



PLUM SPRING CLINIC  
Holistic Wellness Center

## Informed Consent Document Use of Ketamine

### Introduction

Ketamine is an “off-label” treatment for various chronic, treatment-resistant medical conditions. Ketamine is a Schedule III medication that has been used for many years as an anesthetic and analgesic agent. It is used in a great many clinical situations because of its extraordinary record of safety. It is now used off-label for treatment of depression, obsessive-compulsive disorders, alcoholism, substance dependencies, panic attacks, post-traumatic stress disorder (PTSD), chronic pain, eating disorders, and other medical conditions associated with a history of trauma, anxiety or subjectively-experienced high levels of distress. It is not FDA-approved for these conditions, although there are scientific studies supporting its use in these conditions.<sup>7-12</sup> The FDA has approved the use of intranasal esketamine (SPRAVATO) for drug-resistant depression. This is very expensive and generally not prescribed with the psychological support that our Ketamine-Assisted Therapy treatment includes. Generic ketamine can be used as a nasal spray at a much lower cost with probably equal effectiveness.

The effectiveness of ketamine treatment of chronic, treatment-resistant medical conditions lies in part in its ability to induce altered states of consciousness (see **Ketamine-Induced Non-Ordinary States of Consciousness** in our **Ketamine Assisted Therapy Manual**). It is used in some clinical settings (primarily by anesthesiologists) by infusion without attendant psychological support. There is mounting recognition that it may be more effective when combined with adequate preparation, support and guidance during the sessions and subsequent integration of insights derived from the non-ordinary state of consciousness (NOSC) made possible with proper set, setting and dosage.<sup>13</sup>

### How Does It Work?

The current understanding of ketamine’s mode of action is as an agent working through the glutamate neurotransmitter system. This is a different pathway than that of other psychiatric drugs such as SSRIs, antipsychotics, and benzodiazepines. Ketamine is classified as a dissociative anesthetic; dissociation meaning a temporary sense of disconnection from one’s ordinary reality and usual self.

### **How Do We Use this Medicine to Help Our Clients?**

You will be entering a program that will prepare you for your ketamine session(s) and assist you in integrating your experience(s) afterwards. You will work with one or two individuals during the course of your treatment; these relationships will build as you progress through your experiences with ketamine and KAT. We believe that the nature of this relationship is central to the effectiveness of your program. We are experienced clinicians, knowledgeable and skilled in developing relationships. We want our connections with you to be reliable, understanding, patient, respectful and safe. We will help you to understand what to expect from KAT and to answer any and all questions you have about the experience and how it works. We will work with you to be open and trusting. All of our programs are customized to the specific circumstances of each participant and are developed collaboratively.

We believe that Ketamine- Assisted Therapy is made effective through access to Non-Ordinary States of Consciousness (NOSC). Not all of the places that you go will be “nice” ones. In each of us are dark domains, fear, anger, shame and sadness, that in our ordinary states of consciousness we are reluctant to explore. These dark places and the reluctance to visit them are an ongoing hindrance to your capacity to heal. For many of our clients, it is the safe passage through these dark places, accompanied by a guide who “knows the territory,” that leads to profound healing. The benefits of these ‘passages’ are a ‘rewiring’ of deeply habituated ways of thinking and behaving that perpetuate the cycle of illness. The rewiring leads to a path of greater ease through life with less worry, more joy and more loving and meaningful relationships with others, with more acceptance and less conflict.

**A Note on the Varieties of Non-Ordinary States of Consciousness (NOSC) You Might Experience.** Appended to this KAT Manual is a description of the varieties of NOSCs that you might experience. By signing this Informed Consent document, you acknowledge reading and understanding the possible effects of this medicine.

### **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 disturbing to you. A proportion of clients will experience little or no changes as a result of their KAT and some individuals will consider their experience to be disturbing and to have had negative consequences. The ketamine experience itself is designed to enable your

own healing wisdom to be accessed and beneficial to you. The supportive therapy you will receive will aid you in making your experience(s) valuable and understandable to you.

### **Sublingual Use of Ketamine**

The purpose of sublingual and intranasal ketamine sessions is to assess your responsiveness to this medicine and help us determine the dosage range most likely to benefit you. Oral, sublingual and intranasal administration can generate a range of NOSCs. These routes of administration have been studied extensively and used with clients to address a range of medical and mood issues. For some individuals, oral and sublingual administration will be used as a stage towards the use of intramuscular administration. Some individuals may be treated solely with sublingual or intranasal ketamine. The sublingual method can be equivalent in effect to the intravenous (IV) method and less expensive and cumbersome. Please understand that if you prove to be responsive to the ketamine experience, treatment may well continue for a period of time based on your continued response and benefit, as well as prevention of relapses. In concert with you, we will work out a schedule appropriate to your needs, history and responsivity. The literature indicates a remission rate for treatment-resistant depression of 40–50% using multiple sessions of either the low-dose IV drip method or the sublingual method. Relapses do occur and may require periodic additional sessions. Over time, a certain number of patients may become unresponsive to further ketamine sessions. Based on growing clinical experiences, we believe the sublingual method, either on its own or with the IM sessions—within a framework of therapeutic support designed explicitly for the ketamine experience—will exceed this rate of response.

