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Informed Consent for Ketamine Assisted Psychotherapy (KAP)

This consent form contains information about the use by psychotherapy patients of medically prescribed ketamine taken sublingually while simultaneously engaged in psychotherapy. This procedure is called “ketamine assisted psychotherapy,” KAP in short.

Please be aware that the Food and Drug Administration (FDA) has not yet established the appropriateness of KAP and its use is considered off- label, the only official indication for the use of ketamine being anesthesia. KAP is thus considered an experimental treatment. Participation in KAP is completely voluntary, and you have the option to choose more traditional psychotherapy services rather than to engage in KAP.

This informed consent document gives you information that may be helpful to you in deciding whether to engage in KAP. The information contained in this form pertains only to the therapeutic aspects of KAP; information about other general aspects of the psychotherapy that we offer, such as office policies and procedures, fees for services, cancellation policy, and confidentiality, and your consent to them are contained in a separate informed consent document.

Background on the medical and psychiatric use of ketamine

Ketamine is only available by prescription from a medical provider, a physician or nurse practitioner. It is a drug regulated by the Drug Enforcement Agency (DEA) as a Schedule III medication and as such has long been used safely as an anesthetic and analgesic agent. Ketamine is also approved for use by the FDA, which has conducted evaluations of the risks and benefits associated with its use.

The administration of ketamine in sub-anesthetic doses to treat depression, alcoholism, substance use disorders, post-traumatic stress disorder, obsessive compulsive disorder, and other psychiatric diagnoses is a relatively new, off-label use of ketamine. Ketamine is increasingly used as a treatment for various chronic treatment-resistant mental and emotional conditions, often used after other treatment approaches have been unsuccessful. While the scientific data is not completely clear, research suggests ketamine may help grow new neural connections once diminished by chronic stress, leaving many people feeling relief.

The literature indicates a 70% response rate to ketamine of patients with treatment resistant depression, and a remission rate of 40-50%. Ketamine for depression has become popularized through medical infusion clinics. At infusion clinics, a patient is administered ketamine through intravenous (IV), intramuscular (IM), or intra-nasal routes. Symptoms can be relieved through this process alone, but the underlying issues that caused the symptoms may persist. Ketamine

treatment is generally considered inappropriate for persons with a history of psychosis, mania or schizophrenia, or who are currently taking benzodiazepines, stimulants, or MAOI's.

Ketamine Assisted Psychotherapy

Some psychotherapists have begun integrating ketamine into their psychotherapeutic practices as an effective adjunctive path for healing, with the benefits of ketamine enhanced by a personalized approach and the support of a trusted psychotherapist. While ketamine administered without psychotherapeutic assistance has helped with symptoms of mental and emotional problems, it is the belief of many clinicians that KAP with a skilled and experienced therapist can enhance the benefits of ketamine so that healing occurs at a deeper and longer lasting level. The use of ketamine within a personal therapeutic relationship can help the patient better identify and work through difficult experiences and behavior patterns, providing new insights and healing that might not have been possible otherwise. Ketamine assisted psychotherapy may allow a person to gain access to the causes of their struggles that were previously outside their awareness.

Becoming a KAP patient

Your medical provider, a physician or nurse practitioner who practices independently from, but coordinates your treatment plan with, your KAP therapist, will medically assess you to diagnose you and to ensure your safety when using ketamine. Your medical provider will also ask you to read and sign an informed consent document, much like this one, but with additional information about the physical and medical effects and potential side effects of ketamine. If in the judgment of that medical provider, you are assessed as an appropriate candidate for treatment with ketamine and KAP, you will then authorize your medical provider and your KAP psychotherapist to consult about how KAP might best work for you. You and your prescribing medical provider (not your KAP therapist) will decide on the dose and frequency of your ketamine; professional responsibility for those medical decisions lies exclusively with your prescribing medical provider. Your KAP therapist will consult with your medical provider whose assessment will assist your KAP therapist to formulate a psychotherapeutic treatment plan to meet your particular KAP needs.

