# **Informed Consent Document for IV Ketamine Treatments**

## **Interpersonal Psychiatry Kansas City**

Patient Name:	

This consent form describes the use of ketamine for treating depression, bipolar depression, other mental health disorders and chronic pain and will help you decide if you want to be treated with ketamine. Ketamine is approved by the U.S. Food and Drug Administration (FDA) for use as an anesthetic. There is evidence that ketamine might be useful in relieving depressive symptoms in people with depression who have not responded to traditional medications and therapies. This form provides important information about what you will be asked to do during the treatment period, about the risks and benefits of ketamine treatment, and about your rights as a patient.

- If you have any questions about anything in this form, you should ask the treating psychiatrist for more information.
- You may also wish to talk to your family or friends about your treatment.

## WHAT IS THE PURPOSE OF TREATMENT WITH KETAMINE?

We invite you to receive ketamine treatments because you have been diagnosed with Major Depression Disorder, Bipolar Disorder, other mental health disorders, and/or Chronic Pain and have not experienced relief from depressive symptoms with traditional medications and therapies.

#### WHAT WILL HAPPEN DURING KETAMINE TREATMENT?

**Initial Visit:** 

You will initially be seen by a psychiatrist who is familiar with the requirements that must be met for receiving ketamine for depression, bipolar depression, other mental health disorders and/or chronic pain.

Your psychiatrist will conduct a diagnostic interview and history. You will undergo a psychiatric evaluation with an emphasis on psychiatric diagnosis and your past treatment history with antidepressants.

Additional testing, including psychological, laboratory or medical tests, might be required to finally determine whether you meet the inclusion/exclusion criteria for receiving ketamine. These tests will be discussed with you if they are needed.

Your psychiatrist will also carefully review all medical diagnosis and your medical history.

#### WHAT WILL OCCUR ON KETAMINE TREATMENT DAYS?

Depending on your baseline blood pressure, it is possible that you may be told to take a low dose of clonidine (0.1mg) by mouth on the morning and evening of the day before your ketamine treatment. Clonidine is approved by the FDA for treatment of high blood pressure, Attention Deficit Disorder, neuropathic pain, seizure disorder, mood disorder and migraine headache. However, clonidine has also been shown to keep blood pressure under good control in patients who may need this during IV ketamine treatments.

It will be important that you not have any solids or milk for 6 hours leading up to your ketamine arrival time. It is important that you have no liquids, water, or medications of any kind for 2 hours leading up to your ketamine arrival time. However, it is also important that you drink 2 glasses of water 2 hours prior to your ketamine arrival time to help open up your veins for IV placement. Your treating psychiatrist will give you instructions on what to do about any morning medications you normally take. You will receive instructions about your arrival time and must bring a responsible adult with you for transportation back home after the treatment. You will not be able to drive yourself since you might experience some drowsiness and dizziness for a few hours after each treatment. Once you are checked in by a staff member, the psychiatrist will meet with you in your room prior to your ketamine treatment. The psychiatrist will discuss your current symptoms and administer the PHO-9 and help come up with the right dosage of IV ketamine treatment to be given. An intravenous (IV) line will be started for administering ketamine. During ketamine treatment, you will be given intravenous (IV) ketamine once a week for 6 weeks. Your treating psychiatrist might also recommend ketamine maintenance treatments in the future if needed.

During each treatment, a sub-anesthetic dose of ketamine will be given slowly over a 40 minute period . The amount of ketamine given will depend on your weight. The amount given is calculated by multiplying your weight in kilograms (kg) times 0.5 mg per kilogram for the first IV ketamine infusion. For example, a 154 lb (70Kg) individual will be given a total of 35 mg. The dose of ketamine given for treating depression is much lower than that required when it is used as an anesthetic. During the treatment, your heart rate, breathing, blood pressure, the oxygen content in your bloodstream, electrocardiogram (ECG) are monitored and you are observed for any evidence of confusion or agitation. After the completion of the ketamine infusion, you will be monitored by staff during a recovery period that will usually

last 30-45 minutes. Ketamine is known in rare cases to cause side effects such as confusion and hallucinations and you will be monitored for these.

At the end of the recovery period, your family member or friend will drive you home. Someone will need to supervise you at home for the first few hours after you come home, and you will not be able to work or drive for the rest of the day.

You cannot drive, use alcohol or any drugs, conduct business or any work-related activities for the rest of the day.