### **Does Everyone Benefit?**

As with all medical care, there are both benefits and risks to pursuing a treatment program such as KAT. Psychedelic assisted therapy has over 70 years of scientific study and much is understood about it, but it is by no means an exact science. There are no guarantees made as to the result of such treatments. Some individuals may experience a worsening of symptoms (increased anxiety and depression) during or following the treatment program. This treatment program is not currently reimbursed by health insurance.

*During the course of your treatment program it is essential that you share with your facilitator second thoughts, untoward experiences or feelings of distrust, or instances where you feel you were unheard or not respected or that the therapist said or did the wrong thing. Such “events” are not uncommon. What your team will do is support you learning to move through these events towards a level of greater trust and honesty.*

*Many people who seek treatment programs with us have a history of having been hurt by other people - often people in a position of authority or who were supposed to protect that person. KAT can be understood as a powerful tool to learn how to lean into caring relationships.*

## **Eligibility for KAT**

1. This consent form contains information about the use of subanesthetic doses of ketamine for medical and psychological purposes. Ketamine has been administered by intravenous, intramuscular, 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 at your first visit in order to participate in this treatment program. 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 informed consent to the treatment program which includes guided support and the use of ketamine. Please read this consent form carefully, and feel free to ask questions about any of the information.
2. Before participating in ketamine treatment, you will be carefully interviewed to determine if you are eligible for ketamine therapy, including a medical/psychiatric history, review of your medical/psychiatric records, and possibly the 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 our policy that you prevent pregnancy while exposing yourself to ketamine or in the immediate aftermath of its use. Untreated hypertension is a contraindication to ketamine use because the substance can cause a rise in blood pressure. 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 KAT. 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-Assisted Therapy**

During the ketamine administration session, you will be asked to make three agreements with the therapist(s) or facilitator(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,
2. You agree to never use physical violence during a session, and
3. You agree to remain at the location of the session until the therapist(s) decides you are ready to leave.
4. You agree to have an adult driver take you home and stay with you overnight.

The length of ketamine sessions varies from person to person and from experience to experience. With either sublingual, intranasal or intramuscular methods, or in combination, you will be under ketamine's influence for at least one hour. When used intramuscularly (IM) ketamine will be given as an injection into the shoulder or buttocks at doses of 50 mg to 300 mg (doses higher than 150 mg are unusual). The choice of dose will depend on prior exposure to ketamine and other psychedelics, body weight, and sensitivity. Naïve subjects will receive a lower or sublingual dose at their 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. Individuals experienced with psychedelics may receive a higher initial dose. Ketamine IM can create 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 with a sublingual dose.

Sublingual ketamine can be given in several forms including liquid, lozenges (also called troches) and rapidly dissolving tablets (RDTs). In any of these forms, ketamine will penetrate the oral mucosa—lining of your mouth—and will be absorbed over 5 to 15 minutes. This will give us a measure of your responsivity to ketamine. Additional doses may be given to you during the session to enable optimal effect for you.

Intranasal sprays of generic ketamine are an alternative form of administration. There is slightly faster and more effective absorption of the medicine when given intranasally. This allows a bit closer titration of dose over the course of your session.

### **Integration Sessions:**

After ketamine use, you will have follow-up sessions that focus on integration of your experience. You may ask the attendant any questions you 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 administration of the dose has been given.

**Potential Risks of KAT:**

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 to three hours after the administration. It is possible you may fall asleep, though this is a rare event. Visual, tactile and auditory processing are affected by the drug. 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. Music that may be familiar may not be recognizable. Synesthesia may occur. (Synesthesia is a phenomenon in which one sensory stimulation leads to another unrelated sensory stimulation; for example, hearing a sound may be perceived as seeing a color). Ordinary sense of time will morph into time dilation. Because of the risk of nausea and vomiting, please refrain from eating and drinking for three or four 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—as an oral dissolving tablet.

