INFORMED CONSENT FOR KETAMINE TROCHE HOME 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 necessary participation, 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 Divine Health Group 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 Divine Health Group.

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 – KETAMIINE THERAPY

This is a home-based option for self-administered oral troche, liquid, or lozenge. Your blood pressure, heart rate, and oxygen saturation should be monitored while utilizing Ketamine at home. YOU MUST OBTAIN A BLOOD PRESSURE CUFF AND APPROPRIATE VITAL MACHINES ON YOUR OWN. The duration of the procedure varies from 60-120 minutes.

To obtain vital signs, you measure temperature, pulse, respirations, blood pressure, and oxygen saturation using tools such as a thermometer, watch, stethoscope, sphygmomanometer, and pulse oximeter. These measurements require proper patient positioning, correct equipment use, and consistent technique to ensure accuracy. If you are unfamiliar with how to obtain correct vitals, please seek assistance from Divine Health Group staff prior to treatment.

Ketamine is to be kept under lock and key, and never shared with anyone else. Unless otherwise agreed upon, a family member or trusted companion should be present during the hour and a half following treatment. Do not drive while you are sedated or under the influence of ketamine, and do not drive for the remainder of the day after taking a dose of ketamine; you may again drive the following day, after a night of sleep.

2. RISKS/SIDE EFFECTS

Side effects normally depend on the dose given. The dose being used for this purpose is generally lower than anesthetic doses. Side effects often go away on their own. The incidence of side effects are greater the higher the dose of Ketamine.

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 treatment*

• *out of body experience during the treatment*

• *change in motor skills*

These symptoms dissipate following the troche. You should not drive the day of your Ketamine use and can resume driving the following day.

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

• *rash*

• *double vision*

• *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*.

• *Risk of other medications interacting with ketamine can occur. It is very important that you disclose all medications (both prescription and over the counter) and supplements that you are taking*.

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 helpful with a variety of chronic pain syndromes, and with alleviating the cravings for drugs and alcohol. The initial series of ketamine treatment 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 therapy. These effects may not be long lasting and will most likely require further treatments. 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 PRECAUTIIONS MUST I TAKE?

• *I will not eat or drink for at least six hours before my Ketamine appointment. I may, however, drink clear liquids for up to two hours before treatment. I will take all my usual morning medications with a few sips of water before the treatment, 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*.

• *I will not conduct business or make any important decisions the remainder of the day after treatment*.

• *I must refrain from alcohol or other substances prior to, and for 24 hours after treatment*.

• *I must tell the clinic about all medications I am taking, especially narcotic pain relievers or barbiturates*.

• *If I experience a troublesome side effect, I should contact the medical staff of the Divine Health Group at 719-413-5261. If I cannot reach them directly, I should call my primary care doctor, call 911, or go to my local emergency room.*

5. IMPORTANT CAVEATS

KETAMINE 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 treatments are meant to augment (add on to, not be used in place of) a comprehensive treatment plan. We advise you 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 treatments, 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 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 treatment, 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 treatment. Please tell the doctor if you do not wish to receive the treatment.

7. WIITHDRAWALL OF TREATMENT

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

8. WARNINGS AND PRECAUTIONS

Sedation: KETAMINE may cause sedation or loss of consciousness. In some cases, patients may display diminished or less apparent breathing. In clinical trials, 48% to 61% of treated patients developed sedation and 0.3% to 0.4% treated patients experienced loss of consciousness. Because of the possibility of delayed or prolonged sedation, patients must monitor their vitals for at least 2 hours at each treatment session.

Dissociation: The most common psychological effects of KETAMINE were dissociative or perceptual changes (including distortion of time, space and illusions), derealization and depersonalization (61% to 84% of treated patients developed dissociative or perceptual changes). Given its potential to induce dissociative effects, patients will be carefully assessed for psychosis before administering Ketamine; treatment will be initiated only if the benefit outweighs the risk. Because of the risks of dissociation, patients must be monitored by a healthcare provider for at least 2 hours at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting.

Respiratory Depression: Respiratory depression was observed with the use of Ketamine. In addition, there were rare reports of respiratory arrest. Because of the risks of respiratory depression, patients must monitor oxygen via pulse oximetry for changes in respiratory status for at least 2 hours (including pulse oximetry) at each treatment session.

Abuse and Misuse: KETAMINE is a Schedule III controlled substance (CIII), and may be subject to abuse and diversion. Assessment of each patient's risk for abuse or misuse will be completed prior to prescribing as well as continually monitoring all patients for the development of these behaviors or conditions, including drug-seeking behavior, while on therapy. Individuals with a history of drug abuse or dependence are at greater risk; therefore, will be carefully considered prior to treatment.

9. 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 treatment, and for the duration of your psychiatric symptom.

I agree to allow Divine Health Group 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 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 treatment without my consent.

I also know that ketamine 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 Divine Health Group about the procedure and had all of your questions answered including those about risks and alternatives.

Patient Signature Date