

INFORMED CONSENT FOR KETAMINE INFUSION THERAPY

Before you decide to take part in this procedure, it is important for you to know why it is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Read the information below closely and discuss it with family and friends as you wish. Ask Mr. Levites if there is anything that is not clear, or if you would like more details. Take your time to decide. If you do decide to take part, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with Mr. Levites. Ketamine is approved by the FDA for anesthesia, and for sedation during medical procedures. Since its approval in 1970, it has been widely used in operating rooms and emergency departments. Ketamine's use for the treatment of depression, anxiety, chronic pain, OCD, or drug or alcohol abuse is off-label and has not been approved by the FDA.

1. PROCEDURE – KETAMINE INFUSION THERAPY

An intravenous line (IV) will be started in an extremity (arm, hand, or leg) so you can receive ketamine. Your blood pressure, heart rate, and oxygen saturation will all be monitored throughout the infusion procedure under a physician's supervision. You will be given a subanesthetic dose of ketamine, by slow continuous infusion. The duration of the infusion varies from 40 and 55 minutes for depression, and 2 to 4 hours for chronic pain. Depending upon your response to this first infusion, we may increase the dose incrementally with your subsequent infusions to maximize your response. We will also often adjust the infusion rate during each infusion, depending on how you are responding, to maximize the effectiveness of each infusion. Adjuvant medications may also be administered if necessary, such as anti-nausea medication, mild sedatives for agitation, etc.

2. RISKS/SIDE EFFECTS

Risk of ketamine: Side effects normally depend on the dose and how quickly the injection is given. The dose being used for this purpose is generally lower than anesthetic doses, and will be given by slow continuous infusion. Side effects often go away on their own. The incidence of side effects is higher with more prolonged infusions.

Common side effects, greater than 1% and less than 10%:

- hallucinations
- vivid dreams and nightmares
- nausea and vomiting
- increased saliva production
- dizziness
- blurred vision
- increased heart rate and blood pressure during the infusion
- out of body experience during the infusion
- change in motor skills

These symptoms dissipate when the infusion is stopped. If they are severe, another medication such as a sedative can be used to treat the symptoms. You should not drive the day of an infusion and can resume driving the following day.

Uncommon side effects, greater than 0.1% and less than 1%:

- rash
- double vision
- pain and redness in the injection site
- Increased pressure in the eye
- jerky arm movements resembling a seizure

Rare side effects, greater than 0.01% and less than 0.1%:

- allergic reaction
- irregular or slow heart rate
- arrhythmia

- low blood pressure
- cystitis of the bladder: inflammation, ulcers, and fibrosis
- Even more severe side effects up to and including death are possible, but extremely unlikely, such as a fatal allergic reaction to one of the medications.

Other Risks:

- Ketamine can cause various symptoms including but not limited to flashbacks, hallucinations, feelings of unhappiness, restlessness, anxiety, insomnia and disorientation.
- The uncommon risk of a dosing error, or unknown drug interaction that may require medical intervention including intubation (putting in a breathing tube), or hospitalization.
- Starting an IV may cause temporary discomfort from the needle stick, bruising, or infection. Fainting may also occur.
- Risk of other medications interacting with ketamine. It is very important that you disclose all medications (both prescription and over the counter) and supplements that you are taking.
- Ketamine may not help your depression, bipolar disorder, PTSD, anxiety, other mental health condition, or chronic pain syndrome.

3. BENEFITS

Unlike conventional anti-depressants, ketamine has been associated with a rapid decrease in depression, bipolar, and PTSD symptoms. It has also been shown to be helpful with a variety of chronic pain syndromes, and with alleviating the cravings for drugs and alcohol. The initial series of infusions is used to prolong the longevity of improvement. While the goal is improvement of symptoms, results cannot be guaranteed, and there is no way to predict how any individual will respond to ketamine infusion therapy. These effects may not be long lasting and will most likely require further infusions. Ketamine is not the only option for patients with treatment-resistant depression. There are other alternatives, including electroconvulsive shock therapy (ECT) and transcranial magnetic stimulation (TMS). Ketamine is not the only option for patients with chronic pain. Other alternatives include pain medicines, anticonvulsants, physical therapy, cognitive-behavioral therapy, steroid injections, spinal pumps, spinal cord stimulation, and surgery. Ketamine is also not the only option for alcohol and drug abuse.

