric interview with a psychiatrist to talk about the challenges you are experiencing with your moods and to confirm your diagnosis. The interview will take about 30minutes.

The study doctor will discuss the screening test results with you. If the screening tests show that you are not eligible to take part in the study, you will not be enrolled. Other treatment options will be discussed with you.

Baseline Visit

If you are found to be eligible to take part in this study, you will have a baseline visit for additional tests and procedures:

- You will have an EKG to check your heart function.
- Urine will be collected for drug screening. If you can become pregnant, part of this sample will also be used for a pregnancy test. To take part in this study, you must not be pregnant.
- You may have an fMRI scan of your brain. If you are not able to have an fMRI, you may still be able to participate in the study and the fMRI will not be performed. This scan will be used as a baseline to compare against fMRI scans done later in the study to look for changes in neuroplasticity. Neuroplasticity is the ability of the brain to change its structures through growth and reorganization.
- You will answer questionnaires about your: symptoms caused by the disease and/or treatment, emotions, anxiety, depression, quality of life, well-being, overall health, and risk of suicide. They will take about 30-45 minutes total to complete.

Preparatory Psychotherapy Sessions

On Days 1 and 6, you will have preparatory psychotherapy sessions. The goal of these sessions is to connect with your therapy team (a therapist and their assistant), discuss your goals and concerns, learn about the effects of psilocybin, and receive training to manage anxiety. Each session will last about 1½ to 2 hours.

During the preparatory sessions, you and your therapy team will discuss your life-expectancy, existential outlook, beliefs about death and afterlife, worldview, and goals or desires you may have. The team will also:

- Teach you mindfulness/grounding techniques and breathing exercises.
- Review your history or any past experiences similar to psilocybin-assisted psychotherapy, including if you have used hallucinogens in the past, as well as any past mystical or transformative experiences.
- Review with you the expectations for the psychotherapy sessions during this study and address any concerns you may have.
- Give you instructions for dietary, medication, and substance restrictions leading up to your psilocybin/placebo doses. You will be asked to not drink alcohol for 24 hours before receiving psilocybin/placebo. There are no restrictions on drinking alcohol after the psilocybin/placebo session.

You will work with the same therapy team during this study. The sessions will also be monitored by Dr. Sujin Ann Yi, a clinical psychologist in the Department of Palliative, Rehabilitation, and Integrative Medicine. Your therapy sessions will be video recorded.

You will also answer the questionnaire about your risk of suicide during these sessions.

Study Groups

After completing the preparatory psychotherapy sessions, you will be randomly assigned (as in the flip of a coin) to 1 of 2 groups. This is done because no one knows if one study group is better, the same, or worse than the other group. You will have an equal chance (50/50) of being assigned to either group:

- If you are in **Group 1**, you will receive psilocybin (25 mg).
- If you are in **Group 2**, you will receive the placebo (100 mg of Niacin).

Neither you nor the study staff will know if you are receiving psilocybin or the placebo. However, if needed for your safety, the study staff will be able to find out what you are receiving.

After the 2-month follow up (described below), you will be told which group you were assigned to. If you were assigned to Group 2, you will be offered to receive 2 sessions of psilocybin with counseling. This will be discussed with you.

First Psilocybin/Placebo Session

On Day 7, you will receive your first dose of psilocybin/placebo. You will be asked to eat only a light breakfast (low fat and no more than 400 calories) before the session.

Before receiving psilocybin/placebo, you will have the following tests:

- Blood (about 1½ tablespoons) will be drawn for routine and immune system tests.
- If you can become pregnant, a urine sample will be collected for a pregnancy test.

Psilocybin/placebo is given by the research nurse. It will be in pill form, and you will take it by mouth. The session will take place in a comfortably furnished room in the Integrative Medicine Center at MD Anderson. You will be encouraged to sit or lie down on the couch with eye shades (if desired) and headphones. You will be instructed to use the techniques you learned in the preparatory therapy sessions and investigate any unwanted emotions you may feel. Your therapy team will stay with you during your psilocybin session. Efforts will be made to talk as little as possible, but supportive therapy will be provided as needed.

Your blood pressure and pulse will be measured before you receive psilocybin/placebo and then again at 1, 2, 3, and 6 hours after you receive psilocybin/placebo. If the doctor thinks it is needed, your blood pressure and pulse may be measured more often.