## WHAT ARE THE RISKS OF KETAMINE TREATMENT?

You may experience one or more of the risks indicated below associated with ketamine treatment. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with you receiving ketamine.

Although the overall potential physical risks of ketamine treatment are small, some risks described in this consent document, if severe, may cause death.

There are no physical risks associated with the psychiatric diagnostic and assessment procedures.

#### **Risks of Ketamine:**

## Likely

Feeling lightheaded, "high", exhilarated, and/or happy: floating sensations, and/or temporarily having difficulty concentrating, paying attention, or remembering as many items as usual from a list (like items on a grocery list); mild and temporary increases in blood pressure.

## Less likely

Feeling dizzy, sleepy, anxious, blurry vision, perceptual disturbances, nauseated.

## Rare:

Feeling sad, scared, confused, and/or disoriented; moderate and temporary increases in blood pressure; flashbacks or hallucinations.

## Risks of the Infusion Procedure/Blood Draws

## <u>Likely</u>

The risks of blood drawing and IV insertion include discomfort, bruising, and/or minimal bleeding.

## Less likely

Occasionally during blood drawing procedures, people may experience dizziness or feel faint.

## Rare

Although rare, another risk associated with blood drawing and catheter insertion is infection at the site of insertion. Rarely irritation, redness, itching or rash may also occur if a topical anesthetic (numbing cream) is used.

## **APPENDIX**

## **Ketamine Inclusion/Exclusion Criteria**

#### 1. Inclusion criteria

- a. Current DSM 5 diagnosis of MDD, Bipolar Depression, PTSD or other Mental Health Disorder known to benefit from IV ketamine treatments
- b. Diagnosis of chronic pain
- c. Identification of a responsible adult able to transport the patient to and from ketamine treatments.

## 2. Exclusion criteria

- a. Psychotic Disorders
- b. Current illicit drug use or substance dependence
- c. Currently pregnant or breastfeeding
- d. Medical history or conditions that preclude use of IV ketamine treatments
- e. Unable to provide informed consent.

## PATIENT AGREEMENT FOR TREATMENT

I have read this informed consent document. I understand the potential risks and benefits associated with IV ketamine treatments as explained in this document. I may withdraw consent at any time. I have been given adequate opportunity to have my questions answered by the treating psychiatrist. I hereby consent to receive IV ketamine treatments.

Patient Name (Printed)	
Patient Signature	Date
Psychiatrist (Printed)	Date
Psychiatrist Signature	Date

# **Ketamine Scheduling Form**

Full Name:		
DOB:		
Gender:		
Address:		
Your Cell Phone Number/Phone Number:		_
Cell Phone Number of Person Who Will Be Transporting	g You:	
Email Address:		
Preferred method of Communication (Circle One): Pho	one/VM Text	Email

# Adult Pre-Ketamine Medical History Form

Full Name:
DOB:
Height
Weight
Primary Care Doctor
Psychiatrist
YOUR PAST MEDICAL HISTORY Please indicate YES or NO to all questions below and explain any yes answers to the right
Abdominal Aortic Aneurysm
Blood Clots/DVT
Congestive Heart Failure
Coronary Artery Disease
Epilepsy/Seizures
History of Heart Attack/MI
High Blood Pressure
HIV/AIDS
Irregular Heart Beat
Supplemental Oxygen
Pacemaker and/or defibrillator
History of Pulmonary Embolus

# PLEASE LIST ALL DRUG ALLERGIES OR ADVERSE REACTIONS: Allergy Reaction LIST ALL MEDICATIONS INCLUDING DOSAGES Medication Dose Directions for Use Reason SURGERIES OR HOSPITALIZATIONS IN THE PAST Year

ANESTHESIA HISTORY: Circle Either Yes/No
Have you ever had general anesthesia or sedation before?
Did you have any complications with anesthesia?
Please explain any yes answers above:
CIRCLE ANY OF THE FOLLOWING SYMPTOMS IN THE PAST 2 WEEKS:
Ankle swelling Chest Pain Chest Pressure Cold Symptoms Cough Easy Bruising/bleeding Fever Hives or Rash Joint Swelling or Pain Muscle Weakness Nose Bleeds Shortness of Breath Wheezing  Please explain any of the circled items above:

## **NPO Instructions on Days of IV Ketamine Treatments**

- 1. No solids or milk of any kind for 6 hours leading up to ketamine arrival time.
- 2. No water or medications of any kind for 2 hours leading up to ketamine arrival time.
- 3. Make sure to drink 2 glasses of water 2 hours prior to your ketamine treatment. This will help to open up your veins for the IV.
- 4. You may have clear liquids including water in moderation until 2 hours prior to your ketamine arrival time. No caffeinated beverages.
- 5. Make sure to take any scheduled blood pressure medications on the mornings of your IV ketamine treatment.
- 6. If you have been instructed to take Clonidine prior to your ketamine treatment, take your morning dosage of Clonidine 2 hours prior to your ketamine arrival time.