4. WHAT SAFETY PRECAUTIONS MUST I TAKE?

- I will not eat or drink for at least six hours before each of the infusions. I may, however, drink clear liquids for up to two hours before an infusion. I will take all of my usual morning medications with a few sips of water before an infusion, EXCEPT for Lamictal, any benzodiazepines, and any sedating drugs including narcotic pain medication.
- I will NOT drive a car, operate hazardous equipment, or engage in hazardous activities for 24 hours after each treatment as reflexes may be slow or impaired. Another adult will need to drive me home.
- I will not conduct business or make any important decisions the remainder of the day after an infusion.
- I must refrain from alcohol or other substances prior to, and for 24 hours after an infusion.
- I must tell the clinic about all medications I am taking, especially narcotic pain relievers or barbiturates.
- If I experience a troublesome side effect after I leave the clinic, I should contact the medical staff of the Florida Mind Health Center at (352) 448-6062. If I cannot reach him directly, I should call my primary care doctor, call 911, or go to my local emergency room.

5. IMPORTANT CAVEATS

KETAMINE INFUSION THERAPY IS NOT A COMPREHENSIVE TREATMENT FOR DEPRESSION, ANXIETY OR ANY PSYCHIATRIC SYMPTOMS; NOR FOR CHRONIC PAIN, NOR FOR DRUG AND ALCOHOL ABUSE.

Your ketamine infusions are meant to augment (add on to, not be used in place of) a comprehensive treatment plan. We advise you to be (and I agree to be) under the care of a qualified mental health professional (or an internal medicine or family physician with experience and skill in treating psychiatric illnesses) while receiving ketamine infusions, and for the duration of your psychiatric symptoms. Pain patients should be under the care of a pain management physician as well as a primary care provider – we provide ketamine infusions only, and do not diagnose or provide comprehensive pain management treatment INCLUDING the prescription of pain medications. Follow up medications may be suggested but these will be the responsibility of your treating physician.

SPECIAL NOTE ON SUICIDAL IDEATION

Psychiatric illnesses (especially, depression), chronic pain, and addictions carry the risk of suicidal ideation (thoughts of ending one's life). Any such thoughts you may have now, at any time during the weeks of your ketamine infusions, or at any point in the future, which cannot immediately be addressed by visiting with a mental health professional should you to seek emergency care at an ER or to call 911.

KETAMINE USE DURING PREGNANCY OR BREAST FEEDING IS NOT GENERALLY RECOMMENDED

6. VOLLUNTARY NATURE OF THE TREATMENT

You are free to choose to receive or not receive the ketamine infusion. Please tell the doctor if you do not wish to receive the infusion.

7. WIITHDRAWALL OF TREATMENT

Your doctor has the right to stop the infusion at any time. They can stop the infusion with or without your consent for any reason.

8. PATIENT CONSENT

I agree to be under the care of a qualified mental health professional (or an internal medicine or family physician with experience and skill in treating psychiatric illnesses) while receiving ketamine infusions, and for the duration of your psychiatric symptom.

I agree to allow Florida Mind Health Center to access all information pertaining to my mental healthcare and permission to speak to my mental healthcare provider to discuss my condition and the administration of Ketamine Infusion therapy.

I know that ketamine is not an FDA approved treatment for depression, bipolar disorder, or PTSD.

I know that my taking part in this procedure is my choice.

I know that I may decide not to take part or to withdraw from the procedure at any time.

I know that I can do this without penalty or loss of treatment to which I am entitled.

I also know that the doctor may stop the infusion without my consent.

I also know that ketamine infusion therapy may not help my depression, bipolar disorder, or PTSD.

I have had a chance to ask the doctor questions about this treatment, and those questions have been answered to my satisfaction.

The possible alternative methods of treatment, the risks involved, and the possibility of complications have been fully explained to me.

No guarantees or assurances have been made or given to me about the results that may be obtained.

You should not sign this Consent until you have spoken with the medical staff of the Florida Mind Health Center about the procedure and had all of your questions answered including those about risks and alternatives.

Patient Consent:

Signature

First name Last name

_____/_____/_____
Date

Clinician Acknowledgement:

Signature

First name Last name

_____/_____/_____
Date