

KETAMINE-ASSISTED THERAPY

INFORMED CONSENT

Introduction

This consent form contains information about the use of sub-anesthetic dosages of ketamine for therapeutic purposes. 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 conditions is a newer "off-label" use of ketamine. Mental health use of ketamine has become relatively widespread 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 anti-depressant. Ketamine has been administered by intravenous (IV), intramuscular (IM), sub-lingual (SL), oral, and intra-nasal routes. It has often been used after other treatment approaches have been unsuccessful.

Ketamine is now increasingly clinically used as an "off-label" treatment for various chronic "treatment-resistant" mental health conditions. Ketamine is a Schedule III medication that has long been used safely as an anesthetic and analgesic agent. It is now used, often effectively, for treatment of depression, alcoholism, substance use disorders, PTSD, and other mental health conditions.

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 psychedelic effects. Recent work has demonstrated the possibility of an anti-depressant response to low dosages of ketamine (administered intravenously, intra-nasally, or sublingually) that produce minimal psychedelic effects. This anti-depressant effect tends to be more sustained with repeated use resulting in a cumulative effect. It is our view that a psychedelic dissociative experiences may well be instrumental in providing a more robust effect. This might include a positive change in outlook and character that we term a "transformative response." We may employ both methods together as will be described below.

Essential to both methods is a time-out from 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 along with the exploration and experience of other possible states of consciousness are singularly impactful.

Monitoring

It is essential that you be followed very closely during and after your treatment. This will include blood pressure and pulse measurements—as appropriate. Both Amanda and Prentice will be with you for the entirety of your medicine sessions. Follow-up will be by telephone, email, or in-person contact as needed.

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 therapy support you will receive will aid you in making your experience 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.

Two modes of treatment

You will be administered ketamine via two methods: sublingual (SL) and intramuscular (IM) injection. Both of these methods are covered in this one consent form. They each have specific benefits.

#1. The purpose of the SL ketamine is to initiate the experience gently. Some people find the IM ketamine experience to be too abrupt. The SL ketamine provides a “runway” effect for the “take-off” that the IM ketamine will provide. Some sessions are done using only SL ketamine but at a significantly higher dose. The ketamine will penetrate the oral mucosa (the lining of your mouth) and will be absorbed rapidly in that manner. We will have you hold the SL ketamine in your mouth for 12 minutes, then spit it into a cup to end the absorption process. You’ll then rinse your mouth and prepare for the IM administration.

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

These may prove to be helpful 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 therapeutic milieu in connection with therapists who have a view of your issues, hopes, desires, and struggles. As a byproduct of your experience, you may feel improvement in your emotional state and a reduction in symptoms that bother you such as depression, anxiety, and post-traumatic symptoms. You might also 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 behaviors.

With respect to IM ketamine, we are asking that new patients consider making a commitment for three IM sessions as a minimum exposure to ketamine though we do believe that a single session provides many people a valuable and therapeutic experience. Additional sessions can be scheduled if deemed appropriate and beneficial. We understand also that you can withdraw from our treatment at any time.

The literature indicates a 70% response rate to ketamine and a remission rate for patients with treatment resistant depression (using the low dose IV drip method, or the sublingual method) of 40-50%. This is the percentage of patients having remissions from their symptoms 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. We believe that combining ketamine with intensive psychotherapy enhances these response rates.

ELIGIBILITY FOR KETAMINE TREATMENT

Once you indicate that you have understood the benefits and risks of this therapy, you will be asked to sign this form at your first visit in order 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 for participation in ketamine-assisted therapy.

Please read this Consent Form carefully, and feel free to ask questions about any of the information in it.

Before participating in ketamine treatment, you will be carefully interviewed to determine if you are eligible for ketamine therapy. This will include a medical and psychiatric history and a review of your medical and psychiatric records if necessary.

Pregnant women and nursing mothers are not eligible because of potential harmful effects on the fetus or nursing child. We strongly encourage you to protect yourself against pregnancy while undergoing ketamine-assisted therapy or in the immediate days after its use.

Untreated hypertension is a contra-indication to ketamine use as it can cause a rise in BP.

Ketamine should not be taken if you have untreated hyperthyroidism.

