KHRYSALIS PSYCHOTROPICS P.C.
SUBANESTHETIC KETAMINE INFORMED CONSENT

INTRODUCTION

This consent form contains information about the use of subanesthetic ketamine for mental health indications. Ketamine has been approved by the Food and Drug Administration (FDA) for use as an anesthetic agent for many years. The use of ketamine in lower, subanesthetic doses to treat depression and other mental health disorders is a newer, off-label use of ketamine. This means the FDA does not endorse the use of ketamine for depression, or as a psychotherapeutic agent, and classifies such uses as investigational. After you understand the risks and benefits of this Ketamine therapy treatment, you will be asked to sign this form as a pre-condition to your participation and therapy. In order for you to decide whether you should undertake this therapy, you'll need to confirm that you understand enough about its risks and benefits and that you are making an informed decision. This process is known as informed consent.

Ketamine is a novel psychiatric treatment, and good quality evidence exists for treatment of major depressive disorder, bipolar depression, substance use disorders, post-traumatic stress disorder, and eating disorders. Lesser quality evidence exists for obsessive compulsive disorder and anxiety disorders. While it is not formally approved by the FDA, there are now many studies that demonstrate it may be an effective and rapid treatment option. Benefits may occur after only one treatment, though typically an initial course of several treatments are required for a more robust and enduring response. If your symptoms respond to this initial course of ketamine therapy, you may receive further treatments. You may still elect to be treated with other medications and ongoing psychotherapy. Similarly, you may also need additional periodic ketamine treatments or other therapies. There is no guarantee that your symptoms will respond to treatment. Maintenance treatment frequency is decided on a case by case basis. Most often approximately monthly, but may range from weekly to quarterly. Some people report persistent effects after only one or a few treatments but this is less common.

By signing this document you indicate that you understand the information and that you give your consent for the medical procedures to be performed during your participation in ketamine treatment. Please read this consent form carefully, and feel free to ask questions about any of the information in it.

ELIGIBILITY

Before participating in ketamine therapy, you will be screened by a medical provider to determine if you are eligible, including a medical history and psychiatric history. Pregnant

women, nursing mothers, and women of child-bearing age who are not using an effective method of birth control should not receive ketamine. If you become pregnant while participating in this program, you should notify your medical providers immediately as the effects of ketamine on the unborn child are undetermined.

OVERVIEW OF SESSIONS

During the ketamine administration session, you will be asked to make two agreements with your provider to ensure your safety and well-being:

1. You agree to follow any direct instructions given to you by the medical provider until the medical provider decides that the session is over, and you agree to remain at the location of the session until the provider decides you are ready to leave. The length of a ketamine session is approximately 1 – 2 hours, and you may need to remain in the recovery area for up to an hour following administration.
2. Ketamine is typically given as either an intravenous (IV) infusion ("drip") or intramuscular (IM) injection, but also can be provided as a nasal spray, sublingually, or by mouth. For IV infusions, an intravenous catheter is placed and ketamine is subsequently infused, typically over the following 40 minutes. For IM treatment, ketamine is given as an intramuscular injection into the shoulder or buttocks. You will be offered an eye mask as well as music, and prompted to "go inwards" during the more intense part of the experience, as it may become difficult to talk during this point. Your perception and mental state will be temporarily altered by the ketamine, until it wears off. For IV and IM administrations, a medical provider will be present the entire time to make sure you are comfortable and to monitor for safety concerns.
3. You may ask your provider any questions you may have concerning the procedure or effects of ketamine at any time. Your consent to receive ketamine may be withdrawn and you may discontinue your participation at any time up until the actual dose has been administered.

AS-NEEDED MEDICATIONS

If you become anxious, agitated, or uncomfortable you may be offered a sedative agent, but typically all that is needed is reassurance. If nauseous you may be offered an anti-nausea agent. These medications may be given through the IV, sublingually, or intramuscularly.

RECOVERY TIME

The non-ordinary state of consciousness produced by ketamine usually lasts approximately 45 minutes for an IV infusion or IM injection, but these effects, as well as side effects, are likely to persist to a lesser extent for the next 3-6 hours. For other routes of administration, this timeline is extended. Because of residual effects on balance and

dizziness, you should not drive until you have had a full night of sleep. You are required to have another person drive you home.

AFTER TREATMENT

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 drive again the following day, after a night of sleep.

