

Informed Consent for Ketamine Treatment

Introduction

Thank you for choosing to be part of Shefa's Shuva ketamine retreat experience. As an extension of our values of support and education, we are providing you with this informed consent document to understand and agree to all of the facets of this unique experience. Please read the following information carefully, and sign at the end of the document certifying that you agree to the below terms. You will have access to a copy to keep.

If you have any questions, please check with the Shefa team (flow@shefaflow.org). It is important to us any questions or concerns you have been fully addressed before signing this document. If you would like to learn more about informed consent in psychedelic space, you can read [this recent article](#).

Ground Rules & Agreements

1. Confidentiality and Privacy

- Safety and vulnerability emerge from a sense of trust. We ask that whatever is said and shared within the context of the Shuva cohort stay within the group experience. Please feel free to share your experience and what you learned with others, but please refrain from sharing identifying information or personal details about the direct experience of other Shuva cohort members.
- All participants understand that Shuva staff and facilitators may occasionally discuss with each other content that came up in the circle for the purposes of safety, debriefing and evaluation, planning future events, and keeping the organization in alignment with the needs of the circle attendees.
- Some Shuva group facilitators are mandated reporters in the State of California. Mandated reporting laws exist to protect children, adults over the age of 60 and those who present an imminent risk to themselves or others.
- Shefa staff may take pictures of the experience, and will ask participants directly if they may be used in future promotional materials.

2. Personal Safety

To participate in Shuva, you must agree to the following. Mark "X"

- ☐ I attest that all information pertaining to my personal health history has been accurately communicated to the Shuva team physician to the best of my ability.

- ☐ I understand and agree that my participation in Shuva is voluntary and at my own risk.
- ☐ I understand that Shuva is intended as a personal growth experience and is not a substitute for psychotherapy or medical treatment.
- ☐ I agree to indemnify and hold harmless Shefa: Jewish Psychedelic Support of their agents, contractors, affiliates, officers, physicians, and partners from and against any and all injuries, losses, damages, reasonable costs (including reasonable attorneys' fees and expenses), liabilities or expenses arising from or caused by my participation in Shuva.
- ☐ I understand that Shefa: Jewish Psychedelic Support reserves the right to decline any individual interested in participating in any Program at any time and for any reason Shefa may deem appropriate.
- ☐ I understand that I must arrange for transportation to and from the retreat—it is not permitted to drive at all until after a period of 6 hours of sleep or the following day.
- ☐ I have read and understand the medical guidelines for Ketamine listed below:

Ketamine Medical Guidelines

Background Information

Ketamine is a Schedule III medication that was approved by the FDA for use as an anesthetic agent in adult and pediatric populations several decades ago. The administration of ketamine in significantly lower, sub-anesthetic doses to treat pain, depression, or other psychiatric diagnoses is a newer, off-label use of ketamine, as is its use for existential, psychological and spiritual struggles and personal growth. Psychiatric use of ketamine has become relatively wide-spread in recent years, has been studied and promoted by researchers at the National Institute of Mental Health, and has had front-page publicity as an antidepressant with its own novel pharmacological mechanism of action. During Shuva, Ketamine will be administered through intramuscular (IM) routes.

How Does It Work? What happens?

The current, most probable, understanding of ketamine's mode of action is as an NMDA antagonist working through the glutamate neurotransmitter system. This is a very different pathway than that of other psychiatric drugs such as the SSRIs, SNRIs, lamotrigine, anti-psychotics, benzodiazepines, etc.

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, antidepressant and, potentially, psychedelic effects. While more recent research has demonstrated the possibility of an antidepressant response to low doses of ketamine administered intravenously, intra-nasally, injected intramuscularly or taken sublingually (orally) that produce minimal psychedelic effects, it

is possible that psychedelic, 'dissociative' experiences maybe helpful in providing a more robust effect. This may include a positive change in outlook and character; a "transformative" response.

Eligibility for Ketamine Treatment

Pregnant women are not eligible because of potential effects on the fetus. 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.

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. Information on ketamine's interaction with other medicines is only partially available and it will be assessed as to your eligibility for this experience. Ketamine should not be taken if you have untreated hyperthyroidism. There have also been reports of some decrease in immune function in patients receiving surgical doses of ketamine. Ketamine has an extensive record of safety and has been used at much higher doses for surgical anesthesia, without respiratory depression.

Nuts and Bolts

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 1.5 hours following IM administration of ketamine. You will continue to remain under ketamine's influence at a lesser level for at least one hour. Under the care of Dr. Stephen Taus, ketamine will be given as an intramuscular injection into the shoulder at doses of 0.8-1.2 mg/kg or less. The choice of dose will depend on prior exposure to ketamine and other psychedelics, body weight, and sensitivity.

