



## HELIOS PSYCHIATRY INC.

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### **KETAMINE ASSISTED PSYCHOTHERAPY (KAP)** **INFORMED CONSENT**

#### **Introduction**

Ketamine is now an “off-label” treatment for various chronic “treatment-resistant” mental conditions. Ketamine is a Schedule III medication that has long been used safely as an anesthetic and analgesic agent and now, often effectively for treatment of depression, alcoholism, substance dependencies, PTSD and other psychiatric diagnoses.

**How Does It Work?** The current, most probable, understanding of ketamine’s mode of action is as an NMDA antagonist working through the glutamate neurotransmitter system. This is a very different pathway than that of other psychiatric drugs such as the SSRIs, SNRIs, lamotrigine, antipsychotics, benzodiazepines, etc.

Ketamine is classified as a dissociative anesthetic, dissociation meaning a sense of disconnection from one’s ordinary reality and usual self. At the dosage level administered to you, you will most likely experience mild anesthetic, anxiolytic, antidepressant and, potentially, psychedelic effects. While more recent work has demonstrated the possibility of an antidepressant response to low doses of ketamine administered intravenously, intra-nasally and sublingually (orally) that produce minimal psychedelic effects, this effect tending to be more sustained with repeated use—in other words, a cumulative effect—it is our view that psychedelic, ‘dissociative’ experiences may well be instrumental in providing a more robust effect. This may well include a positive change in outlook and character that we term a ‘transformative’ response. We tend to employ both methods together as will be described herein.

Essential to both methods is a time-out of usual experience, this period being of varying duration, usually 30 minutes to 2 hours, that tends to be dose and method of administration related. Relaxation from ordinary concerns and usual mind, while maintaining

conscious awareness of the flow of mind under the influence of ketamine is characteristic. This tends to lead to a disruption of negative feelings and obsessional preoccupations. It is our view that this relief and the exploration and experience of other possible states of consciousness are singularly impactful. As therapists we act as guides to the experience and process the experience and its impacts with our patients before and after the sessions.

### **Monitoring:**

It is essential that you be followed very closely during and after your treatment. This will include Blood Pressure and pulse measurements, some psychological measurements before and after your session and then there is follow-up telephone and in-person contact.

You will be entering a psychotherapy program that will prepare you for your ketamine session(s) and assist you in integrating your experience(s) afterwards. This program emphasizes the possibilities for change and the seriousness of your and our effort to assist you.

**How Long Will It Take Before I Might See Beneficial Effects?** You may experience important changes in personality, mood and cognition during treatment, in the aftermath, and in the days and weeks that follow. Some experiences may be temporarily disturbing to you. The ketamine experience itself is designed to enable your own healing wisdom to be accessed and beneficial to you. The psychotherapy support you will receive will aid you in making your experience(s) valuable and understandable to you. We will endeavor to assist you in changing patterns of mind and behavior that are of concern and cause you difficulty.

## **Why Ketamine Assisted Psychotherapy?**

The purpose of the **intramuscular ketamine experience** is to create a non-ordinary (“altered”) state of consciousness in order to facilitate profound transpersonal (“transcendental”, “mystical”, “spiritual”, “religious”) peak experiences.

These may prove to be auspicious in resolving your existential problems, accelerating your psycho-spiritual growth and leading to a deep personal transformation and optimization of your lifestyle. Such change is best facilitated within a structured supportive psychotherapeutic milieu in connection with therapists who have a view of your issues, hopes, desires, and struggles. As a byproduct of your experience you may well feel improvement in your emotional state and reduction in symptoms that bother you such as depression, anxiety, and post-traumatic manifestations. You may well notice that you are a bit different after a ketamine experience and that difference may well be liberating and allow for new mindfulness and new behavior.

We are asking that new patients make a commitment for three IM sessions as a minimum exposure to ketamine. We understand that you are able to withdraw from our treatment at any time.

Your experience will be unique to you. And if you and we decide to have additional sessions using ketamine, each of your sessions will be different. All such journeys are adventures that cannot be programmed. They evolve from your own being in relation to this substance. While it is best to form an intention for your journey, you may or may not be able to hold onto that. Indeed, no holding on is best and the journey will flow whether or not you hold on and resist, or follow the path that unfolds and relax into it. Holding on is the main source of

anxiety in this and other related journeys. A ketamine session can be light, dark, or both. There will be concepts, visions, encounters, and you may well deal with your own death, mortality, and immortality. Not everyone enjoys the journey, but everyone comes through it.