Ketamine generally causes a significant but not dangerous increase in blood pressure (BP), but usually not in pulse rate. We will have a pulse oximeter and blood pressure cuff to monitor pulse rate, blood oxygenation, and blood pressure on site throughout your session, if deemed necessary. If blood pressure monitoring reveals that your blood pressure is too high, you may be offered an anti-hypertensive medicine (clonidine) to remedy this. There is also a very small risk of lowering BP and pulse rate. Agitation may occur during the course of a ketamine session. If your agitation is severe, you may be offered a tranquilizer, lorazepam, orally or by injection to help you relax. This too is a rare event in our experience. The administration of ketamine may also cause the following adverse reactions: tachycardia (elevation of pulse), diplopia (double vision), nystagmus (rapid eye movements), 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 surgical anesthesia). The dose to be used in this subanesthetic 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, usually up to eight hours after

administration. 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 and dissociative 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 KAT work. They will stop! You will receive help and ongoing guidance from your attendant.

### **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 with hallucinogens (“psychedelics”). Ketamine is a controlled substance and is subject to Schedule III rules under the Controlled Substances 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. We and our colleagues doing clinical ketamine work have not had patients become dependent on ketamine.

### **Urinary Tract Problems:**

Repeated high-dose, chronic use of ketamine has caused urinary tract symptoms and even permanent bladder dysfunction in individuals abusing the drug. This is believed not to occur within the framework of treatment programs under the supervision of a physician.

### **Alternative Procedures and Possibilities:**

No other procedure is available in medicine that produces ketamine’s effects. Major depressive disorder (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. Chronic medical

conditions that have not responded to standard of care therapy and that are associated with anxiety and/or a history of trauma may respond to KAT.

**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 Therapy and its use is considered off-label; the only official 'indication' for use of ketamine being anesthesia. However, The FDA has approved the use of intranasal esketamine (SPRAVATO) for drug-resistant depression. This is very expensive and not prescribed with the psychological support that our Ketamine-Assisted Therapy treatment includes. 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. It is not yet a mainstream treatment, though there are now studies demonstrating that it may be an effective treatment in a broad range of conditions responding poorly to mainstream treatments.<sup>7-10, 12</sup> That effect generally occurs with more than one KAT session 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 Therapy, you may still elect to be treated with medications and ongoing psychotherapy to try to reduce the possibility of relapse and anxiety. Over time, you may also need additional ketamine treatments or other therapies to maintain your remission. As a medical doctor, Dr. Sharp and Dr. Winslow may offer to assist you with other medications, to consult with your therapists, other practitioners and MDs, and to make recommendations to you about your treatment in addition to our ketamine work. You may, if you wish, consult with Dr. Sharp and Dr. Withrow about these treatment matters. Your decision to undertake Ketamine-Assisted Therapy is completely voluntary. Before you make your decision about participating in KAT, you may ask—and will be encouraged to ask—any questions you may have about the process. Withdrawal from the KAT program is always an option. Even after agreeing to undertake Ketamine-Assisted Therapy, you may decide to withdraw from treatment at any time prior to administration of the medicine.

**Cancellation Policy:**

The scheduling of an appointment involves the reservation of time specifically for you. In order for therapy to be effective, it is important you commit to that time. If you are unable to attend your scheduled appointment, **patients must call 48 hours in advance or they will be charged a full appointment fee.** The appointment may be considered cancelled if a patient arrives more than 15 minutes after the scheduled appointment time. Patients will be asked to keep a credit card on file and this will be charged for missed appointments without prior approval.

### **Professional Fees**

Ketamine-Assisted Therapy is an **investment in you, your relationships, your family, and your life.** Our fee is established by a combination of our education, knowledge, experience, expertise and time.



### **Informed Consent Attestation**

By signing this form, I agree to the following:

1. I have fully read this informed consent document describing Ketamine-Assisted Therapy.
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 temporary unusual psychological and physiological effects. Ketamine may be helpful for my symptoms, may have no effect or may lead to a worsening of my symptoms or the appearance of other undesirable effects.
4. I understand that I am to have no food or drink at least three, and preferably four, hours prior to my ketamine session.
5. I understand that I will need to have someone drive me home from the sessions, and that I must not engage in any driving or hazardous activity for at least eight hours or more, depending on the continued presence of effects after my session has concluded.
6. 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.
7. I have been given a signed copy of this Informed Consent document to keep.
8. I understand the risks and benefits, and I freely give my consent to participate in KAT as outlined in this form, and under the conditions indicated in it.
9. I understand that I may withdraw from KAT at any time up until the actual administration of the medicine.
10. I give PSC permission to review my medical and mental health records.

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Printed Name: \_\_\_\_\_

### **Physician/Therapist Statement**

I have carefully explained the nature of Ketamine-Assisted Therapy 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 KAT. A medical problem or language or educational barrier has not precluded a clear understanding of the subject's involvement in KAT.

Signature of Physician: \_\_\_\_\_

Date: \_\_\_\_\_