Ketamine Infusion Informed Consent

M Kathryn Schaefer MD 850 W Hind Dr Suite 102, Honolulu Hawaii 808-261-1121 www.BotoxOahu.com

Before you decide to take part in this procedure, it is important for you to know why it is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Modern day anesthetic techniques are very safe, and serious complications are rare. Please keep this in mind while reading this document. It is our legal and ethical responsibility to inform you of potential complications, but it is not our intention to increase your anxiety prior to ketamine therapy.

Read the information below closely and discuss it with family and friends if you wish. Ask one of the clinical staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the staff.

In some studies, ketamine has been shown to provide rapid-acting antidepressant effects from a single infusion. Ketamine is widely used in emergency departments and operating rooms for the purposes of surgical sedation. **Ketamine has not been approved by the Food and Drug Administration (FDA) to treat depression. This is not a research study, but is rather a clinical procedure. This procedure is not being monitored by the Institutional Review Board (IRB) or FDA.** New studies continue to find that ketamine is beneficial in more situations such as anxiety, PTSD, OCD, CRPS/RDS, fibromyalgia, etc.

A. Procedure

An intravenous (IV) line will be started to receive the infusion. Your heart rate, rhythm and blood pressure will be monitored. The level of oxygen in your blood will be monitored by a monitor attached to your finger (pulse ox). Under the supervision of an anesthesiologist or CRNA, you will receive ketamine through your IV over 40 minutes. The dose you receive will be based on your weight. After the infusion, you will continue to be monitored for approximately 30 minutes or more. Once the anesthesiologist or CRNA has decided that you can be released to the care of your family member or friend, you will be allowed to go home. You cannot drive home after the procedure. You should not make important decisions or operate machinery for the rest of the day. If you do not have someone to drive you home, the infusion will be cancelled that day at your expense. **You cannot drive the day of the infusion, but you can drive the following day.**

B. Risks/Discomforts

Any procedure has possible risks and discomforts. The procedure may cause all, some or none of the risks or side effects listed. Rare, unknown, or unforeseeable (unexpected) risks may also occur. These may include: allergic reaction, seizure, nerve damage, loss of consciousness, pain, infection, bleeding, heart attack, brain damage or even death.
Side effects normally depend on the dose and how quickly the injection is given. The dose being used is lower than the approved anesthetic doses to induce general anesthesia and will be given slowly over approximately 40 minutes. These side effects often go away on their own. No lingering effects have been reported.

Common side effects (greater than 1 out of 100 but less than 10 out of 100)

- Vivid dreams, nightmares, and Out-of-body experience during the infusion
- Nausea and vomiting
- Increased saliva production
- Blurred vision or Dizziness
- Disrupted motor skills
- Increased blood pressure and increased heart rate (approx. 20% of the normal rate is usual) during the infusion

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The above symptoms will go away when the infusion is stopped. At higher doses than used for this purpose, one can see increased blood pressure in the lungs and fast breathing.

Uncommon side effects (less than 10 out of 1,000)

- Jerky arm movements, which resemble a seizure (as a result of increased muscle tension) and
- Double Vision or Cross-eye movements
- Rash
- Pain and redness at the site of the injection
- Increased pressure in the eye

Rare side effects (less than 10 out of 10,000)

- Allergic reaction
- Irregular heart rate or slowing down of heart rate Low blood pressure
- Arrhythmia

Other risks

Misuse (drug abuse) of ketamine has been reported in the past, although at higher doses. Reports have indicated that ketamine can cause various symptoms, including but not limited to flashbacks, hallucinations, feelings of unhappiness, restlessness, anxiety, insomnia, or disorientation.

As ketamine is used for sedation in surgery, the doses used in this study may cause drowsiness. There is a potential risk of dosing error or unknown drug interaction that may cause significant sedation and may require medical intervention including intubation (putting in a breathing tube).
As a result of ketamine, you may experience the above reactions and require continued hospitalization for management of your mental and physical health. This medication may not help or even worsen your depression.

Risk of venipuncture: The risks of starting an IV include temporary discomfort from the needle stick, bruising, and infection. Fainting could also occur, resulting in injury.

Risk of other medications: If you are currently taking certain medications on a daily basis within 24 hours prior to and/or after receiving ketamine, you will not be able to take these medication(s) while receiving a ketamine infusion without clearance or approval of the physicians involved in administering ketamine. This is due to concerns for potential increased sedation and/or trouble breathing.

Examples include:

- Sedatives (e.g. clonazepam, lorazepam, alprazolam, valium)
- Tramadol
- Narcotics (e.g. codeine, Percocet, Norco, etc.)

C. Benefits

Ketamine has been associated with a decrease in depression symptoms, with results lasting for days to weeks after a single infusion. There is a lot of variation in the duration of relief. Ketamine may improve your symptoms of depression, but these effects may not be long-lasting. Assuming that ketamine is proven to be beneficial for you, the best results come from a

series of infusions combined with a multimodal approach to your situation for long term benefits. Individual needs vary, but some people will continue to benefit from a monthly "booster" infusion.

D. Risk Management

You must report any unusual symptoms or side effects at once to the staff. Ask the treatment staff if you have any questions regarding the following:

- Your medication
- Your reaction to medication Any possible related injury
- Your participation in the clinical treatment

On the day of an infusion, **you may NOT engage in any of the following.**

- Driving
- Drinking alcohol or taking any illicit drugs Conducting business
- Participating in activities which require you to rely on motor skills and memory

E. Voluntary Nature of Treatment

You are free to choose the ketamine infusion or not. Please tell the doctor if you do not wish to receive the infusion. Not receiving the ketamine infusion does not affect your right to receive any other treatments offered.

F. Withdrawal of Treatment

Your doctor or the treatment staff has the right to stop the treatment at any time. They can stop the infusion with or without your consent for any reason.

G. Patient Consent

I know that ketamine is not an FDA approved treatment for depression. I know that taking part in this procedure is my choice. I know that I may decide not to take part or to withdraw from the procedure at any time. I know that I can do this without penalty or loss of treatment to which I am entitled. I also know that the doctor may stop the infusion without my consent. I have had a chance to ask the doctors and staff questions about this treatment. They have answered those questions to my satisfaction. The nature and possible risks of a ketamine infusion have been fully explained to me. The possible alternative methods of treatment, the risks involved, and the possibility of complications have been fully explained to me. No guarantees or assurances have been made or given by anyone as to the results that may be obtained.

I state by my signature below that I have read the information above. I know the conditions and procedures of the treatment. I know the possible risks and benefits from taking part in this treatment.

_____	_____	_____
Patient Name (Print)	Patient Signature	Date

_____	_____	_____	_____
Doctor Signature	Date	Witness Signature	Date