

Ketamine Therapy Informed Consent Form

What is Ketamine?

Ketamine is now 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 use disorders, and other psychiatric diagnoses.

How Does It Work?

The current understanding of ketamine's mechanism of action is as an NMDA antagonist working through the glutamate neurotransmitter system. It is classified as a dissociative anesthetic. At sub-anesthetic dosages you will most likely experience analgesic, anxiolytic, antidepressant, and dissociative effects. Ketamine may also serve to facilitate a shift in your perspective and emotional state.

Monitoring

You will be monitored closely before, during, and after your treatment. This will include blood pressure and heart rate measurements before and after your session. There will be medical supervision and support during your treatment session.

How Long Will It Take Before I Might See Beneficial Effects?

You may experience changes in perspective, 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.

Eligibility/Participation in Ketamine Therapy

Before participating in ketamine treatment, you will be carefully interviewed to determine whether you are eligible for treatment, 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 contraindication to ketamine use as the substance causes a rise in blood pressure. Similarly, a history of heart disease may make you ineligible to participate.
- Information on ketamine's interaction with other medicines is only partially available and it will be assessed as to your eligibility for Ketamine Therapy.
- Ketamine is not recommended if you have hyperthyroidism.

Overview of Ketamine Therapy

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. Ketamine will be given as an intramuscular injection generally at doses of 50 mg to 125 mg. Intravenous dosages will start at 0.5mg/kg and can be titrated to effect generally not exceeding 1.0mg/kg. The choice of dose will depend on prior exposure to ketamine and other psychedelics. Novice subjects will receive a lower dose in the initial session. It is always better to start with a lower dose to reduce anxiety and become familiar with what a substance may produce in you. There is always an opportunity to make a choice for a larger dose at a future date—if appropriate.

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 (set) in a safe and conducive setting. That will require prior sessions to your use of the drug. After ketamine use, it is recommended that you have follow-up sessions that focus on integration of your experience. It may lead to further sessions, if you so wish, and if that is in accord with your therapist's view of your treatment.

Potential Risks of Ketamine (IM) Assisted Therapy

You will be asked to stay still during the ketamine administration because your sense of balance and coordination will be adversely affected until the drug's effect has worn off. 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 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 be distorted.

Because of the risk of nausea and vomiting, please refrain from eating and drinking for at least the 6 hours preceding the session. On the day of treatment, if you eat prior to the 6-hour fasting period, eat lightly. Hydrate well prior to the 6-hour fasting period.

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. If you have been or are presently diagnosed with similar severe mental disorders, you may not be a candidate for Ketamine Therapy.

Potential for Ketamine Dependence and Addiction

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. 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 supervision of a licensed physician.

Alternative Procedures and Possibilities

No other procedure is available in medicine that produces ketamine's effects. Alternatives for such conditions treated with ketamine are usually 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. 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, data, and all 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

The Food and Drug Administration (FDA) has not yet established the appropriateness of Ketamine Therapy, and its use is considered off-label. The only official indication for use of ketamine 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 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 Therapy, 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.

Even after agreeing to undertake Ketamine Therapy, you may decide to **withdraw** from treatment at any time.

By signing this form, I agree that:

1. I have fully read this informed consent form describing Ketamine Therapy.
2. I have had the opportunity to raise questions about ketamine treatment.
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 that I am to have no food or drink for 6 hours prior to my ketamine session.
5. 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.
6. I have been given a copy of this informed consent form.
7. I understand the risks and benefits, and I freely give my consent to participate in as outlined in this form, and under the conditions indicated.
8. I understand that I may withdraw from treatment at any time, up until the actual injection/infusion has been given.

Printed Name: _____

Signature: _____

Date: _____

Reference:

Wolfson, P. E. (2014). Wolfson, P. E. (2014). Ketamine (IM) assisted psychotherapy (KAP): A model for informed consent. *International Journal of Transpersonal Studies*, 33(2), 185–192.. *International Journal of Transpersonal Studies*, 33 (2).
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