



RAINFALL  
— MEDICINE —

## **Informed Consent**

### **Introduction:**

Ketamine is now an “off-label” treatment for various chronic “treatment-resistant” mental conditions. Ketamine is a Schedule III medication that has long been used safely as an anesthetic and analgesic agent. Also, it is now often used effectively for treatment of depression, addiction, PTSD, chronic pain, and other psychiatric diagnoses as well as for existential, psychological and spiritual crises and growth.

### **How does it work?**

The current and most probable understanding of ketamine’s mode of action is as an NMDA antagonist working through the glutamate neurotransmitter system. This is a different pathway than that of other psychiatric drugs such as SSRIs, SNRIs, anti-psychoics, benzodiazepines, etc.

Ketamine is classified as a dissociative anesthetic meaning one can dissociate or disconnect from one’s ordinary reality and usual self. At the dosage level administered to you, you will most likely experience mild anesthetic, anxiolytic, anti-depressant and, potentially, transformative or psychedelic effects. Recent work has demonstrated the possibility of an anti-depressant response to low dosages of ketamine administered intravenously, intramuscularly (IM), intra-nasally and sublingually (orally) that produce minimal psychedelic effects. This effect tends to be cumulative or more sustained with repeated use. It is our view that the psychedelic or dissociative experiences may well be instrumental in providing a more robust effect. This may well include a positive change in outlook and character that we term a transformative response. We employ both sublingual and intra-muscular (IM) modalities.

Essential to both methods are “time-outs” from usual experience and varies in duration usually between 20 minutes to 2 hours. This tends to be dependent on dose and route of administration. Relaxation from ordinary concerns and usual mind while maintaining a conscious awareness of the flow of mind under the influence of ketamine is characteristic. This tends to lead to a disruption of negative feelings and obsessional preoccupations. It is our view that this relief and the exploration of other possible states of consciousness are impactful. You will have people acting as guides to the experience to help you process before and after the sessions.



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### **Monitoring:**

Although this is a very safe medicine, it is essential that you be followed very closely during and after your treatment. This may include blood pressure and psychological measures before each session. You have the option to follow up and be supported by us by telephone, email, and in-person contact. We appreciate and look forward to your reports.

### **How long will it take before I might see beneficial effects?**

You may experience important positive changes in personality, mood and cognition during treatment, in the immediate aftermath, and in the days and weeks that follow. Although the results may vary between patients and there is **NO GUARANTEE OF AN EXACT RESPONSE**. Please note, some experiences may be temporarily difficult or disturbing to you. The ketamine experience itself is designed to enable your own healing wisdom to be accessed and to become beneficial to you. The support you will receive will aid you in making your experience(s) valuable and understandable to you. We will endeavor to assist you in changing patterns of mind and behavior that are of concern and cause you difficulty.

## **Why Ketamine Sessions?**

The purpose of the sub-lingual ketamine lozenge sessions is to generate a robust anti-depressant or other benefit to help with PTSD, addiction, chronic pain, etc. This benefit often occurs over time with repetition of administration of the lozenges in concert with intramuscular sessions. For certain individuals, only the lozenge experience may be utilized.

We generally begin treatment with you by assessing responsiveness to the lozenge, this is to precede the first IM session. This enables us to make a decision about the effectiveness of the lozenge and to adjust the dose. The literature indicates a response rate to treatment resistant depression of 40-50%. This information is coming primarily from using the low dose IV drip method. Relapses do occur and may require periodic additional sessions. Over time, a certain small number of patients may become unresponsive to further ketamine sessions.

The sub-lingual method, which is equivalent or stronger in effect and much less expensive and cumbersome than the IV method, variably coupled with IM sessions may exceed the rate of response quoted above.



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The purpose of the intramuscular ketamine experience is to create a non-ordinary or altered state of consciousness in order to facilitate a profound and transformative experience. This experience has been described at times as “transcendent”, “mystical”, “spiritual” or a “peak” experience. It has also been referred to as an “epiphany.” This may prove to be auspicious in resolving your existential problems, shifting your relationship to your suffering, accelerating your psycho-spiritual growth and leading to a deep personal transformation and optimization of your lifestyle. Such change is best facilitated within a structured supportive environment in connection with medical personnel who have a view of your struggles, issues, hopes and desires. As a byproduct of your experience you may well feel improvement in your emotional state and reduction in symptoms that bother you such as depression, anxiety, and post-traumatic manifestations. You may well notice that you are a bit different after a ketamine experience and that difference may well be liberating and allow for new mindfulness and new behavior.

