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## **INFORMED CONSENT FOR IM KETAMINE THERAPY**

This consent form contains information about the use of sub-anesthetic ketamine for the treatment of psychiatric disorders. Ketamine has been approved by the FDA for use as an anesthetic agent for many years. The use of ketamine in a lower, sub-anesthetic dose to treat depression and other psychiatric disorders is a newer off-label use of ketamine and is typically used only after other treatment approaches have been unsuccessful. Ketamine is not a first-line treatment for depression, anxiety, OCD, PTSD and other psychiatric conditions. After you understand the risks and benefits of this treatment, you will be asked to sign this form in order to participate in this treatment. You will be given a signed copy of this form to keep as a record. In order for you to decide whether you should undergo this therapy, you should understand enough about its risks and benefits to make an informed decision. This process is known as *informed consent*.

**By signing this document, you indicate that you understand the information and that you give your consent for the medical procedures 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.**

## **ELIGIBILITY FOR KETAMINE TREATMENT**

Before participation in ketamine treatment, you will be carefully screened using a number of tests and procedures to determine if you are eligible for ketamine therapy, including a medical history, a physical exam, a psychiatric history and possibly psychological testing.

Pregnant women, nursing mothers, and women who can have children and are not using effective birth control will not participate in ketamine treatment. If you become pregnant while participating in this program, you must notify Dr. Hayse immediately as the effects of ketamine on the unborn child are undetermined. Individuals with unstable heart conditions (such as a recent MI), untreated thyroid disease, active drug use, active psychosis, current bipolar mania and uncontrolled hypertension will not participate in ketamine treatment.

## **OVERVIEW OF SUB-ANESTHETIC KETAMINE THERAPY**

During the ketamine administration session, you will be asked to make two (2) agreements to ensure your safety and well-being:

1. You agree to follow any direct instructions given to you until it is agreed that the session is over, and
2. You agree to remain at the location of the session until it is decided you are ready to be returned to your home.

The length of the ketamine session will be approximately one hour, and you will remain in the recovery area for up to an hour following the treatment. Ketamine will be given as either an intramuscular (IM) injection into the shoulder or buttocks or as an intravenous infusion at doses of approximately 0.5mg/kg body weight (range is 0.1-1mg/kg). Unless otherwise agreed upon, a

family member or trusted companion should be present during the hour and a half following the treatment. Do not drive while you are sedated or under the influence of ketamine,

If you become anxious or uncomfortable, you may receive a sedative agent, midazolam (trade name Versed) or lorazepam (trade name Ativan). If nauseated, you may be offered ondansetron (Zofran). These medicines can be given as a sublingual or IM dose. If your blood pressure becomes elevated, you may be offered Clonidine. During the treatment session, there will be someone present to make sure you are comfortable and monitor the procedure. Usually you will remain alert and able to talk during the procedure, but your perception and mental state will be altered by the ketamine, and you will return to a normal mental state rapidly when the treatment is over. When you have returned to your usual state of consciousness, you will share your experience with Dr. Hayse.

You may ask any questions you have concerning the procedure or effects of ketamine at any time. Your consent to receive ketamine may be withdrawn, and you may discontinue your participation at any time up until the actual injection has been given.

### **ESTIMATE OF EXPECTED RECOVERY TIME**

The non-ordinary state of consciousness produced by ketamine usually lasts about 45 to 50 minutes, but can last for one to two hours. However, the reduced sense of balance with dizziness and possible nausea when moving your head gradually subsides over three to six hours.

### **POTENTIAL RISKS OF SUB-ANESTHETIC KETAMINE THERAPY**

You will be asked to lie still during the ketamine administration because your sense of balance and coordination will be very poor until the effect has worn off, from two to four hours after the injection. Participants have also reported blurred vision, slurred speech, mental confusion, excitability, inability to see things that are actually present, inability to hear or to feel objects or one's body, anxiety, nausea and vomiting. **To minimize the likelihood of the latter two, you should not eat a meal during the six hours preceding the session.**

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 5mg/kg used for a surgical anesthesia). The dose to be used in the sub-anesthetic ketamine therapy is much lower (less than 1.5mg/kg).

### **Driving an automobile or engaging in hazardous activities should not be undertaken for 12 hours after treatment with ketamine.**

In terms of physical risks, ketamine should not be taken if you have hyperthyroidism. There have also been reports of some decrease in immune function in patients receiving surgical doses of ketamine. It does raise blood pressure, so you should have the approval of your doctor to take ketamine if you have high blood pressure. However, it has been used for many years as a general anesthetic for children, the elderly and those with severe physical illnesses because it is safer than most general anesthetics.

