

PLEASE PRINT ALL INFORMATION

_____ LAST NAME	_____ FIRST NAME	_____ MI
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_____ DOB (MM/DD/YYYY)	_____ SOCIAL SECURITY NUMBER
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GENDER/SEX <input type="checkbox"/> MALE <input type="checkbox"/> FEMALE <input type="checkbox"/> TRANSGENDER <input type="checkbox"/> PREFER NOT TO SAY
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_____ PREFERRED PHONE NUMBER	_____ ALTERNATE PHONE NUMBER
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_____ MAILING ADDRESS		
_____ CITY	_____ ST	_____ POSTAL CODE

RECEIVE APPOINTMENT REMINDERS? <input type="checkbox"/> TEXT <input type="checkbox"/> EMAIL <input type="checkbox"/> PHONE <input type="checkbox"/> NONE
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_____ EMAIL ADDRESS

RECEIVE EMAIL FROM SHRINK SAVANNAH? <input type="checkbox"/> YES <input type="checkbox"/> NO
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_____ EMPLOYER OR SCHOOL	_____ PROFESSION/FIELD OF STUDY
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_____ PRIMARY PHYSICIAN	_____ PHONE
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_____ PRIMARY INSURANCE	_____ GROUP POLICY NUMBER
_____ SECONDARY INSURANCE	_____ POLICY NUMBER

_____ EMERGENCY CONTACT	_____ PHONE
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_____ CURRENT MEDICATION	_____ DOSAGE
_____ CURRENT MEDICATION	_____ DOSAGE
_____ CURRENT MEDICATION	_____ DOSAGE

KNOWN ALLERGIES _____ _____ _____
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KETAMINE TREATMENT: PATIENT FINANCIAL RESPONSIBILITY

Patient Financial Responsibility Acknowledgement

Patient Name: _____ Patient DOB: _____

The undersigned patient acknowledges the following:

- Shrink Savannah will not submit/file claims for services rendered for Ketamine Infusion Therapy nor will the patient submit/file claims for services on their own. Ketamine Therapy is currently not approved by the FDA; therefore, Shrink Savannah is unable to file insurance claims for this treatment.
- I have read and understand the Informed Consent for Ketamine Treatment provided by Shrink Savannah.
- Ketamine costs \$450.00 per treatment session. Nasal Ketamine Treatment costs \$300 with maintenance and \$250 subsequent when performed within a 4 weeks period of time. Troche costs \$150.
- I understand that if I receive Ketamine Treatment, I am financially responsible for all costs associated with this treatment. Shrink Savannah does not provide receipts for treatment with additional codes.
- I understand that Shrink Savannah will not submit or file claims for services rendered for Ketamine Treatment Therapy nor will I submit or file claims for services on my own.
- I have had a consultation visit with my provider to discuss Ketamine Treatment Therapy.
- I understand that following my treatment session(s), I will be unable to drive, operate machinery or do anything where I need to be alert.
- I understand I must have a confirmed driver for each treatment session.
- I have been informed of all the information outlined above and agree to pay Shrink Savannah the cost for the services to be rendered..

 PATIENT NAME (PRINT)

 SIGNATURE

 DATE

FOR OFFICE USE ONLY

 AMOUNT QUOTED

 DATE

 PROVIDER OR MANAGER SIGNATURE

NOTES

INFORMED CONSENT FOR KETAMINE TREATMENT

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. 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 participate, 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 our staff.

Depression can be a severe, recurring, disabling, and life-threatening condition. Current medical treatments including, but not limited to are only marginally effective. You have chosen this procedure because other treatments have not been successful.

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.

PROCEDURE

1. You will be taken to a private room in order to receive the ketamine treatment. You will be accompanied by a member of the medical provider team.
2. **IV KETAMINE TREATMENT**
If your treatment involves an infusion, an intravenous line (IV) will be started in your arm so that you can receive the drug. Your heart rate and blood pressure will be checked before the procedure begins. The level of oxygen in your blood will be checked by a monitor attached to your finger. You will receive ketamine through a vein in your arm over the course of approximately 40-60 minutes on one occasion. The dose you receive will be based on your body weight. Most commonly patients receive 0.5mg of ketamine per kilogram.
3. **NASAL KETAMINE TREATMENT**
If your treatment involves the ketamine to be administered nasally, a Nasal Ketamine Compound will be administered. Your heart rate and blood pressure will be checked before the procedure begins. The level of oxygen in your blood will be checked by a monitor attached to your finger. You will receive ketamine nasally over the course of approximately 40-60 minutes on one occasion. The dose you receive will be based on your body weight. Most commonly patients receive 0.5mg of ketamine per kilogram.
4. Your heart rate and rhythm and blood pressure will be monitored at the end of the treatment.

5. After receiving the treatment, you will be asked to rate the severity of your depression. You may be asked to rate these symptoms at 10, 40, 80, 110, 240, and 360 minutes after infusion. You may also be asked to write a detailed account of your experience later that evening.
6. You will be monitored and then released to the care of a family member or friend. You cannot drive home after the procedure and should not make important decisions or operate complicated machinery for the rest of the day.

