

— Journey to New Hope —

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KETAMINE-ASSISTED PSYCHOTHERAPY (KAP) CONSENT

This consent form contains information about the use of ketamine for mental health and psychological wellness. Please read this consent form carefully. Before signing this document, please make sure you have had all of your questions and concerns addressed by Dr. Chakoian.

This consent form includes the following sections:

1. Brief history of ketamine's use in medical settings
2. Off-label ketamine use for mental health and wellness
3. Conditions that are treated versus those that may not a good fit for KAP
4. What to expect when you are experiencing a ketamine medicine session
5. Preparation, Ketamine medicine session safety measures and planning, and Integration following the medicine sessions
6. Risks of Ketamine
7. Alternatives to Ketamine
8. Explanation of your voluntary participation and right to withdraw from therapy at any time
9. Informed consent attestation and patient agreements for KAP sessions
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1. Brief History of Ketamine

Ketamine was approved by the Food and Drug Administration (FDA) for use as an anesthesia medication in 1970. Ketamine continues to be used as an anesthetic or as a sedative for medical procedures, typically in emergency settings because it is safe and easy to use, especially compared to other anesthetics.

After more than 40 years of use in both humans and animals for sedation and anesthesia, the first trials of ketamine for treatment-resistant depression were conducted by the National Institutes of Mental Health. The results were promising and represented a breakthrough in the treatment of depression for people who had not responded adequately to conventional therapies.

The original protocol for ketamine use in mental healthcare with the NIMH did not integrate psychotherapy, which many psychiatrists and therapists felt was necessary to realize the full promise of ketamine. Because of this, pioneers in the field began providing ketamine treatment as a part of a comprehensive and holistic package of psychotherapy. In this model of care, thoughtful attention is given to each client's mental health history, including the significance of adverse life experiences to the development of the symptoms and conditions being treated with ketamine. The results of this combination of psychotherapy with ketamine yielded impressive and longer-lasting benefits, and the list of conditions treated soon expanded to include PTSD and anxiety.

2. Off-Label Ketamine Use for Mental Health and Wellness

Ketamine is increasingly used “off label” by licensed providers to address issues of psychological and emotional wellness. Off-label is a term used to describe the appropriate use of a prescribed medication for reasons other than its FDA approval, when its regular use is generally accepted as safe and appropriate by the medical community. Off-label use of medications is legal and a common practice, as testing medications for all possible uses would be prohibitively expensive and would delay bringing medicines to practice where they may show great benefit. About one in five of all prescriptions issued in the United States is an off-label use.

Ketamine administration has been shown to be both safe and effective for a number of mental health conditions, both in a medication-only model, and in combination with psychotherapy. Ketamine administration combined with other therapies has been termed Ketamine Assisted Therapy, or Ketamine Assisted Psychotherapy (KAT or KAP). This model usually involves pre- dosing preparation sessions, and post-dosing integration sessions, with greater attention paid to the emotional state, mindset, and the setting in which the ketamine is administered.

While there is currently no recognized national certification for ketamine providers, the American Society of Ketamine Physicians, Practitioners, and Psychotherapists (ASKP3) is closest to establishing this, and they have issued ethical guidelines for its use. I adhere to their guidelines, ethical standards and codes, which can be found on their website (askp.org).

3. Conditions that are treated versus conditions that may not a good fit for KAP:

Dr. Chakoian will meet with you for an intake appointment in which he will review your mental health history and goals, as well as discuss physical health concerns and current medications. Conditions for which KAP may be very helpful include depression, post-traumatic stress, grief, burn-out, and anxiety/overwhelm.

There are also some psychiatric conditions that make ketamine use a higher risk, and we will review your symptom history to be sure the treatment is safe for you. Conditions and symptoms that would be contraindications (not safe to proceed with KAP) include active psychosis or diagnoses of schizophrenia/schizoaffective disorder, Bipolar Disorder Type 1, manic symptoms, borderline personality disorder, or derealization/depersonalization.

There are some medical conditions that increase risks of ketamine. Dr. Chakoian will not administer ketamine if you are pregnant or nursing, because the long term effects on a fetus, or a nursing child, aren't yet fully known. Actively preventing pregnancy is recommended while you are receiving ketamine treatment, and if you're not 100% sure of your status, pregnancy tests will need to be completed prior to proceeding (available on request). Ketamine can cause a small and temporary increase in blood pressure, similar to the rise experienced during light exercise. Dr. Chakoian will discuss options if your blood pressure is already high before ketamine is administered. If you have a history of heart conditions, Dr. Chakoian may need to consult with your primary care provider or cardiologist. Ketamine should not be taken if you have untreated thyroid conditions. If you have sleep apnea, you may be asked to bring any devices you use during sleep.