When the effects of psilocybin/placebo have ended (about 7-8 hours after dosing), you will answer questionnaires about your experience and state of consciousness during the session. For example, you will be asked about the emotions you felt and if you had a mystical-type experience or lost sense of time and space. They will take about 10 minutes total to complete. You will also answer the questionnaire about your risk of suicide.

Your psilocybin/placebo session will be video recorded. If you have a negative hallucinatory experience that you remember as “real,” the recording can disprove this.

You may have a friend or family member with you during the psilocybin/placebo session. You will need a responsible adult available to take you home after the session.

On Day 8, between Days 9-10, and/or between Days 10-13 as needed, you will have psychotherapy sessions. These sessions will be similar to your preparatory sessions, but they will focus more on talking about what you experienced during the psilocybin/placebo session and monitoring you for side effects. You will also answer the questionnaire about your risk of suicide during these sessions.

Second Psilocybin/Placebo Session

On Day 14, you will receive your second dose of psilocybin/placebo. Then, you will have psychotherapy sessions on **Day 15 and between Days 16-20**. You will have the same tests and procedures as described above in the "First Psilocybin/Placebo Session" section.

Follow-Up Visits

At 2 weeks (on Day 28) after your second psilocybin/placebo session, you will have follow-up visits. At these visits:

- You will answer questionnaires about your: symptoms caused by the disease and/or treatment, emotions, anxiety, depression, quality of life, well-being, overall health, and risk of suicide. They will take about 30-45 minutes total to complete.
- You may have an fMRI scan of your brain.
- At 2 months only:
    - You will answer questionnaires about your: symptoms caused by the disease and/or treatment, emotions, anxiety, depression, quality of life, well-being, overall health, and risk of suicide. They will take about 30-45 minutes total to complete.
    - You will be told which study group you were assigned to. If you were assigned to Group 2, you will be offered to receive 2 sessions of the therapeutic psilocybin dose with counseling. This will be discussed with you.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for the following:

- Tell the study team about any symptoms or side effects you have, follow study directions, and come to all study appointments (or contact the study team to reschedule).
- Tell the study doctor/study staff about all medications that you are taking or plan to take, including prescription and over-the-counter medications, supplements, vitamins, and herbal remedies. You may not be allowed to take certain medications during this study.

What happens if I say yes, but I change my mind later?

You can leave the research at any time; it will not be held against you.

You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you withdraw from this study, you can still choose to be treated at MD Anderson.

If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor who can then decide if you need to have any visits or tests to check on your health.

If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the study doctor can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

Is there any way being in this study could be bad for me? (Detailed Risks)

While on this study, you are at risk for side effects. You should discuss these with the study doctor. The more commonly occurring side effects are listed in this form, as are rare but serious side effects. You may also want to ask about uncommon side effects that have been observed in small numbers of patients but are not listed in this form. Many side effects go away shortly after treatment is stopped, but in some cases side effects may be serious, long-lasting or permanent, and may even result in hospitalization and/or death.

Side effects will vary from person to person, and some may occur after you have stopped receiving treatment. Tell the study staff about any side effects you may have, even if you do not think they are related to the study drugs/procedures.

Psilocybin Side Effects

Medical Risks
Increased heart rate and blood pressure are common during the psilocybin session but are rarely clinically significant. Study staff will take blood pressure measurements using a blood pressure cuff, and the study doctor will administer blood pressure medications if needed. Other possible side effects during the psilocybin session include:

• transient (temporary) mild headache • dizziness • weakness	• drowsiness (feeling sleepy) • tremor (shaking) • nausea	• tingling sensations • blurred vision • dilated (enlarged) pupils.

The following are the most commonly reported physiological reactions, which will be monitored by study staff and typically resolve by the end of the dosing session:

• cardiovascular changes (including increased blood pressure and heart rate)	• headache	• nausea

Psychological Risks
The primary effects of psilocybin administration are psychological and include changes in perception, thinking, and emotion. Depending on the individual, these changes can range from very mild to extremely intense. You may experience powerful emotions, both pleasant and unpleasant. Your sense of time may be altered, such that time seems to pass more quickly or slowly than usual. There is a risk that you may find some of these effects frightening.