In terms of psychological risk, ketamine-induced experience has been shown to worsen certain psychotic symptoms in people who suffer from schizophrenia or other psychotic disorders. It may also worsen underlying psychological problems in people with severe personality disorders. During the experience itself, some people have reported frightening peak experiences. These frightening experiences, however, may be still paramount to your transition to your recovery with help and ongoing guidance.

The long-term effects of ketamine are not well understood. There have been reports of cognitive and bladder dysfunction.

### **POTENTIAL FOR KETAMINE ABUSE AND PHYSICAL DEPENDENCE**

Ketamine belongs to the same group of chemicals as Phencyclidine (Sernyl, PCP, “angel dust”). This group of chemical compounds is entitled arylcyclohexylamines and are classified as hallucinogens (“psychedelics”). Ketamine is a controlled substance and is subject to Schedule III control under the Controlled Substance Act of 1970. Medical evidence regarding the issue of drug abuse and dependence suggests that ketamine 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 a 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.

### **ALTERNATE PROCEDURES**

No other procedure is available to produce the specific effect ketamine has. Major depression is usually treated with medications and psychotherapy. Subanesthetic ketamine therapy is a new treatment option when these approaches are unsuccessful. Electroconvulsive therapy (ECT), transcranial magnetic therapy (TMS), and vagal nerve stimulation have also been used for treatment-resistant depression. Ketamine may reduce the tolerance that sometimes occurs with opiate medications, and is generally used along with other pain-relieving medications only after the first-line treatment options have failed to successfully control pain.

### **CONFIDENTIALITY**

Your privacy and all therapy records will be kept confidential. They will be maintained with the same precautions as ordinary medical records. However, health care providers involved in your care will have access to information contained in your record. Privacy and confidentiality of the record will be protected to the extent provided by law. The results of the ketamine therapy may be published.

### **INJURIES AND/OR ILLNESS**

If you become ill or sustain an injury during your participation in the program, contact Dr. Hayse immediately.

### **VOLUNTARY NATURE OF PARTICIPATION**

You should know that the Food and Drug Administration (FDA) has not yet established the effectiveness of subanesthetic ketamine therapy. Furthermore, under the Federal Food, Drug, and Cosmetic Act, ketamine is indicated for use only as an anesthetic agent. This means that the FDA does not endorse the use of ketamine as a psychotherapeutic agent or as a treatment for pain and classifies subanesthetic ketamine therapy as an investigational therapy.

Ketamine therapy is a new treatment for depression and is not a mainstream treatment, though there are several research studies that demonstrate that it can be an effective treatment. The effect generally occurs after several treatments and does not permanently relieve depression. If the depressive symptoms respond to ketamine, you will still be treated with medications and psychotherapy to try to reduce the rate of relapse. You may also need additional ketamine treatments or other therapies to maintain remission.

Your decision to undertake ketamine therapy is completely voluntary. Before you make your decision about participating in ketamine therapy, the doctor will give you a chance to ask any questions you may have about the procedure.

### **TERMINATION OF THE TREATMENT**

Even after agreeing to undergo ketamine therapy, you may decide to withdraw from the treatment at any time.

### **FOLLOW-UP AFTER TREATMENT**

After completing a single ketamine treatment, or a series of ketamine treatments, it is important to follow-up within two weeks with your primary provider, whether that be your psychiatrist, psychotherapist or primary care physician.

**I understand that I am to have nothing in my stomach for 6 hours prior to each treatment.**

**Initial:** \_\_\_\_\_

**I understand that I need to have someone drive me home from the treatments, and not engage in any driving or hazardous activity on the day of the treatment.**

**Initial:** \_\_\_\_\_

### **INFORMED CONSENT**

By signing this form I agree that:

1. I have fully read this informed consent form describing sub-anesthetic ketamine therapy.
2. I have had the opportunity to ask questions of Dr. Hayse and have received satisfactory answers.
3. I fully understand that the ketamine sessions can result in a profound change in mental state and may result in unusual psychological and physiological effects.
4. I have been given a signed copy of this informed consent form, which is mine to keep.
5. I understand the risks and benefits, and I freely give my consent to participate in ketamine therapy as outlined in this form, under the conditions indicated in it.

6. I understand that I may withdraw from ketamine therapy at any time up until the actual injection has been given.

SIGNATURE \_\_\_\_\_

DATE \_\_\_\_\_

PRINTED NAME \_\_\_\_\_

TREATMENT NUMBER:

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