

INFORMED CONSENT FOR KETAMINE INFUSION

Ketamine is approved by the FDA for use in children and adults for anesthesia and as a pain reliever during medical procedures. When administered in low-dose infusion, ketamine may provide relief of symptoms of depression, anxiety, bipolar disorders, obsessive-compulsive disorders (OCD), and post-traumatic stress disorders (PTSD).

Ketamine has <u>not</u> been approved by the FDA to treat depression, anxiety, bipolar disorder, OCD, or PTSD.

1. PROCEDURE – KETAMINE INFUSION THERAPY

An intravenous line (IV) will be started in an extremity. Your blood pressure, heart rate, and oxygen saturation will all be monitored throughout the first two infusions under the supervision of a nurse practitioner. You may elect to forego the vital sign monitors for further infusions, but there will always be a nurse practitioner in the office during infusions.

2. RISKS/SIDE EFFECTS

The ketamine dose being used is lower than anesthetic doses and will be given slowly over 40-60 minutes. If you are experiencing side effects, immediately notify the individual administering the infusion. Slowing the infusion rate may improve or resolve them.

Common possible side effects may include (but are not limited to):

- Fast or irregular heart beat
- Increased or decreased blood pressure (elevated blood pressure may be treated with oral clonidine)
- Confusion, irritation, or excitement
- Floating sensation or hallucinations
- Twitching, muscle jerks, and/or muscle tension
- Change in appetite or thirst, metallic taste
- Headaches
- Nausea or vomiting (may be treated with oral ondansetron)
- Memory changes

Rare side effects include (but are not limited to):

- Allergic reaction
- Increase in pressure inside the eye or involuntary eye movements



- Bladder inflammation
- Respiratory depression or complications

Other Risks:

- Ketamine can cause various symptoms including but not limited to flashbacks, feelings of unhappiness, restlessness, anxiety, insomnia and disorientation.
- There is a potential risk of dosing error or unknown drug interaction that may require medical intervention including intubation (putting in a breathing tube) or hospitalization. It is very important that you disclose all medications, both prescription and over the counter, that you are taking.
- The risk of venipuncture may include temporary discomfort from the needle stick, bruising, or infection. Fainting may also occur.
- Ketamine may not help your symptoms of depression, anxiety, bipolar disorder, OCD, or PTSD.

You must report any unusual symptoms or side effects at once to the medical staff.

On the day of the infusion, you should NOT engage in any of the following for 12 hours after the infusion:

- driving
- drinking alcohol or using any recreational drugs
- conducting legal business
- participating in activities which require you to rely on motor skills or memory

Ketamine use during pregnancy is not recommended. Urine pregnancy testing is recommended prior to first infusion and every two weeks during active infusions if you are of childbearing capacity.

I Agree or Decline (or this section is Not Applicable to me) that I have completed a urine or serum pregnancy test prior to the first infusion and will continue to test every two weeks during active infusions. I shall inform Happier You, LLC if any tests come back positive. AGREE _____ DECLINE _____ N/A _____

Signature:

4. BENEFITS

Ketamine is NOT a comprehensive treatment and is meant to augment (add to, not be used in place of) psychiatric treatment. Ketamine has been associated with a decrease in

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depression, anxiety, bipolar, OCD, and PTSD symptoms with results lasting for days to weeks to months. There is no way to predict how any single person will respond to ketamine infusion therapy. These effects may not be long lasting and most likely will require further infusions.

5. VOLUNTARY NATURE OF THE TREATMENT

You are free to choose to receive or not receive the ketamine infusion. Please tell the nurse practitioner if you do not wish to receive the infusion or wish at any time during the infusion.

6. WITHDRAWAL OF TREATMENT

The nurse practitioner has the right to stop the infusion at any time. They can stop the infusion with or without your consent for any reason.

7. PATIENT CONSENT

- I acknowledge and understand that ketamine is not an FDA approved treatment for depression, anxiety, bipolar disorder, OCD, or PTSD and may not improve my symptoms.
- I acknowledge that I am consenting to this procedure without any undue pressure or while under the influence of drugs or alcohol and that taking part in this procedure is my choice.
- I acknowledge and understand that I may elect not to have the infusion performed and do so without penalty.
- I acknowledge and understand that I may withdraw from the infusion at any time and may do so without penalty.
- I know that the nurse practitioner may stop the infusion without my consent.
- I acknowledge that Happier You, LLC, may deny infusions due to lack of professional conduct, medical complexity, or lack of compliance with office protocol.
- I have had a chance to ask questions about this treatment, and I have had those questions answered to my satisfaction.
- I acknowledge and understand the nature and possible risks of a ketamine infusion.
- No guarantees or assurances have been made or given to me about the results that may be obtained.

Patient Signature:	Date:	