We may well ask that new patients undergoing IM treatment make a commitment for three IM sessions as a minimum exposure to this method of employing ketamine. This allows for familiarization with this potent experience and the amplification of its benefits.

We understand that you are able to withdraw from our treatment at any time.

Your experience will be unique to you. If we decide to have additional sessions, each of your sessions will be different. There is however, no way for us to predict the effect or to guarantee a response. The number of sessions varies based on personal needs and treatment responses. We cannot pre-program your experience. We do our best to give a prognostic view as we learn with you how ketamine affects you. All ketamine journeys are adventures and can vary in intensity. They evolve from your own being in relation to the substance. While it is best to form an intention for your journey, you may or may not be able to hold onto that. Indeed, not holding on is best and the journey will flow whether or not you hold on and resist. Relax into it, trust the process and follow the path that unfolds before you. Breathe deeply and surrender softly into the experience. Holding on too tightly is the main source of anxiety. A ketamine session can be light, dark, or both. There will be concepts, visions, encounters, and you may well deal with your own death, mortality and immortality. Some journeys are enjoyable and filled with awe and some are difficult, but everyone grows from their experience.



## **Eligibility for Ketamine Therapy**

Before participating in ketamine treatment you will be carefully interviewed to determine if you are eligible. This will include a medical history, a physical exam if deemed necessary, review of medical/psychiatric records, and possibly administration of psychological tests to assess your state of mind.

Pregnant women and nursing mothers are not eligible. The effects of ketamine on pregnancy and the fetus have not been studied.

Untreated hypertension is a contra-indication to ketamine use as the substance can cause a rise in blood pressure. Similarly, a history of stroke or heart disease may make you ineligible to participate.

Information on ketamine's interaction with other medicines is only partially available and it will be assessed as to your eligibility for treatment.

Ketamine should not be taken if you have untreated hyperthyroidism. There have also been reports of some decrease in immune function in patients receiving surgical doses of ketamine.

Ketamine has an extensive record of safety and has been used at much higher doses for surgical anesthesia without respiratory depression.

## **Overview of Ketamine Therapy**

During the ketamine administration session you will be asked to make two agreements with the support staff to ensure your safety and well-being:

1. You agree to follow any direct instructions given to you by the support staff until it is determined that the session is over.
2. You agree to remain at the location of the session until the support staff decides you are ready to leave.



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The length of sessions varies from person-to-person and from experience-to-experience. You will be mostly internally focused for the first 45 to 90 minutes following IM administration of ketamine. After that time period, you will continue to remain under ketamine's influence at a lesser level for at least another hour. Under my care, ketamine will be given as an IM injection in the shoulder or buttocks at usual doses of 50 mg to 130 mg. The choice of dose will depend on prior exposure to ketamine or similar medicines, body weight, and sensitivity. Naive subjects will receive a lower dose initially. It is always better to start with a lower dose to reduce anxiety and become familiar with the effects. There is always an opportunity to make a choice for a larger dose at a future date. It is harder to correct a difficult experience because of too high an initial dose than to slowly and comfortably move upward over time. Ketamine IM creates an unusual experience of formlessness and a dissolving of boundaries. It has novel effects on the mind. It is much better to have an initial learning experience with the medicine.

The initial IM and subsequent IM sessions may be preceded by administration of one or more sublingual lozenges each containing 50-100 mg of ketamine. It will dissolve slowly and we ask you not to swallow your saliva for at least 10 minutes. Ketamine will penetrate the oral mucosa, the lining of your mouth, and will be absorbed rapidly in that manner. This will give us a measure of your responsiveness to ketamine. We advocate that you do not use alcohol or other unprescribed drugs preceding ketamine sessions as this may have negative emotional and physiological consequences.