RISKS/DISCOMFORTS

Any procedure has possible risks and discomforts. The procedure may cause all, some or none of the risks or side effects listed below. Rare, unknown, or unforeseeable (unexpected) risks also may occur.

RISK OF KETAMINE

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 and will be given slowly over approximately 40-60 minutes. These side effects often go away on their own. No lingering effects have been reported.

COMMON SIDE EFFECTS

(Greater than 1% and less than 10%: between 1 out of 100 and 10 out of 100)

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

The above symptoms will go away when the treatment is complete, or another medication such as a short acting benzodiazepine may help. Thus, you should not drive the day of an infusion, but you can drive the following day.

These two side effects typically happen with high doses:

- Increased blood pressure in lungs
- Fast breathing

INFORMED CONSENT FOR KETAMINE TREATMENT

UNCOMMON SIDE EFFECTS

(Greater than 0.1% and less than 1%: between 1 out of 1,000 and 10 out of 1,000)

- Jerky arm movements, resembling a seizure (as a result of increased muscle tension) and cross-eye
- Double vision
- Rash
- Pain and redness in the site of injection
- Increased pressure in the eye

RARE SIDE EFFECTS

(Greater than 0.01% and less than 0.1%: between 1 out of 10,000 and 10 out of /10,000)

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

OTHER RISKS

Misuse (drug abuse) of ketamine has been reported in the past. Reports have indicated that ketamine can cause various symptoms, including but not limited to flashbacks, hallucinations, feelings of unhappiness, restlessness, anxiety, insomnia, or disorientation. Individuals with a history of drug misuse or dependence can develop a dependency on ketamine.

As ketamine is used for sedation in surgery, the doses used in this study may cause sleepiness. 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. Experiencing these symptoms may cause you to need medical hospitalization.

If receiving treatment through infusion, risk of venipuncture (risks of drawing blood include temporary discomfort from the needle stick, bruising, and infection). Fainting could also occur.

Risk of discomfort in answering questionnaires. Some of the questions about your alcohol or drug use and mental health may cause some distress. To minimize discomfort the questions can proceed at your pace.

Risk of electrocardiographic monitoring or electrocardiogram. To perform this test, we will attach electrodes to the skin of your chest. There is minimal risk involved in this procedure beyond minor discomfort in removing the electrodes.

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), Antibiotics (e.g., azithromycin, clarithromycin), Antifungal agents (e.g., ketoconazole), Tramadol

RISK MANAGEMENT

You should report any unusual symptoms or side effects at once to our staff. Ask the medical 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 should NOT engage in any of the following.

- Driving
- Drinking alcohol
- Conducting business
- Participating in activities which require you to rely on motor skills and memory

VOLUNTARY NATURE OF TREATMENT

You are free to choose the ketamine treatment or not. Please notify the medical staff if you do not wish to receive the treatment. Not receiving the ketamine treatment does not affect your right to receive any other treatments offered or care at Shrink Savannah.

WITHDRAWAL OF TREATMENT

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

BENEFITS

Ketamine has been associated with a decrease in depression symptoms, with results lasting for days to weeks. Ketamine may improve your symptoms of depression, but these effects may not be long-lasting

PATIENT INFORMED CONSENT AGREEMENT

I understand that Ketamine is not approved by the FDA for treatment of depression.

I understand that participation in this treatment is by choice.

I understand that I may withdraw from the treatment at any time.

I understand that I may withdraw from the treatment at any time without penalty or loss of benefits.

I understand that Shrink Savannah reserves the right to discontinue the infusion without my consent.

Shrink Savannah has provided me with with opportunities to ask questions about this treatment. My questions have been answered.

The nature and possible risks of a ketamine infusion have been fully explained to me.

I have been informed of the risk of driving after a Ketamine Infusion Treatment.

I have been advised by Shrink Savannah/Chad Brock, MD that I should not drive following a treatment and I have arranged for transportation.

The alternative methods of treatment, the risks involved, and the possibility of complications/side effects have been fully explained to me.

No guarantees or assurances have been made or given by any member of the Shrink Savannah/Chad Brock, MD staff as to the results that may occur.

I STATE BY MY SIGNATURE BELOW THAT I HAVE BEEN INFORMED,

I HAVE THOROUGHLY READ AND I UNDERSTAND THE TREATMENT INFORMATION ABOVE.

I HAVE BEEN INFORMED AND I FULLY UNDERSTAND THE CONDITIONS AND PROCEDURES OF THIS TREATMENT.

I HAVE BEEN INFORMED AND I FULLY UNDERSTAND THE POTENTIAL RISKS AND THE BENEFITS ASSOCIATED WITH PARTICIPATING IN THIS TREATMENT.

PRINTED NAME OF PATIENT OBTAINING AND AGREEING TO CONSENT FORMS

SIGNATURE OF PATIENT OBTAINING AND AGREEING TO CONSENT FORMS

DATE