There have also been reports of a decrease in immune function in patients receiving high doses of ketamine. This has been seen when ketamine is used at much higher doses such as those used for anesthesia during surgery.

When these simple precautions are taken, ketamine has an extensive and consistent record of safety

OVERVIEW OF KETAMINE THERAPY

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

1. You agree to follow any direct instructions given to you by the practitioners until it is determined that the session is over.
2. You agree to remain at the location of the session until the therapists assess that it is safe for you 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 30 minutes to one hour or more. With the sublingual 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 ranging from 50 mg to 100 mg. 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, a dissolution of boundaries, and has novel effects on the mind.

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 environment (setting). After ketamine SL and IM use, you will have follow-up sessions that focus on the integration of your experience and may lead to further sessions if you wish and if that is in accord with your therapist's view of your treatment.

At any time, you may ask the practitioners any questions you may have concerning the procedure or effects of ketamine. Your consent to receive ketamine may be withdrawn by you and you may discontinue your participation at any time up until the actual SL dose or IM injection has been given.

POTENTIAL RISKS OF KETAMINE 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. This is typically two to three hours after the injection. It is possible you may fall asleep, though this is a rare event. Other adverse effects may include blurred and uncomfortable vision but will not be an issue since you will be wearing an eyeshade until the main effects have worn off. Also possible are 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 ketamine. Music that may be familiar may not be recognizable. Synesthesia (a mingling of the senses) may occur. Ordinary sense of time often will morph into time dilation or contraction.

Because of the risk of nausea and vomiting, please refrain from eating and drinking for at least the 2 hours preceding the session and have only a light meal before that time. Please also hydrate well but not in the final 2 hours before the medicine session.

If you are prone to nausea, 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 but usually not pulse rate. If blood pressure monitoring reveals that your blood pressure is too high, you may be offered a blood pressure medicine (clonidine) to remedy this. There is also a very small risk of lowering blood pressure 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 anorexia (loss of appetite). Tinnitus (buzzing in the ears) is also a possible side effect.. The dose to be used in this sub-anesthetic ketamine-assisted therapy is low (2mg/kg or less) compared to doses for surgery so is less risky.

Driving an automobile or engaging in hazardous activities should not be undertaken until all effects have worn off. 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 ketamine-assisted therapy work. They will stop! You will receive therapeutic assistance 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 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 has not occurred within this framework (dose) of treatment.

We and our colleagues doing clinical ketamine work have not had patients become dependent on ketamine.

ALTERNATIVE OPTIONS

No other procedure is available in medicine that produces ketamine's effects. Depression, PTSD, and bipolar disorders are usually treated with anti-depressant medications, tranquilizers, mood stabilizers, and psychotherapy. Electro-Convulsive 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 a comprehensive and usually residential treatment programs.

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 therapy and its use is considered "off-label." The only "official" use of ketamine is for procedural sedation and 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 therapy 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-assisted therapy 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 YOUR OPTION!!!

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

INFORMED CONSENT ATTESTATION

By signing this form, I agree that:

1. I have fully read this informed consent form 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 my mental state and may result in unusual psychological and physiological effects.
4. I give my consent to the use of ondansetron for nausea or clonidine for high blood pressure.
5. I have been given a 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-assisted therapy as outlined in this form, and under the conditions indicated in it.
7. I understand that I may withdraw from ketamine-assisted therapy at any time up to and until the oral solution or injection has been given.
8. I understand that I am to have no food or drink at least 2 and preferably 3 hours prior to my ketamine session. I understand that I need to have

someone drive me home from the sessions and not to engage in driving or any other hazardous activities for at least 6 to 12 hours or more depending on the continued presence of effects after my session has concluded.

- 9. I understand and agree that I will be billed for any missed sessions or sessions not cancelled within 24 hours of the appointment time.

Signature (Client/parent or guardian of minor client)

Date

Printed Name

PHYSICIAN/ THERAPIST STATEMENT

I have carefully explained the nature of Ketamine treatment 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 ketamine-assisted therapy. No medical issue, language barrier, or educational barrier has precluded a clear understanding of the subject's involvement in ketamine-assisted therapy.

Signature of Physician

Date

Signature of Therapist

Date