All clients will be accepted on a case-by-case basis after an intake appointment and medical review has been completed. Regardless of diagnosis, Dr. Chakoian has the obligation to decline to treat patients when he assesses that ketamine treatment is not appropriate for their care.

4. What to expect when you are experiencing a ketamine medicine session

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, anti-depressant and, potentially, psychedelic effects. Non-ordinary (“altered”), transpersonal (“transcendental”, “mystical”, “spiritual”, “religious”) peak experiences often

occur. Research has demonstrated the possibility of an antidepressant response to low doses of ketamine—administered intravenously or intramuscularly. The antidepressant effect tends to be more sustained with repeated use—in other words, a cumulative effect.

Although the physical effects of ketamine are fairly predictable, patients' psychological and emotional experiences with ketamine are unique, and each of your sessions could be very different. You may experience immediate and profound changes in mood and perspective, or you may not experience much of anything. Ketamine can have significant effects even without a memorable psychedelic or dissociative experience. Specifics about the internal ketamine experience itself are hard to describe, and to predict. Therefore, you will be encouraged to approach the dosing sessions with a sense of curiosity and openness. You may have read or heard descriptions of other people's experiences, but your experience will likely differ in some ways from other people's. It will be most helpful to let go of any expectations of the ketamine medicine session as much as you're able. While we can identify goals for your treatment outcomes, it is best to not be attached to certain expectations for the ketamine journey itself. Your approach to, and use of the period following ketamine dosing can be just as important, or more important than the treatment itself.

Using ketamine in the context of psychotherapy can create an enhanced window of opportunity to make significant changes in your patterns of thoughts, emotions, and behaviors. The integration support that will follow the ketamine dosing is meant to support and encourage you to derive meaning and utility from the dosing session, and to explore any changes in your perspective revealed by the ketamine experience.

More robust and lasting effects generally occur with repeated ketamine treatments, and when treatment is one of multiple approaches you use simultaneously to enhance wellness in your life. It is likely that ketamine alone will not permanently relieve depression or other mental health conditions. You may still want or need to engage in other therapies, which may include other psychiatric medications, as well as activities to try to reduce the possibility of symptom relapse. You may benefit from intermittent ketamine treatments to maintain a remission of symptoms. Rarely, people can stop benefiting from additional ketamine sessions. In those cases, it may be best to take an extended break from the treatment or stop treatments permanently.

5. Preparation, Ketamine medicine session safety measures and planning, and Integration following the medicine sessions

Ketamine treatment will begin with one or more preparation sessions. We will talk about your current condition and intentions for treatment, and design and plan for the dosing session, which will be tailored to your preferences and goals. Dr. Chakoian will want to address any concerns and questions you have before you are administered ketamine. Some of the areas we will cover during our preparation will include preferences for your comfort and the physical space, the use of sound and music, aromatherapy, and how we will signal and communicate with each other during the session. When we agree that we're adequately prepared, a ketamine dosing session will be scheduled. We will likely plan for a 2 to 3 hour session, depending on the route of administration, the number of doses you are given, your familiarity with the treatment, and how much immediate integration work you wish to do. Most dosing sessions will be followed by one or more non-dosing integration sessions, when we will review your experience, process any insights you achieved and identify how you might integrate this new information into your life, and consider changes or adjustments for future dosing sessions.

Taking the time for thorough preparation and follow up sessions can be as important as the ketamine treatment itself. These aspects are also what makes KAP different from recreational ketamine and IV ketamine infusion facilities. Dr. Chakoian believes this approach makes the most out of your investment of time, resources, and experience, and adds to the overall safety of the treatment. The week or two after a ketamine dosing session can be a unique window of opportunity to make use of any insights or perspective shifts that you experienced. Alternating the ketamine dosing session with integration

appointments gives us the time and space to discuss, process, and contextualize the experiences. Together, we will aim to maximize your treatment benefits by approaching the preparation and integration sessions as opportunities to actively and deliberately apply the benefits of ketamine to your life goals.

Dr. Chakoian administers ketamine either by an intramuscular injection in the arm, or orally, using a dissolvable tablet, or possibly as an injection under the skin. We may use multiple different routes over the course of your treatment. At this time, Dr. Chakoian does not administer ketamine intravenously (IV) but can help you find facilities that do, if we determine that would be the best option for you. Dr. Chakoian does not provide ketamine for home use.