POTENTIAL RISKS OF SUBANESTHETIC KETAMINE THERAPY

You will be asked to lie still during and after ketamine administration because your sense of balance and coordination will be impaired until the effect has worn off. It is possible you may fall asleep. Other adverse effects include blurred and uncomfortable vision, slurred speech, mental confusion, excitability, altered/diminished ability to see things that are actually present, altered/diminished ability to hear or to feel objects accurately including one's own body, visual or auditory illusions (psychedelic effects), a sense of movement despite laying still, nausea and vomiting, and anxiety. Visual, tactile and auditory processing are affected by the drug. Music that may be familiar may seem out of the ordinary. Synesthesia, a mingling of the senses, may occur, and your sense of time may be altered. Psychedelic effects are likely. These experiences may be frightening or euphoric. Those with bipolar disorder are also at risk for a precipitated manic or hypomanic episode, but this risk is lowered by treatment with a mood stabilizer. Rarely, ketamine may worsen depression, anxiety, or suicidal thoughts. You should not receive Ketamine if you have schizophrenia. Ketamine may also cause the following: tachycardia (elevation of pulse), increases in blood pressure, diplopia (double vision), dizziness, nystagmus (rapid eye movements), elevation of intraocular pressure (feeling of pressure in the eyes), anorexia (loss of appetite), impaired breathing, laryngospasm (closing of the airway), apnea (stop breathing) or increased gastric secretions. The above reactions are more likely and of greater intensity with higher doses of ketamine, such as when used in surgical anesthesia (around 5 mg/kg and higher). In contrast the doses used in subanesthetic ketamine treatments are much lower, and usually range 0.5 - 1.5 mg/kg. Starting at a low dose and slowly increasing reduces the incidence and intensity of side effects. Because of the risk of nausea and vomiting, please refrain from eating and drinking for at least the 4 hours preceding the session. Driving an automobile, operating machinery, or engaging in hazardous activities should not be undertaken until the following day, after a full night of rest. You will be assessed for safety prior to leaving the office premises, but must not drive for the remainder of the day after receiving ketamine. In terms of physical risks, ketamine should not be taken if you have untreated hyperthyroidism. There have also been reports of some decrease in immune function in patients receiving surgical doses of ketamine, however this has not been seen in

subanesthetic doses. Ketamine has an extensive record of safety and has been used at much higher doses for surgical anesthesia, but may still cause respiratory depression. Untreated hypertension is a contraindication to ketamine use as the substance may cause a rise in blood pressure. Similarly, a history of heart disease may make you ineligible to participate. Repeated, high dose, chronic abuse of ketamine, has been shown to cause urinary tract symptoms and even permanent bladder dysfunction, though in medical use this is rare. In terms of psychological risk, ketamine may worsen certain psychotic symptoms in people with schizophrenia or other serious mental disorders, but alternatively has also been occasionally used to successfully treat psychotic depression. It may also worsen underlying psychological problems in people with severe personality disorders, or alternatively may help them.

POTENTIAL FOR KETAMINE ABUSE AND PHYSICAL DEPENDENCE

Ketamine belongs to the same group of chemicals as phencyclidine (Sernyl, PCP, "Angel dust"). Collectively, this group is in the chemical class of arylcyclohexylamines, and are further classified as hallucinogens or dissociative psychedelics. Ketamine is a controlled substance and is subject to Schedule III rules under the Controlled Substance Act of 1970. Evidence suggests that ketamine has a low to medium risk of drug abuse and dependency: somewhat higher than classical psychedelics (psilocybin, LSD), but lower than other well-known drugs of abuse (alcohol, nicotine, opioids, amphetamines). Cravings have been reported by some individuals and there are documented cases of overuse of illicitly obtained and diverted ketamine. In addition, ketamine can have effects on mood (feelings), cognition (thinking), and perception (imagery) that may make some people want to use it repeatedly. Such potential for abuse or development of a ketamine use disorder is greater when it is used outside of the office, where there is no monitoring from a physician or other provider, therefore ketamine should never be used except under the direct supervision of a licensed medical provider.

ALTERNATIVE PROCEDURES AND POSSIBILITIES

No other procedure is available to produce the specific effect ketamine provides, though electroconvulsive therapy (ECT), transcranial magnetic stimulation (TMS), vagal nerve stimulation, and deep brain stimulation (DBS) are alternatives that may offer improvement in depressive symptoms for those with treatment resistant depression. Some evidence suggests classical psychedelics, like psilocybin, are effective, but clinical trials are ongoing and this treatment is not yet available in clinical practice. Major depressive disorder (MDD) and bipolar depression are optimally treated with a combination of medications and psychotherapy.

CONFIDENTIALITY

Your privacy and all therapy records will be kept confidential. They will be maintained with the same precautions as ordinary medical records.

VOLUNTARY NATURE OF PARTICIPATION

Your decision to undergo ketamine treatment is completely voluntary. Before you make your decision about participation, you may ask and will be encouraged to ask any questions you may have about the process. Withdrawal from ketamine treatment is always your option. Even after agreeing to undergo ketamine treatment, you may decide to withdraw at any time.

PATIENT'S INFORMED CONSENT

By signing this form I agree that:

1. I understand that I am to have no food or drink 4 hours prior to my ketamine session.
2. I understand that I need to have someone drive me home from the sessions, and should not engage in any driving or hazardous activity until the next day
3. I have fully read this informed consent form describing subanesthetic ketamine therapy.
4. I have had the opportunity to raise questions and have received satisfactory answers.
5. I fully understand that ketamine can result in a profound change in mental state and may result in unusual psychological and physiological effects.
6. I have been given a signed copy of this informed consent form, which is mine to keep.
7. I understand the risks and benefits, and I freely give my consent to participate.
8. I give my consent to the use of as needed medications including but not limited to: anxiety or agitation, nausea.
9. I understand that I may withdraw from ketamine therapy at any time up until the actual injection has been given.
10. I have fully disclosed all of my medical conditions.

PATIENT SIGNATURE _____ DATE _____

PRINTED NAME _____

PHYSICIAN/CLINICIAN STATEMENT

I have carefully explained the nature of subanesthetic ketamine to this patient. I hereby certify that to the best of my knowledge, the individual signing this consent form understands the nature, conditions, risks, and potential benefits involved in participating. A medical problem or language or educational barrier has not precluded a clear understanding of the subject's participation and treatment.

PROVIDER SIGNATURE _____ DATE _____