The purpose of the **sublingual ketamine lozenge** sessions is to generate a robust antidepressant, or other (PTSD, etc) benefit that often occurs over time with repetition of administration of the lozenges, in concert with the IM sessions. For certain individuals, only the lozenge experience may be utilized.

We generally begin with assessing responsiveness to the lozenge, this to precede the first IM session. This enables us to make a decision about the effectiveness of the lozenge and to adjust the dose. You will be prescribed lozenges for use at home for designated evening ketamine sessions, in between IM sessions, or on their own—lozenges only. Such sessions will be supported with periodic psychotherapy sessions in which you will meet with us.

The literature indicates a response rate to treatment resistant depression (using the low dose IV drip method, or the sublingual method) of 40-50%--the percentage of patients having remissions, this with multiple sessions. Relapses do occur and may require periodic additional sessions. Over time, a certain number of patients may become unresponsive to further ketamine sessions. In our growing experience, the combination of the sub-lingual method (which is equivalent in effect and much less expensive and cumbersome than the IV method) with the IM sessions and within a framework of psychotherapy will exceed this rate of response.

### **ELIGIBILITY FOR KAP**

This consent form contains information about the use of sub-anesthetic doses of ketamine for psychiatric purposes including depression. Ketamine was approved by the FDA for use as an anesthetic agent several decades ago. The administration of ketamine in lower, sub-anesthetic doses to treat pain, depression, or other psychiatric diagnoses is a newer, off-label use of ketamine. Psychiatric use of ketamine has become relatively widespread in recent years, has been studied and promoted by researchers at the National Institute of Mental Health, and has had front-page publicity as the newest antidepressant with its own novel pharmacological mechanism of action. Ketamine has been administered by intravenous, intramuscular (IM), sublingual, oral, and intranasal routes. Often, it has been used after other treatment approaches have been unsuccessful.

Once you indicate that you have understood the benefits and risks of this treatment, you will be asked to sign this form in order to participate in this treatment. You will be given a signed copy of this form to keep for your own records. This process is known as giving *informed consent*.

**By signing this document, you indicate that you understand the information provided and that you give your consent to the medical procedure 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 FOR KETAMINE TREATMENT**

Before participating in ketamine treatment, you will be carefully interviewed to determine if you are eligible for ketamine therapy, including a medical history, a physical exam if deemed necessary, review of your medical/psychiatric records, a psychiatric history and administration of brief psychological tests to assess your state of mind.

Pregnant women and nursing mothers are not eligible because of potential effects on the fetus, or nursing child. The effects of ketamine on pregnancy and the fetus are undetermined, and therefore, it is advisable to protect against pregnancy while exposing yourself to ketamine or in the immediate aftermath of its use.

Untreated hypertension is a contraindication to ketamine use as the substance causes a rise in BP. Similarly, a history of heart disease may make you ineligible to participate.

Information on ketamine's interaction with other medicines is only partially available and it will be assessed as to your eligibility for KAP.

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.

Ketamine has an extensive record of safety and has been used at much higher doses for surgical anesthesia, without respiratory depression.

## **OVERVIEW OF KETAMINE THERAPY--KAP**

During the Ketamine administration session, you will be asked to make two (2) agreements with the therapist(s) to ensure your safety and well-being:

1. You agree to follow any direct instructions given to you by the therapist(s) until it is determined that the session is over, and
2. You agree to remain at the location of the session until the therapist(s) decides you are ready to leave.

The length of ketamine sessions varies from person-to-person and from experience-to-experience. You will be mostly internally focused for the first 45 minutes to one-hour-and-a-half following IM administration of ketamine. You will continue to remain under ketamine's influence at a lesser level for at least one hour. Under my care, ketamine will be given as an intramuscular injection into the shoulder or buttocks at doses of 50 mg to 100 mg (130mg maximally). The choice of dose will depend on prior exposure to ketamine and other psychedelics, body weight, and sensitivity. Naïve subjects will receive a lower dose initial session. It is always better to start with a lower dose to reduce anxiety and become familiar with what a substance may produce in you. There is always an opportunity to make a choice for a larger dose at a future date. It is more difficult to correct a bad experience because of too high an initial dose and the anxiety it may engender. Individuals experienced with psychedelics may receive a higher initial dose. Ketamine IM creates an unusual experience of formlessness and a dissolving of boundaries and has novel effects on the mind. Therefore, it is much better to have an initial learning experience.