The most common psychological side effects of psilocybin include:

• anxiety • panic • experiencing sensations that are not physically real (hallucinations) or false or unrealistic beliefs (delusions); these are known as psychotic symptoms	• difficulty concentrating, verbally communicating, and in general a person's thought process may feel disoriented	• dysphoria (mood swings) • depression

Note: These symptoms (anxiety, depression) are generally temporary, and normally go away when the effects of the drug wear off (within 6-8 hours), but infrequently anxiety, depression, and other forms of psychological distress can continue for days to weeks after the medication session.

Very rarely, psychotic symptoms (having false beliefs - delusions, sensing things that are not real hallucinations, or having ideas that do not make sense [disorganized thoughts]) have lasted for more than 48 hours in research participants treated with other hallucinogens. Although this has not been reported in trials using psilocybin, this may be a possible risk with psilocybin as well.

HPPD ("flashbacks") is a disorder in which perceptual symptoms experienced during the medication session are re-experienced after the session is over. This disorder is believed to quite rare, but how often this actually occurs is unknown.

Although psilocybin is not known to produce addiction, it can be misused or abused. It is theoretically possible that you could develop a pattern of psilocybin misuse due to your experience in this trial; although, this has not been reported in previous trials.

You will never be left alone in the session room, and study therapists will always be available to keep you safe and assist you if you need support. Study therapists will discuss all aspects of the dosing session with you before your session and answer any questions.

After 3 weeks, the following serious side effects were seen with psilocybin:

- Suicidal behavior without self-injury (fewer than 5% of patients)
- Adjustment disorder with depressed mood (fewer than 1% of participants)

During the treatment sessions, you may be more suggestible (easily influenced) and/or vulnerable after taking psilocybin due to changes in your judgement and cognitive function (your ability to think and reason) that may continue for hours.

Niacin Side Effects

It is not known how often the following side effects may occur:

• swelling • low blood pressure (possible dizziness/fainting) • irregular or fast heartbeat • flushing • chills • dizziness • headache • migraine • difficulty sleeping • nervousness • burning sensation of skin • darkening of the skin • change of skin color • areas of dark, thick, velvety skin in body folds and creases • skin rash • itching • hives • dry skin • sweating	• high blood sugar (possible diabetes) • low blood levels of phosphate (possible bone damage) • abnormal blood test (possible pancreas damage) • abdominal pain • diarrhea • upset stomach • burping • gas • nausea • vomiting • stomach ulcer • low platelet count • increased risk of bleeding • liver damage • abnormal liver tests (possible liver damage and/or yellowing of the skin and/or eyes)	• muscle damage, breakdown, weakness, and/or pain • leg cramps • weakness (possibly caused by muscle damage) • pain • abnormal sensation (such as pins and needles) • blurry vision • swelling of the retina (possible vision loss) • lazy eye • high blood levels of uric acid (possible painful joints and/or kidney failure) • cough • difficulty breathing

Niacin may cause low blood cell counts (platelets). A low platelet count increases your risk of bleeding (such as nosebleeds, bruising, stroke, and/or digestive system bleeding). You may need a platelet transfusion.

Rare but serious (occurring in less than 3% of patients)

• fainting • liver failure	• breakdown of muscle tissue (possible kidney failure)	• allergic reaction that may be life threatening (such as difficulty breathing, low blood pressure, organ failure, tissue swelling, voice box spasm, and/or blistering skin rash)

Other Risks

This study uses **psychotherapy** that is meant to lower depression and anxiety and improve mood. There are potential risks for any type of psychotherapy. Therapy is often about making changes or about looking at yourself differently. This can make some people uncomfortable. Thinking about your feelings and emotions may make you feel worse at first, as the therapy progresses.

In rare cases, psychotherapy may even trigger some people to have thoughts about wanting to hurt themselves or end their lives. When this happens, licensed mental health therapists are trained to help you understand and cope with these feelings safely and can change the therapy to be more supportive until you are feeling stronger. It is always important that you tell your mental health therapist right away if you are having any frightening or dangerous thoughts or feelings, or if you are considering harming yourself or someone else.

You may be identifiable in **video recordings** by your image and/or voice.

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaire, you are encouraged to contact your doctor or the study chair.

If you become distressed or are identified to be at risk of suicide, you will be referred to the appropriate psychiatric treatment.