## **Preparing For Your Ketamine Infusion**

Welcome! Thank you for choosing Interpersonal Psychiatry. We look forward to caring for you throughout your infusion process. We have dedicated team members ready to assist you with questions you may have.

**Instructions to Patients:** Please download and print out this packet, reviewing and filling out Informed Consent Document (5 pages), Ketamine Scheduling Form (1 page) and Adult Pre-Ketamine Medical History Form (3 pages) and scan and email all 9 pages to both Dr. Handoo and his assistant Lauren at both: <a href="mailto:irfan@drhandoo.com">irfan@drhandoo.com</a> and Lauren@ip-psych.com

These 3 documents (9 pages total) need to be scanned and emailed back to both Dr. Handoo and Lauren at least 4 days prior to starting ketamine treatments.

If you are not able to scan and email these forms, then drop them off at Interpersonal Psychiatry, 1010 Carondelet Drive, Suite 329, Kansas City, MO 64114 during business hours on Monday thru Friday from 8AM to 6PM.

**Payment Options:** Patients may call and make payment to either Jessica or Lauren at (816) 812-7722 during business hours on Monday thru Friday from 8AM to 6PM. IV ketamine treatments are \$550 per treatment. Patients may pay once a week as they go, or pay for all 6 IV ketamine treatments for \$3300 up front. All major credit cards and debit cards accepted.

Payment for IV ketamine treatments is due at least 4 days prior to starting IV ketamine treatments.

**Scheduling**: Our office will reach out to you at least 2 days or earlier prior to your ketamine treatment day to let you know your ketamine arrival time.

**NPO Instructions**: For your safety and to avoid risk of infusion cancellation, we ask that you strictly follow specific eating and drinking times given.

- 1. No solids or milk for 6 hours prior to ketamine arrival time
- 2. Only clear liquids such as Gatorade or water 2 hours prior to arrival time
- 3. Nothing by mouth 2 hours prior to ketamine arrival time

## Day of Infusion:

- **1.** You will come directly to Interpersonal Psychiatry at 1010 Carondelet Drive, Suite 329, Kansas City, MO 64114 on day of IV ketamine treatments at your ketamine arrival time.
- **2.** Bring a comfortable blanket
- **3.** Wear comfortable clothing
- **4.** Bring headphones along with ketamine infusion playlist music to listen to. We recommend you download "Ketamine Therapy Music and Wellness Instrumentals for Stress Relief 1" to listen on your headphones
- 5. Patients with sleep apnea should bring their CPAP with them every time and may have an extended recovery time.
- **6.** Expect to be at our office for approximately 2 hours. The person dropping you off can plan to pick you up 2 hours after they drop you off. That person will need to come to the office to pick you up after your ketamine infusion and help assist you to the car.
- **7.** Bring your own bottled water so you have your own water to drink after your ketamine treatment.
- **8.** A responsible adult must drive you home and someone should supervise you at home for the first couple hours after you come home.
- **9.** The infusion you received may temporarily impair your coordination, balance, and reflexes for a few hours.
- **10.** Rest and limit activity throughout the entire day of your infusion
- **11.** You may experience lightheadedness, blurry vision, and drowsiness temporarily after your IV ketamine treatment.
- **12.** No alcoholic beverages for 24 hours
- **13.** You may not work or drive for the rest of the day
- **14.** If you become nauseated, drink clear liquids and then slowly progress to a light/bland diet
- **15.** Home medications: Resume medications as instructed by your psychiatrist.
- **16.** No stimulants (such as Adderall) or benzodiazepines (such as Xanax) ever on mornings of ketamine treatments
- **17.** If you experience redness or swelling at IV site, apply a warm damp compress to the area for 20 minutes 3-5 times a day

Please call our office at Interpersonal Psychiatry at (816) 812-7722 for any post infusion questions/concerns

If you are experiencing difficult breathing or any life threatening medical emergency, call 911.