Your individualized dose and route will depend on many factors, including your current condition, your prior experience with ketamine or other psychedelics, body weight, sensitivity to medications, and the length of time we plan for you to have direct effects of the ketamine. Dr. Chakoian will work as efficiently as possible to find a dose and route that works best for you. However, your safety is the top priority, and the process may require adjustments as we understand your response to ketamine.

The length of time you will experience the direct effects of ketamine can vary depending on several factors, but usually ranges from 45 minutes to 2 hours. At higher doses for mental health purposes (which are still magnitudes lower than anesthesia doses), you will most likely be internally focused for at least the first hour or so, and using eyeshades and headphones during that time is recommended.

Ketamine can cause nausea and very rarely can cause vomiting, especially if you are prone to motion sickness. We will talk about ways to minimize the chances of this, and what to do if you are sensitive in this way. You will be asked to not eat, and to limit drinking to small sips, for 3 to 4 hours before ketamine administration. If you tend to get nauseated with medications or motion, we can discuss anti-nausea remedies that you can take at home before coming to the office. If your blood pressure is higher than normal, you may be offered one or more medications before you come to the office for ketamine dosing, or when you arrive, to temporarily lower it.

Dr. Chakoian's primary commitment is to your safety during ketamine treatment. We will discuss instructions for safety during ketamine dosing sessions, and you will be asked to remain at the office until Dr. Chakoian has assessed that you are safe to leave. We will be talking about your transportation plans at the planning session, and you should not drive until the day after a ketamine dosing session.

We will schedule two to three hours for a ketamine dosing session. Your sense of balance and coordination can be affected until the drug's effect has worn off, which can take up to a couple hours. It is possible you may fall asleep, though this is rare and we will make dosing decisions aimed to prevent this, and to optimize your memory for the session. Ketamine can cause blurred and distorted vision, which can increase the chance of nausea, so it is suggested to keep an eye mask on until most of the main effects have worn off.

Dr. Chakoian will not have any physical contact with you during ketamine treatment except for ways in which we have explicitly agreed upon before the session. We will discuss and plan ahead for ways to communicate with each other during your treatment. This will include your needs for getting back and forth to the bathroom if needed, ways to signal for comfort and support needs, communicating the passing of time during the session, and how we will respond to an emergency situation.

Dr. Chakoian will be present throughout the session. In addition there may be a second person, trained to be a "sitter" and experienced in ketamine, to help hold the space and to act as a chaperone. If there is not a sitter present Dr. Chakoian will make a video of the session and give you a copy of the file at the end of the session. This is to guarantee that nothing inappropriate will occur during the session. Just as your medical safety is a top priority, your emotional safety is paramount.

6. Risks of ketamine therapy:

Although uncommon, ketamine may cause uncomfortable reactions. Many of the adverse effects listed below have been reported when ketamine is given in high doses for surgical or procedural anesthesia, many times greater than the doses we will be using, or when it has been used recreationally in very high doses.

You may experience somewhat intense emotional states as well as disturbances in perception during ketamine dosing. Ketamine can be challenging for people who already have perceptual disturbances, and those who have distress with these kinds of experiences should use ketamine with caution or not utilize ketamine, especially at times when symptoms are already severe or impairing in any way. It is suggested that people with Bipolar Disorder may be prone to shift toward a manic condition after using ketamine. Any kind of profound or intense experience may worsen underlying psychological stability in people with severe personality disorders and dissociative disorders. Space and time distortion can occur during ketamine, and it is possible for people with trauma in their personal or generational history to re-experience or revisit traumatic events.

Common side effects

- increased blood pressure and heart rate
- dizziness
- blurred vision, nystagmus
- out of body experience
- change in motor skills, or clumsiness

Rare side effects

- vivid dreams, nightmares, insomnia
- nausea and vomiting
- increased saliva production
- loss of appetite
- soreness or inflammation at the injection site
- rash
- double vision
- increased pressure in the eye
- sudden muscular movements

Very rare side effects

- allergic reaction
- irregular or slow heart rate
- low blood pressure
- cystitis of the bladder: inflammation, ulcers, and fibrosis

Repeated, high dose recreational use of ketamine has caused urinary tract symptoms and even permanent bladder problems. *This has not occurred at the doses used for therapeutic reasons.*

Risk of developing addiction to Ketamine:

Ketamine is classified as a Schedule III narcotic, and is generally referred to as a “controlled substance.” Ketamine and other hallucinogenic compounds when used intermittently do not typically lead to problematic drug tolerance (having decreasing effects after repeated use) or withdrawal symptoms (having unwanted physical and other effects after stopping the drug). Addiction can occur, and tolerance

will occur, with regular use, especially daily use. Cravings for repeated use of ketamine are rare, but can occur, since ketamine can have pleasurable effects on mood, thinking, and perception that can lead to a desire to use it repeatedly. Limiting your ketamine use to intermittent, monitored, in-office dosing essentially eliminates the risk of problematic use. However, if you have any worries about your ketamine treatment, or if you are looking for, or are obtaining ketamine from other sources while you are receiving treatment from me, please inform Dr. Chakoian right away.