Risks of Ketamine

Ketamine is a life-saving medication, and we are creating a safe and controlled container in line with and under the guidance of medical professionals. As with any medication, there are potential risks and side effects. Please read the following.

You will be asked to lie down 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 after the injection. It is possible you may fall asleep.

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
- 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. Music that may be familiar might sound different. Synesthesia (a mingling of the senses) may occur. Ordinary sense of time will

change in unpredictable ways. Because of the risk of nausea and vomiting, please refrain from eating and drinking for at least the 3 hours preceding the session. Hydrate well in that same time frame. If you are unduly nauseated, you may be offered anti-nausea medication in pill or oral dissolving tablet forms.

Ketamine generally causes an increase in blood pressure and sometimes pulse rate. If blood pressure monitoring reveals that your blood pressure is too high, you may be offered clonidine to remedy this. Agitation may occur during the course of a ketamine session. If your agitation is severe, you may be offered medication orally or by injection to help you relax.

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 significantly lower (2 mg/kg or less). *Driving an automobile or engaging in hazardous activities should not be undertaken until all effects have stopped—you must secure a ride home with a friend, relative, or ride-sharing service.*

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. During the experience itself, some people have reported frightening or unusual experiences. These experiences, however, may be of significant value to your recovery or growth from the suffering that may have brought you to your Shuva experience in the first place. This is a return ticket—you will come back to normal consciousness. You will receive psychotherapeutic support during your Shuva experience and we encourage ongoing guidance from a therapist if these effects persist.

Potential for Ketamine Abuse and Physiologic 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 the 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 physician.

Repeated, high dose, chronic use of ketamine has caused urinary tract symptoms and even permanent bladder dysfunction in some individuals abusing the drug or individuals who use the medicine consistently for years. This does not occur within the framework of ketamine-assisted psychotherapy, where use of the medicine is periodic and time-limited.

**I have read and understand the medical guidelines for Ketamine listed above _____
(Initial)**

Confidentiality

Your privacy and all therapy records will be kept confidential. They will be maintained with the same precautions as ordinary medical records.

A Note on Reassuring Physical Touch

Sometimes, facilitators determine that participants may benefit from light, reassuring touch such as a hand hold or light shoulder touch. This will be discussed in depth during the preparation calls, and participants will have an opportunity to state their own preferences and boundaries before the retreat day, as well as on the day of the retreat.

Your Safety is Important to Us

We are dedicated to ethical care and the accountability of our facilitation team and our participants during the arc of our retreat. If there is an incident between you and another participant, or you and a facilitation team member that requires restorative justice or resolution, you will be directed to report the incident to our compliance officer, Erica Siegal (erica@nestharmreduction.com). We will make sure that everyone understands the process during our preparation calls.

Voluntary Nature of Participation

Please be aware that the Food and Drug Administration (FDA) has not yet established the appropriateness of ketamine in psychotherapeutic or psycho-spiritual settings, and its use in exactly this format is considered “off-label”. One official ‘indication’ for use of ketamine is anesthesia, and more recently the FDA approved esketamine (a version of ketamine, administered as a nasal spray) for treatment-resistant depression.

Your awareness of this is key to understanding any liability associated with your use of ketamine.

Your informed consent indicates you are aware of this situation.

By signing this document, you indicate that you understand the information provided and that you give your consent to the medical procedure to be performed during your participation in ketamine treatment. Please read this consent form carefully, and feel free to ask questions about any of the information in it.

- ☐ I have had the opportunity to raise questions and have received satisfactory answers from Shuva facilitators.
- ☐ I fully understand that the ketamine session can result in a profound change in mental state and may result in unusual psychological and physiological effects.
- ☐ I give my consent to the use of medication if deemed necessary for agitation (Lorazepam), to medication for nausea (ondansetron), and for high blood pressure (clonidine).
- ☐ I understand that I am to have no food or drink 3 hours prior to my ketamine session.
- ☐ I understand that I need to have someone drive me home from the session, and not engage in any driving or hazardous activity for at least 4 hours or more -- depending on the continued
- ☐ presence of effects after my session has concluded.
- ☐ I understand the risks and benefits, and I freely give my consent to participate in Shuva as outlined in this form, and under the conditions indicated in it.
- ☐ I understand that I may withdraw from Shuva at any time, up until the actual injection has been given.
- ☐ I understand that physical touch can be a part of this experience, and I am prepared to state my own boundaries regarding touch.
- ☐ I understand that once I am registered, refunds are not possible.
- ☐ I give Shuva facilitation staff permission to contact the following person as my emergency contact if need be:

Name and relationships: _____

Phone number: _____

I voluntarily sign my name evidencing acceptance of the provisions of this agreement.

Signature

Date