The initial IM injection will be preceded by administration of a sublingual lozenge containing 50 mg of ketamine. It will dissolve slowly and we ask you not to swallow your saliva for at least five minutes. Ketamine will penetrate the oral mucosa—lining of your mouth—and will be absorbed rapidly in that manner. This will give us a measure of your responsivity to ketamine. At the end of the session you will be given lozenges and a plan for their use at home preceding the next IM session. We suggest you use the lozenge in the evening at least two hours before your usual bedtime; that you lie in a quiet, comfortable space, assuming a meditative attitude, listen to gentle non-lyric containing music of your choice; not watch television or use the computer; and do not drive afterward or operate potentially hazardous machinery. We advocate that you do not use alcohol preceding ketamine sessions as this may have negative emotional and physiological consequences.

Preparation for a ketamine session requires assessment by your therapist of your readiness and a sense of connection between you and your therapist. We are engaging in a therapeutic endeavor to benefit you and those who are affected by you. Together, we are creating a state of mind (set) in a safe and conducive setting. After ketamine IM and sublingual use, you will have follow-up sessions that focus on integration of your experience and may lead to further sessions, if you so wish, and if that is in accord with your therapist's view of your treatment.

You may ask the therapist(s) any questions you may have concerning the procedure or effects of ketamine at any time. Your consent to receive ketamine may be withdrawn by you, and you may discontinue your participation at any time up until the actual injection or lozenge has been given.

### **POTENTIAL RISKS OF KETAMINE KAP THERAPY**

You will be asked to lie still during the ketamine administration because your sense of balance and coordination will be adversely affected until the drug's effect has worn off—generally two and up to four hours after the injection. It is possible you may fall asleep. Other possibilities for adverse effects include blurred and uncomfortable vision (you are advised to keep your eyes closed until the main effects have worn off), slurred speech, mental confusion, excitability, diminished ability to see things that are actually present, diminished ability to hear or to feel objects accurately including one's own body, anxiety, nausea and vomiting. Visual, tactile and auditory processing are affected by the drug. Music that may be familiar is not ordinary. Synesthesia—a mingling of the senses may occur. Ordinary sense of time will morph into time dilation.

**Because of the risk of nausea and vomiting, please refrain from eating and drinking for at least the 6 hours preceding the session. And eat lightly when you do. Hydrate well in that same time frame.**

**If you are unduly nauseated, you may be offered an anti-nausea medication—ondansetron—in pill or oral dissolving tablet forms.**

**Ketamine generally causes a significant increase in blood pressure but usually not pulse rate. If blood pressure monitoring reveals that your blood pressure is too high, you may be offered**

**clonidine to remedy this.**

**Agitation may occur during the course of a ketamine session. If your agitation is severe, you may be offered lorazepam orally or by injection to help you relax.**

The administration of Ketamine may also cause the following adverse reactions: tachycardia (elevation of pulse), diplopia (double vision), nystagmus (rapid eye movements), elevation of intraocular pressure (feeling of pressure in the eyes) and anorexia (loss of appetite). The above reactions occurred after rapid intravenous administration of ketamine or intramuscular administration of high doses of ketamine (in a range of greater than 5 mg/kg used for a surgical anesthesia. The dose to be used in this sub-anesthetic ketamine therapy is much lower (2 mg/kg or less).

**Driving an automobile or engaging in hazardous activities should not be undertaken until all effects have stopped--and if for any reason they continue a driver may be necessary. You will be assessed for safety prior to leaving the office premises.**

In terms of psychological risk, ketamine has been shown to worsen certain psychotic symptoms in people who suffer from Schizophrenia or other serious Mental Disorders. It may also worsen underlying psychological problems in people with severe Personality Disorders.

During the experience itself, some people have reported frightening and unusual experiences. These frightening experiences, however, may be of paramount value to your transition to recovery from the suffering that brought you to your KAP work. They will stop! You will receive psychotherapeutic help and ongoing guidance from your therapist.

### **POTENTIAL FOR KETAMINE ABUSE AND PHYSICAL DEPENDENCE**

Ketamine belongs to the same group of chemicals as Phencyclidine (Sernyl, PCP, "Angel dust"). This group of chemical compounds is known chemically as Arylcyclohexylamines and is classified as Hallucinogens ("Psychedelics"). Ketamine is a controlled substance and is subject to Schedule III rules under the Controlled Substance Act of 1970. Medical evidence regarding the issue of drug abuse and dependence suggests that ketamine's abuse potential is equivalent to that of phencyclidine and other hallucinogenic substances.

