

INFORMED CONSENT FOR KETAMINE-ASSISTED PSYCHOTHERAPY

INTRODUCTION

This consent form contains information about the use of sub-anesthetic doses of ketamine for mental health 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 mental health diagnoses is a newer, off-label use of ketamine. Ketamine use for mental health has become relatively wide-spread in recent years; it has been studied and promoted by researchers at the National Institute of Mental Health and has had front-page publicity as the newest antidepressant. Ketamine has been administered by intravenous (IV), intramuscular (IM), subcutaneous (SC), sublingual (SL), oral, and intranasal routes. Often, it has been used after other treatment approaches have been unsuccessful.

Ketamine is increasingly applied “off-label” for the clinical treatment of various chronic and “treatment-resistant” mental conditions. It is a Schedule III medication that has been used safely as an anesthetic and analgesic agent since 1970, and now, often effectively for the treatment of depression, alcoholism, substance dependencies, PTSD, and other mental health diagnoses.

Ketamine is classified as a dissociative anesthetic, dissociation meaning a sense of disconnection from one’s ordinary reality and usual self. There are two possible dosage levels that may be administered to you at Sub Rosa. The first is a lower dose administered sublingually that will most likely cause you to experience mild anesthetic, anxiolytic, antidepressant and, potentially, psychedelic effects. Recent work has demonstrated that this lower dose, administered as a sublingual solution, causes an antidepressant response and potentially psychedelic effects. In general, the antidepressant effect tends to be more sustained or have a cumulative effect, with repeated use. The second is a higher dose IM shot that may cause a psychedelic experience that is often instrumental in providing a more robust clinical effect. This may well include a positive change in outlook and character that we term a “transformative” response.

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.

Monitoring It is essential that you be followed closely during and after your treatment. This will include blood pressure and pulse measurements, as appropriate, and psychological assessment tools administered before your first and subsequent sessions to measure effects.

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 effort and our effort to assist you. For most people entering ketamine-assisted psychotherapy (KAP), there will be a sustained period for therapy to continue to benefit emotional healing and growth. Support from family, partners, and close friends is desirable, and they will be included in sessions or parts of sessions as deemed appropriate by you and us as your therapists.

How fast does ketamine work? Ketamine has a rapid onset and is a short acting powerful psychedelic with the potential of transformative experiences. Regarding the acute effects of ketamine, with sublingual administration, it generally takes about 10 – 15 minutes to begin feeling the effects, which then subside in about 60 – 90 minutes. With intramuscular administration, it generally takes 3 – 5 minutes to begin feeling the effects, which then subside in about 45 – 60 minutes.

This onset of antidepressant effects typically occurs within 24 hours and has been known to last up to 2 weeks. Ketamine administration has been shown to effectively interrupt acute suicidal ideation in some patients. Repeated administrations over a short amount of time tends to result in more durable and clinically significant effects. KAP is a non-linear process and relief from symptoms may wax and wane before stabilization of gains is achieved. Effectiveness of treatment can typically be assessed within a few sessions, although with some clients with more complicated psychological conditions, a longer course of treatment may be needed.

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

These may prove 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 setting in connection with therapists who know your issues, hopes, desires, and struggles. As a byproduct of your experience, you may feel improvement in your emotional state and reduction in symptoms that bother you such as depression,



anxiety, and post-traumatic manifestations. You may notice that you are a bit different after a ketamine experience and that difference may be liberating and allow for new mindfulness and new behavior.

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 medicine. While it is best to form an intention for your journey, you may or may not be able to hold on to that. The journey will flow whether you hold on and resist or follow the path that unfolds and relax into it, but not holding on is best. Holding on is the main source of anxiety in this and other related journeys. A ketamine session can be light, dark, or both. Not everyone enjoys the journeys, but everyone comes through them.

Sublingual The purpose of the sublingual ketamine solution sessions is to generate a robust anti-depressant, or other (PTSD, etc.) benefit that often occurs over time with repetition of administration of the oral solution. For many individuals, only the oral solution experience may be utilized, and it alone may be sufficient for healing.

ELIGIBILITY FOR KAP TREATMENT

Once you indicate that you have understood the benefits and risks of this treatment, you will be asked to sign this form before your first visit to participate in this treatment. 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.

Before participating in KAP treatment, you will be carefully interviewed to determine if you are eligible for ketamine-assisted psychotherapy, including a medical/mental health history, review of your medical/mental health records if necessary, and administration of psychological testing to assess your state of mind and whether KAP is an appropriate treatment choice for you.

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 protect yourself 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.



Ketamine should not be taken if you have untreated hyperthyroidism. There have also been reports of some decreases in immune function in patients receiving surgical doses of ketamine. Nevertheless, ketamine has an extensive and consistent record of safety when used at much higher doses for surgical anesthesia.