7. Alternatives to Ketamine:

No other procedure is available in medicine that produces the same effects as ketamine. However, other treatments for mood and anxiety disorders include anti-depressant and antianxiety medications, mood stabilizing medications, psychotherapy, electroconvulsive therapy (ECT), transcranial magnetic stimulation (TMS), psychotherapies, somatic therapies, as well as no treatment. Ketamine can also be combined with most of these treatment options.

8. Explanation of your voluntary participation and right to withdraw from therapy at any time:

Aside from the Spravato preparation (also called “esketamine,” which is an extraction of ketamine prepackaged in a nasal spray), the Food and Drug Administration (FDA) has not yet approved ketamine for mental and emotional wellness applications. KAP’s use of ketamine is considered off-label, and the only official FDA indication for the use of ketamine is for anesthesia. Your awareness of this situation is key to understanding our shared responsibility associated with your use of ketamine. Transparency and collaboration are a necessary part of your ketamine treatment. Dr. Chakoian values your partnership and will be available to answer your questions and address your concerns. If at any point you decide that ketamine is not the way you want to address your treatment goals, you are always free to decide not to accept it, and can stop treatment any time.

KETAMINE-ASSISTED PSYCHOTHERAPY INFORMED CONSENT ATTESTATION

By signing this form I indicate that:

1. I have fully read the attached material describing ketamine therapy, and have discussed the treatment with David Chakoian, M.D.
2. I have had the opportunity to ask questions, to receive satisfactory answers, and to discuss ketamine treatment and its potential risks, benefits, and alternatives.
3. 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.
4. I understand there is a possibility that symptoms may return between ketamine treatments, or after I stop treatment.
5. I understand that treatment is completely voluntary and that I may withdraw from ketamine therapy at any time.

PATIENT AGREEMENTS FOR KETAMINE TREATMENT

1. I will not eat and will limit fluids to sips for at least four hours before a ketamine dosing appointment. I will inform Dr. Chakoian if I did not follow these guidelines prior to any ketamine administration.
2. I will take all of my usual medications on the day of a ketamine dosing appointment, unless discussed otherwise with Dr. Chakoian. If I have not, I will inform Dr. Chakoian prior to any ketamine administration.
3. I will not drive a car or operate potentially dangerous tools or equipment until the morning after being administered a dose of ketamine. I will continue to not drive if my thinking seems at all altered or slowed, as rarely there can be some residual effects the next day.
4. I will not conduct business, sign legal documents, or make important consequential decisions for the remainder of the day after a ketamine dosing appointment.
5. I understand that Dr. Chakoian has advised me to not use alcohol, cannabis, or other intoxicants for at least 24 hours before and after a ketamine dosing appointment. I will inform Dr. Chakoian about recent intoxicant use before I am administered ketamine. If a pause in use will be difficult, or might lead to withdrawal symptoms, I will discuss this with Dr. Chakoian.
- 6. If I experience a troublesome side effect after I leave the clinic and do not know how to address it, I will contact Dr. Chakoian. If I cannot reach him directly, or I am having a medical urgency, I will call my primary care doctor, call 911, or go to my local emergency room.**
7. I will inform Dr. Chakoian if I am using, seeking, or have obtained ketamine from sources other than him while I am in treatment.
- 8. I will talk with Dr. Chakoian about any thoughts of suicide during treatment. If I am struggling with suicidality and my safety is at risk, I understand that I am advised to seek immediate emergency care at an emergency room or call/text to 988 or call 911 for emergent assistance.**

9. I will remain at Journey to New Hope (or other location that the medication is administered) after a ketamine session until he determines I am safe to leave, and I will provide information about my transportation home.

Signature of Patient.

Date

Printed Name of Patient

PHYSICIAN STATEMENT I have explained the nature of ketamine therapy to the above patient. I 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 therapy. I assessed for any medical problems, language or educational barriers that might prevent a clear understanding of the patient's involvement in ketamine therapy and found none, or have adequately addressed them, to the best of my ability.

Signature of Physician.

Date

Printed Name of Physician