

## **Informed Consent to Ketamine Assisted Psychotherapy (KAP)**

### About this informed consent document

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. 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 as a current psychopharmacological treatment

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 taken during psychotherapeutic treatment, aka KAP

Interested in providing the most advanced and effective care for their patients, psychotherapists as well as physicians have studied the science and benefits related to ketamine. 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.

### The KAP experience

Three full hours will be reserved for your KAP session. After you self-administer your prescribed sublingual ketamine in our office in accordance with the instructions given to you by

your medical provider, your KAP psychotherapist will support and guide you as you encounter and explore emotional issues that arise during the KAP session. You agree to follow any direct instructions that your psychotherapist gives to you until the therapist determines that the session is over, and to remain at the location of the session until the therapist decides that you are ready to leave.

Ketamine is formally classified as a “dissociative” anesthetic, dissociation meaning a sense of disconnection from one’s ordinary experience of reality and self. At the dosage typically self administered during KAP, most people experience mild anesthetic, anxiolytic (anxiety reducing), antidepressant and, potentially, psychedelic effects though these latter effects are typically minimal. The antidepressant effect tends to have a cumulative effect, that is, be more sustained with repeated use. It has been speculated that dissociative experiences are associated with greater and longer lasting beneficial effects. This may also include a positive change in outlook and character that some describe as profound and transformative.

You should be aware that some emotional and other experiences that arise during KAP may be temporarily disturbing to you. Visual, tactile and auditory processing may be altered. A mingling of the senses and emotions may occur. Your ordinary sense of time may become dilated, meaning your perception of the passage of time may be different than the actual passage of time.

When the session ends you may still be under the influence of ketamine so leaving with a friend or family member is strongly recommended. Driving an automobile or engaging in hazardous activities should not be undertaken until all effects have stopped. You will meet with your therapist either the following day or within the week in order to help you process your KAP experience.

### Chaperone

If you are engaging in a KAP session remotely or self-guided, you agree that you will have a friend or family member present for the duration of your KAP session and you understand that we will not proceed with a KAP session if a chaperone is not present. For sessions conducted in our office, we strongly recommend that you have a chaperone present to take you home after your session is complete. You will provide us with the name and contact information for your chaperone. You acknowledge and agree that, if you choose to proceed with KAP in our office without a chaperone, you acknowledge that you are acting against clinical advice and waiving liability related to your decision.

### Confidentiality

As you may participate in group KAP, either in person or through a virtual session, or as you may come into contact with other patients in our office, you agree that you will keep any information that you learn regarding the identity of any other patient, including but not limited to individuals with whom you may participate in group therapy sessions (in person or virtually), confidential. You agree not to disclose such information unless required by law.

You understand that your presence in your therapist's office or on a virtual setting from time-to-time may be visible to third parties, including the chaperones of other patients, friends and family members of other patients, and others present in the office or virtual setting.

#### Emergency protocol

You acknowledge and agree that, if a medical emergency occurs during your remote or in-office KAP session, your therapist will call 911. You further acknowledge and agree that, if you are receiving KAP services remotely or self-guided, your chaperone also may reach out for emergency medical assistance through 911 in the event of a medical emergency.

#### Movement during KAP session

You acknowledge and agree that your therapist will advise you on whether it is safe to leave a session, such as to use the restroom or to seek fresh air. If your therapist determines that it is safe, if your session occurs in our office, your therapist will accompany you. If your session occurs remotely or in your home, your chaperone will accompany you. You acknowledge and agree that you will comply with your therapist's instructions unless you feel unsafe in doing so. If you choose to leave a session against the advice of your therapist, you release our practice and any therapists providing services to you for any liability related to your actions in leaving the session.

#### Use of Scent

You acknowledge and agree that your therapist may use aromatherapy or scents during your KAP sessions, facilitated by your chaperone if you participate in KAP self-guided or remotely, unless you object orally or in writing to the proposed use of any aromatherapy or scents. Your therapist will discuss the proposed use of aromatherapy or scents with you prior to initiating any use of aromatherapy or scents and will comply with your wishes if you choose to refrain from using, or discontinue the use of, aromatherapy or scents. You retain at all times the ability to revoke any consent for the use of aromatherapy or scents.

#### Use of Touch

You acknowledge and agree that your therapist may use touch therapy during your KAP sessions, facilitated by your chaperone if you participate in KAP self-guided or remotely, unless you object orally or in writing to the proposed use of any touch therapy. Your therapist will discuss the proposed use of touch therapy with you prior to initiating any use of touch therapy, and will comply with your wishes if you choose to refrain from using, or discontinue the use of, touch therapy. You retain at all times the ability to revoke any consent for the use of touch therapy.

#### Disposal

You acknowledge and agree that you will follow the applicable state disposal guidance for any ketamine in your possession that will not be used.

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

Withdrawal from KAP is always at your option. Even after agreeing to undertake KAP, you may decide to withdraw from treatment at any time.

Your agreement

Please read this consent form thoroughly and carefully, and feel free to ask questions about any of the information in it. Once you indicate that you have understood the benefits and risks of this treatment, you will be asked to sign this form. By signing this document, you indicate that you have understood the information provided and that you give your consent to KAP.

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Signature

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Date