It is best practice to avoid taking prescribed stimulant medication or medication in the benzodiazepine class the day prior to ketamine treatment and the day of ketamine treatment. Please notify the Sub Rosa treatment team now if you take either of these medications on a regular basis.

OVERVIEW OF KETAMINE-ASSISTED PSYCHOTHERAPY

During the Ketamine administration session, you will be asked to make three (3) 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, and
3. You will have a ride home from our clinic and will refrain from driving or operating heavy machinery for the rest of the day.

The length of ketamine sessions varies from person to person and from experience to experience. You will be mostly internally focused for the first 30 minutes to one-hour or more. With the oral solution, we refer to this state as a light trance. Following IM administration of ketamine, the experience is much deeper and yet you remain conscious of your experience. With either method or in combination, you will continue to remain under ketamine's influence at a lesser level for at least one hour. IM ketamine will be given as an intramuscular injection into the shoulder at doses of 50mg to 100mg (130mg maximally). The choice of dose will depend on prior exposure to ketamine and other psychedelics, body weight, and sensitivity. 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 at a lower dose.

We may elect a sublingual solution only for your first ketamine treatment. Sublingual solution is held in the mouth and swished for 20 minutes and then spit out into a cup. Ketamine will penetrate the oral mucosa-lining of your mouth and be absorbed rapidly in that manner. The initial oral solution session will give us a measure of your reaction to ketamine.



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 your 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 sublingual solution has been given.

POTENTIAL RISKS OF KETAMINE-ASSISTED PSYCHOTHERAPY

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 within two but up to four hours after the administration. It is possible you may fall asleep, though this is a rare event. 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 present, diminished ability to hear or 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 may not be recognizable. Synesthesia, a mingling of the senses may occur. Ordinary sense of time may morph into time dilation.

Because of the risk of nausea and vomiting, please refrain from eating and drinking for at least 4 hours preceding the session. And eat lightly when you do. Hydrate well the day before your session. If you are unduly nauseated, you may be offered an anti-nausea medication, Ondansetron, in an oral dissolving tablet form.

Ketamine generally causes a significant but not dangerous increase in blood pressure, though usually not pulse rate. If blood pressure monitoring reveals that your blood pressure is too high, you may be offered Clonidine to remedy this. There is also a very small risk of lowering BP and pulse rate.

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 loss of appetite. The above reactions occur after intramuscular administration of high doses of ketamine (in a range of greater than 6mg/kg used for surgical anesthesia). The dose to be used in this sub-anesthetic ketamine therapy is much lower (2mg/kg or less).

Driving an automobile or engaging in hazardous activities should not be undertaken until all effects have stopped; for this reason, you will be required to have someone pick you up from each ketamine session.

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 KAP work in the first place. You will receive psychotherapeutic help and ongoing guidance from your therapist.

Potential for ketamine abuse and physical dependence Ketamine 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 a history of heavy use of psychedelic drugs. In addition, ketamine can have effects on mood (feelings), cognition (thinking), and perception (imagery) that may make 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 has not occurred within the framework of KAP. We and our colleagues doing clinical ketamine work have not had patients become dependent on ketamine.

ALTERNATIVE PROCEDURES AND POSSIBILITIES

No other procedure is available in medicine that produces ketamine’s effects; major depressive disorder or clinical depression (MDD) and post-traumatic stress disorder (PTSD) 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. In addition to the above-mentioned diagnoses, 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.

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 as the only official indication for use of ketamine under the FDA is 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 mental health treatment; the primary studies have been with depression, bipolar disorders, and alcoholism. At Sub Rosa, we work with depression and PTSD, but not bipolar disorders or addiction because we believe the latter are outside the scope of our current expertise. It is not yet a mainstream treatment, though there are now many studies that demonstrate that it may be an effective treatment for these and other conditions. The therapeutic 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, 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. Your decision to undertake ketamine is completely voluntary. Before you make your decision about participating, you may ask, and will be encouraged to ask, any questions you may have about the process.

WITHDRAWAL FROM KETAMINE TREATMENT IS ALWAYS AN OPTION!!!

Even after agreeing to undertake ketamine-assisted psychotherapy treatment, you may decide to withdraw from treatment at any time.



OVERVIEW

I understand that I am to have no food or drink at least 4 hours prior to my ketamine session. I understand that I am to avoid stimulant medication or medication in the benzodiazepine class. 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 to 12 hours or more - depending on the continued presence of effects after my session has concluded.

INFORMED CONSENT ATTESTATION

By signing this form, I agree that:

1. I have fully read this informed consent form describing ketamine treatment.
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 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 ketamine treatment as outlined in this form, and under the conditions indicated in it.
7. I understand that I may withdraw from ketamine treatment at any time, up until the actual IM shot or a sublingual solution has been given.

PATIENT SIGNATURE: _____

DATE OF SIGNATURE: _____

PHYSICIAN STATEMENT

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

PHYSICIAN SIGNATURE: _____

DATE OF SIGNATURE: _____