Phencyclidine and other hallucinogenic compounds do not meet criteria for chemical dependence, since they do not cause tolerance and withdrawal symptoms. However, "cravings" have been reported by individuals with the history of heavy use of "psychedelic" drugs. In addition, ketamine can have effects on mood (feelings), cognition (thinking), and perception (imagery) that may make some people want to use it repeatedly. Therefore, ketamine should never be used except under the direct supervision of a licensed physician.

Repeated, high dose, chronic use of ketamine has caused urinary tract symptoms and even permanent bladder dysfunction in individuals abusing the drug. This does not occur within the framework of our study.

You will be provided just the amount of lozenges necessary for your treatment. They have no

street value.

## **ALTERNATIVE PROCEDURES AND POSSIBILITIES**

No other procedure is available in medicine that produces ketamine's effects. Major Depression (MDD), PTSD and Bipolar Disorders are usually treated with antidepressant medications, tranquilizers, mood stabilizers and psychotherapy. Electroconvulsive therapy (ECT), and the recently introduced Transcranial Magnetic Stimulation (TMS) are also in use for treatment-resistant-depression. Ketamine has also been used in the treatment of addictions and alcoholism as part of comprehensive and usually residential treatment programs, primarily abroad.

## **CONFIDENTIALITY**

Your privacy and all therapy records will be kept confidential. They will be maintained with the same precautions as ordinary medical records. To allow others access to your records, you will have to provide a signed release form. The results of this ketamine therapy may be published in clinical literature. Published reports will not include your name or any other information that would identify you.

## **VOLUNTARY NATURE OF PARTICIPATION**

Please be aware that the Food and Drug Administration (FDA) has not yet established the appropriateness of Ketamine Assisted Psychotherapy and its use is considered off-label, the only official 'indication' for use of ketamine being anesthesia. Your awareness of this situation is key to understanding any liability associated with your use of ketamine. Your informed consent indicates you are aware of this situation.

Ketamine is a new psychiatric treatment—the primary studies have been with depression, bipolar disorders and alcoholism. It is not yet a mainstream treatment, though there are now many studies that demonstrate that it may be an effective treatment. That effect generally occurs with more than one treatment and is most robust when part of an overall treatment program. It may not permanently relieve depression. If your depressive symptoms respond to Ketamine Assisted Psychotherapy, you may still elect to be treated with medications and ongoing psychotherapy to try to reduce the possibility of relapse. Over time, you may also need additional ketamine treatments or other therapies to maintain your remission.

Your decision to undertake Ketamine Assisted Psychotherapy is completely voluntary. Before you make your decision about participating in KAP, you may ask and will be encouraged to ask--any questions you may have about the process.

## **WITHDRAWAL FROM KAP IS ALWAYS YOUR OPTION!!!**

Even after agreeing to undertake Ketamine Assisted Psychotherapy, you may decide to withdraw from treatment at any time.

**I understand that I am to have no food or drink 6 hours prior to my Ketamine session**

**I understand that I need to have someone drive me home from the sessions, and not engage in any driving or hazardous activity for at least 6 hours or more-- depending on the continued presence of effects after my session has concluded.**

### **INFORMED CONSENT**

By signing this form I agree that:

1. I have fully read this informed consent form describing Ketamine Assisted Psychotherapy.
2. I have had the opportunity to raise questions and have received satisfactory answers.
3. I fully understand that the ketamine session(s) can result in a profound change in mental state and may result in unusual psychological and physiological effects.
4. I give my consent to the use of lorazepam if deemed necessary for agitation, to ondansetron for nausea, and for clonidine for high blood pressure.
5. I have been given a signed copy of this informed consent form, which is mine to keep.
6. I understand the risks and benefits, and I freely give my consent to participate in KAP as outlined in this form, and under the conditions indicated in it.
7. I understand that I may withdraw from KAP at any time, up until the actual injection, or lozenge has been given.

SIGNATURE

DATE

\_\_\_\_\_

PRINTED NAME \_\_\_\_\_

\_\_\_\_\_

### **PHYSICIAN/ THERAPIST STATEMENT**

I have carefully explained the nature of Ketamine Assisted Psychotherapy to \_\_\_\_\_. 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 in KAP.

A medical problem or language or educational barrier has not precluded a clear understanding of the subject's involvement in KAP.

\_\_\_\_\_  
Signature of Provider (s)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Provider (s)

\_\_\_\_\_  
Date

\_\_\_\_\_