Please be aware that while your medical provider and KAP therapist will be working in consultation with each other to assist you, they are each separate independent practitioners, each making their own independent assessments and each having exclusive responsibility for the separate aspects of your care that they each provide. The licensure and competence of your KAP psychotherapist is in providing psychotherapy including KAP, but not in prescribing or administering medications such as ketamine.

Overview of KAP

The length of ketamine sessions varies from person-to-person and from experience-to-experience. The sublingual lozenges can be described as a state of "light trance." 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. Your

medical provider will make recommendations regarding dosage. Lozenges dissolve slowly and it is best not to swallow your saliva until after your lozenge has dissolved, typically about 5 minutes. Lozenges may be spit out after the timed absorption period or swallowed. Ketamine will penetrate the oral mucosa—lining of your mouth— and will be absorbed rapidly in that manner.

After ketamine use, you will have follow-up sessions that focus on integration of your experience and may lead to further sessions.

You may ask your therapist 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 lozenge has been given.

Potential Risks of KAP

Generally speaking, you will likely want to lay still during the ketamine administration because your sense of balance and coordination will be adversely affected until the drug's effect has worn off, which is generally 2 to 4 hours after the administration. That said, it is also possible you will feel the impulse to move your body, and that is also welcome and your therapist will be available to support you to navigate the space around you, as needed. It is possible you may fall asleep, though this is a rare event.

Other possibilities for adverse effects include blurred and uncomfortable vision, slurred speech, mental confusion, excitability, diminished ability to see things that are actually 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.

Please eat a light, high protein snack about 2 - 3 hours before taking the lozenge and do not eat anything else prior to the administration. You may drink water for up to 30 minutes prior to the session. Please refrain from consuming caffeine the same day as your session as this is known to counteract the medicine's effects.

Ketamine generally causes a significant but not dangerous increase in blood pressure, though usually not pulse rate. A blood pressure cuff will be used to monitor blood pressure as needed. Agitation may occur during the course of a ketamine session. This is a rare event experience.

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 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—and for this reason **you will be required to have someone pick you up from each ketamine session**. Plan to not drive the rest of the day following your session.

In terms of psychological risk, ketamine has been shown to worsen certain psychotic symptoms in people who suffer from schizophrenia. 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. They will stop! You will receive psychotherapeutic help and ongoing guidance.

The effectiveness of KAP

KAP is a new treatment, still considered experimental and not yet mainstream, though there are now many studies that demonstrate that it may be effective. It does not necessarily permanently relieve symptoms of mental and emotional disorders, however. If your symptoms respond to KAP, you may still elect to be treated with other psychiatric medications and other ongoing non-specific psychotherapy to try to reduce the possibility of relapse. Over time, you may also need additional KAP treatments or other therapies to maintain your improvement or remission.

Your decision to withdrawal from KAP is always an option. Even after agreeing to undertake KAP, you may decide to withdraw from treatment at any time.

AGREEMENTS:

You are asked to make 5 agreements with your KAP therapist to ensure your safety and well-being:

1. You agree to follow any direct instructions given to you by your therapist until it is determined that the session is over.
2. You agree to remain at the location of the session until your therapist decides you are ready to leave.
3. You agree to not engage in any driving or hazardous activity for the rest of the day after your KAP session.
4. You agree to not ingest ketamine until you are directed to do so by your therapist during the session.
5. You agree to schedule and to complete integration sessions with your therapist. You agree to practice self-directed integration methods in-between sessions as explained by your therapist.

By signing below, I understand and acknowledge the following:

1. I have fully read this informed consent form describing ketamine treatment and agree to its terms holding harmless the therapist involved in my care, waiving, releasing and discharging all claims, rights, and/or causes of action, which may arise out of or in connection with my participation in KAP.
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 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.
5. I understand that my KAP therapist is bound by mandatory reporting and duty to warn statutes just as they are in normal therapy sessions.
6. I understand that I may withdraw from ketamine treatment at any time, up until the actual lozenge has been given.
7. I understand that this consent form does not replace or supersede any other consent forms I may have signed with my therapist previously.

Client Signature

Date