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

During an **fMRI**, you may feel mild vibrations throughout your body. The machine will produce a loud knocking noise. This is normal. You will be given earplugs to protect your ears. Some people, especially those who tend to feel uncomfortable in small or

closed spaces, may feel “closed in” and become anxious while in the scanner. The scanner has an intercom, which will allow you to speak to the staff during the procedure. If you feel ill or anxious during scanning, tell the MRI staff and the scanning will be stopped if you wish.

The magnetic field used in MRI scanning may harm you if you have certain types of metal in your body (as might be found in pacemakers, neurostimulators, or certain clips). It may cause problems with devices, such as pacemakers. If you have metal in your body or devices such as a pacemaker, you should discuss this with the study doctor.

If an MRI contrast material is used, your study doctor will tell you about possible side effects or allergic reaction. Contrast agents can cause allergic reactions and kidney damage. Allergic reactions can include mild itching associated with hives but can also result in a serious life-threatening emergency from difficulty breathing. If this occurs, it is treatable. The MRI will require a catheter to be inserted into one of your veins in order to inject the MRI contrast agent. This may cause skin irritation, bleeding, and/or infection.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

You will be told about any new information that may affect your health, welfare, or choice to stay in the research.

Will it cost anything to be in this study? Will I be paid to be in this study?

Psilocybin or placebo (whichever you are assigned to receive) and the psychotherapy sessions will be provided at no cost to you during this study.

You and/or your insurance provider will not have to pay for certain research exams and procedures done that are covered by the study.

You and/or your insurance provider will be responsible for the costs of routine clinical services (such as diagnostic/therapeutic procedures, drugs, devices, laboratory assays, and other services that would ordinarily be ordered for medical care, regardless of whether or not you are participating in a study). There may be extra costs that are not covered by your medical plan that you will have to pay yourself.

Taking part in this study may result in added costs to you (such as transportation, parking, meals, or unpaid leave from work). You may have to pay for medication prescribed to treat or prevent side effects, and you may have to visit the clinic/hospital more often than if you were not participating in this study.

If you have insurance, talk to your insurance provider and make sure that you understand what your insurance pays for and what it does not pay for if you take part in this study. Also, find out if you need approval from your plan before you can take part in the study.

You may ask that a financial counselor be made available to you to talk about the costs of this study.

You will not receive any compensation for taking part in this study.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who need to review this information. Complete secrecy cannot be promised. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

A participant study number will be assigned to you once you have been enrolled in the study. This participant study number will be used to identify your data in the study report and when reporting any data from the study.

Any personal information that could identify you will be removed or changed before data are shared with other researchers or results are made public.

The sponsor, monitors, auditors, the IRB, and the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access.

The results of this research may be published in scientific journals or presented at medical meetings. However, your identity will not be disclosed. Your name and other identifying information will be kept confidential.

Federal law provides additional protections of your medical records and related health information. These are described below.

Will my data be used for future research?

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson, Usona Institute, or shared with other researchers and/or institutions for use in future research.

In some cases, all of your identifying information may not be removed before your data is used for future research. If future research is performed at MD Anderson, the researchers must get approval from the MD Anderson IRB before your data can be used. At that time, the IRB will decide whether or not further permission from you is required. If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data.

If identifiers are removed from your identifiable private information that is collected during this research, that information could be used for future research studies or shared with another researcher for future research studies without your additional informed consent.

What happens if I get hurt from being in this study?

If you get sick or hurt and it is related to your participation in this study, you will be given care at MD Anderson (if you are at the clinic when you are sick or hurt). If you get hurt or sick and you are not at the clinic (for example, you are at home or at another doctor's office):

- call your personal doctor right away (or in an emergency, call 911)
- tell your personal doctor or ER staff that you are in this study (try to give them a copy of this consent form or show them your participant card)
- call the study doctor (Dr. Dr. Moran Amit, at 713-794-5304) or 713-792-2121 (24 hours)

You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. Costs of treatment received because you were hurt or sick will be billed to you or your insurance company. No other form of payment is available.

You may also contact the MD Anderson IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

What else do I need to know?

MD Anderson may benefit from your participation and/or what is learned in this study.

Your information (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
   - The IRB and officials of MD Anderson
   - Usona Institute, a non-profit organization providing the drug for the study
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law).

   Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

E. 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.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under this protocol.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for non-English speakers utilizing the short form consent process (VTPS) and patients who are illiterate.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT