

# Ketamine Assisted Psychotherapy Consent — Consents

## Ketamine Assisted Psychotherapy (KAP) Informed Consent Form

### What is Ketamine?

Ketamine is a validated “off-label” treatment for various chronic “treatment-resistant” mental illnesses. Ketamine is a Schedule III medication that has long been used safely as an anesthetic agent and now, at times, effectively as treatment for depression, substance dependencies, PTSD and other psychiatric diagnoses.

### How Does It Work?

The current, most probable, understanding of ketamine’s mode of action is as an NMDA antagonist working through the glutamate neurotransmitter system. It is classified as a dissociative anesthetic. At the dosage level administered to you, you will most likely experience analgesic, anxiolytic, antidepressant, and psychedelic effects. Ketamine also may bring about “transpersonal,” “mystical,” or “out-of-body” experiences that may also serve to facilitate a shift in your perspective and emotional state.

### Monitoring

It is essential that you be monitored closely during and after your treatment. This may include blood pressure and pulse measurements, some psychological measurements before and after your session, close supervision and support during your treatment session with your psychotherapist, and follow-up telephone and in-person contact with your treatment team. Your therapist will prepare you for your ketamine session(s) and assist you in integrating your experience(s) afterwards.

### 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 immediate 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 psychotherapeutic support you will receive will aid you in making your experience(s) valuable and understandable to you. Some experiences may be temporarily disturbing, but the integration process may greatly help you move to clarity and understanding. Because each person is unique, there is no way to predict the length of treatment, number of treatments, or the outcome of treatment. As you and your psychotherapist get to know one another, they will be able to compare your treatment to other client experiences and make adjustments to the number and duration of treatments.

### Why Ketamine Assisted Psychotherapy (KAP)?

The purpose of KAP is to create a non-ordinary (“altered”) state of consciousness in order to facilitate working through trauma and attachment-related distress. This may include profound transpersonal (“transcendental,” “mystical,” “spiritual,” “religious”) peak experiences that may be beneficial in resolving your existential problems, accelerating your

psycho-spiritual growth and lead you to a deep personal transformation and optimization of your lifestyle. Such change is best facilitated within a structured supportive psychotherapeutic 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 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 well be liberating and allow for new new behaviors and perspectives to emerge. It is frequently the case that a ketamine experience may promote happiness, empathy, loving-kindness to self and others, and a sense of greater self-acceptance and peacefulness. A ketamine session can be light, dark, or both. There will be concepts, visions, encounters, and you may well deal with your own death, mortality, and immortality. Not everyone enjoys the journey, but everyone comes through it—and generally with a measure of positive change and a sense of having had a profound experience that may be life changing. Your experience will be unique to you.

### Participation in Ketamine Assisted Psychotherapy (KAP)

Before participating in ketamine treatment, you will be carefully interviewed to determine whether you are eligible for ketamine therapy, including a medical history, a physical exam if deemed necessary, review of your medical/psychiatric records, a psychiatric history and 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 advisable to protect against pregnancy while exposing yourself to ketamine or in the immediate aftermath of its use.

Untreated hypertension is a contra-indication to ketamine use as the substance causes a rise in blood pressure. Similarly, a history of heart disease may make you ineligible to participate or require permission from a physician.

Information on ketamine's interaction with other medicines is only partially available and interactions with your current medication will be assessed as part of determining your eligibility for KAP.

Ketamine should not be taken if you have hyperthyroidism. There have also been reports of some decrease in immune function in patients receiving surgical doses of ketamine.

### Overview of Ketamine Assisted Therapy (KAP)

During the Ketamine administration session, you will be asked to make two (2) agreements with the therapist(s) to ensure your safety and well-being:

You agree to follow any direct instructions given to you by the therapist(s) until it is determined that the session is over, and

You agree to remain at the location of the session until the therapist(s) decides you are ready 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 45 minutes to one-hour and- a-half following administration of ketamine. You will continue to remain under ketamine's influence at a lesser level for at least one hour. Under my care, you will self-administer oral ketamine at doses of 100 mg up to

200 mg maximum. The dose will depend on prior exposure to ketamine and other psychedelics. It is always better to start with a lower dose to reduce anxiety and become familiar with what a substance may produce in you. Ketamine 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 for familiarization with ketamine and its effects on you. 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 therapeutic state that is based on rapport and trust (our “set up”) in a safe and conducive “setting,” the clinical office. That may require several sessions prior to your use of the drug. After ketamine use, you will have follow-up sessions that focus on integration of your experience and may lead to further sessions, if you so wish.

### Potential Risks of Ketamine Assisted 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— generally two and up to four hours. 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 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 the drug. Familiar music may appear quite different to you, even unrecognizable. Synesthesia, a mingling of the senses, may occur. Ordinary sense of time may morph into time dilation. You may feel nausea, so consider eating lightly or fasting prior to your appointment. Hydrate well prior to the session as ketamine can act as a diuretic. Ketamine generally causes a significant increase in blood pressure but usually not pulse rate.

Agitation may occur during the course of a ketamine session. 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 a surgical anesthesia. The dose to be used in this sub-anesthetic ketamine therapy is much lower (2 mg/kg or less).

Driving an automobile or engaging in hazardous activities should not be undertaken for 6 hours after treatment with ketamine and definitively until all effects have stopped if for any reason they continue longer. 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. If you have been or are presently diagnosed with similar severe Mental Disorders, you may not be a candidate for KAP. During the experience itself, some people have reported unusual or frightening experiences. These experiences, however, may be of paramount value to your transition to recovery from the suffering that brought you to your KAP work. You will receive psychotherapeutic help and ongoing guidance from your therapist.

### 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 as

Hallucinogens (“Psychedelics”). Ketamine is a controlled substance and is subject to Schedule III rules under the Controlled Substance 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 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 some people want to use it repeatedly. Therefore, ketamine should never be used except under the direct supervision of a licensed health professional.

#### Alternative Procedures and Possibilities

No other procedure is available in medicine that produces ketamine’s effects. Major Depression (MDD) and Bipolar Disorders are usually treated with anti-depressant 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. 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. 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 Psychotherapy, and its use is considered off-label, the only official “indication” for use of ketamine being 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 treatment program. It may not permanently relieve depression. If your depressive symptoms respond to Ketamine Assisted Psychotherapy, you may still elect to be treated with medications and ongoing psychotherapy to try to reduce the possibility of relapse. Over time, you may also need additional ketamine treatments or other therapies to maintain your remission.

Your decision to undertake Ketamine Assisted Psychotherapy is completely voluntary. Before you make your decision about participating in KAP, you will be encouraged to ask any questions you may have about the process. Withdrawal from KAP is always your right. Even after agreeing to undertake Ketamine Assisted Psychotherapy, you may decide to withdraw from treatment at any time.

#### Informed Consent

By signing this form I agree that:

I have fully read this informed consent form describing Ketamine Assisted Psychotherapy.

I have had the opportunity to raise questions and have received satisfactory answers.

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.

I agree that I will not engage in any driving or hazardous activity for at least 6 hours or longer after my session has concluded, and that I will not engage in any such activities until the effects of the Ketamine-induced state are no longer present.

Do not drive immediately following a medicinally supported session, even if you may feel the medicine has moved out of your system. By signing this document, you agree to arrange for a ride, either from a family member or friend, through public transportation or from a taxi service. We will provide assistance in helping you arrange transportation and working with you to set up an appropriate schedule to meet your travel needs.

I have been given a signed copy of this informed consent form, which is mine to keep.

I understand the risks and benefits, and I freely give my consent to participate in KAP as outlined in this form, and under the conditions indicated in it.

I understand that I may withdraw from KAP at any time, up until the ketamine has been administered.

Ketamine prescriptions are for use during therapy sessions only. By signing this document you agree to allow your therapist to monitor the amount of ketamine you use during session, and maintain records of how much you have left.

This document also acts as a Release of Information between Wild and Wonderful Life and your prescribing psychiatrist, allowing us to communicate personal information for the purposes of maintaining your prescription. This Release includes information about drug and alcohol abuse, addiction and treatment, mental health assessments relevant to receiving a prescription, and any concerns the therapist may have in regards to your prescription. This Release will terminate at the time you terminate therapy at Wild and Wonderful Life.