Preparation for a ketamine session requires assessment by your provider of your readiness and a sense of connection between you and your provider. We are engaging in a therapeutic endeavor to benefit you. Together, we are creating a state of mind in a safe and comfortable setting. After the sessions you are encouraged to schedule integration sessions so you can learn from and integrate the information received during the ketamine sessions. This may lead to further administration sessions, if you so wish, if that is in accord with your provider's view of your treatment.

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



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## **Potential Risks of Ketamine Therapy**

You will be asked to lie still during the ketamine administration because ketamine will temporarily effect your sense of balance and coordination. This effect will wear off generally 2-4 hours the injection. It is possible you may fall asleep. Other possibilities for adverse effects include blurred vision, uncomfortable vision, double vision, rapid eye movements, elevation of intra-ocular pressure (feeling of pressure in the eyes). You are advised to keep your eyes closed until the main effects have worn off. Other side effects may include slurred speech, anorexia, mental confusion, excitability, anxiety, diminished ability to hear or feel objects accurately including one's own body, nausea, vomiting, and aspiration. Visual, tactile, and auditory procession are affected by the drug. Music that may be familiar may not seem so. Synesthesia, a mingling of the sense may occur. Ordinary send of time may morph into time dilation.

**Because of the risk of nausea and vomiting please refrain from eating and drinking at least 4 hours before a session. Eat lightly even before this 4 hour window. Make sure you are properly hydrated before this 4 hour window begins. Please use the bathroom before every session.**

**If you are unduly nauseated, you may be offered an anti-nausea medication, ondansetron, in pill or oral dissolving tablet forms.**

**Ketamine generally cases a significant increase in blood pressure but usually not pulse rate. If your blood pressure monitoring reveals that your blood pressure is too high, you may be asked to delay your session.**

**Agitation may occur during the course of a session. If your agitation is severe, you may be offered lorazepam or midazolam orally or by injection to help you relax.**

**Driving an automobile or engaging in hazardous activities should not be undertaken until all effects have worn off. We strongly recommend having a driver if the there are any continued effects of the medicine. You will be assessed for safety prior to leaving the session premises. We strongly suggest you follow our recommendations.**



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In terms of psychological risk, ketamine has been shown to worsen certain psychotic symptoms in people who suffer from schizophrenia or other serious mental disorders. It may also worsen underlying problems in people with severe personality disorders. We recommend those patients to these disorders or any history of psychosis to refrain from ketamine therapy.

Ketamine can bring up traumatic memories, may cause you to re-experience past traumas or force you to look at parts of yourself that may be uncomfortable.

During the experience itself, some people have reported frightening and unusual experiences. These frightening experiences, however, may be of paramount value to your transition to recovery from the suffering that brought you to ketamine therapy in the first place. The difficult experiences will stop and you will also receive support and guidance from your providers.

### **Potential for Ketamine Abuse and Physical Dependence:**

Ketamine belongs to the same group of chemicals as phencyclidine (PCP or angel dust). This group of chemical compounds is known Arylcyclohexylamines and are classified as hallucinogens. Ketamine is a controlled substance and is subject to Schedule III rules under the Controlled Substance Act of 1970. Medical evidence regarding the issue of drug abuse and dependence suggests that ketamine's abuse potential is equivalent to that of phencyclidine and other hallucinogenic substances.

Ketamine 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 the history of heavy use. 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.

Repeated, high dose, chronic use of ketamine has caused urinary tract symptoms and even permanent bladder dysfunction in individuals abusing the drug. This does not generally occur in our low dose, infrequent use parameters in the office setting.



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## **Alternative Procedures and Possibilities**

No other procedure is available in medicine that produces ketamine's effects. Major Depression, PTSD and Bipolar Disorders are usually treated with anti-depressant medications, tranquilizers, mood stabilizers and psychotherapy. Electroconvulsive Therapy (ECT), and the recently introduced Transcranial Magnetic Stimulation (TMS) are also in use for treatment resistant depression. Ketamine has also been used in the treatment of addictions and alcoholism as part of a comprehensive treatment program.

## **Confidentiality**

Your privacy and all therapy records will be kept confidential. They will be maintained with the same precautions as ordinary medical records. To allow others access to your records, you will have to provide a signed release form. The results of this ketamine therapy may be published in clinical literature. Published reports will not include your name or any other information that would identify you. If you chose to participate in ketamine group therapy you are agreeing to work within the confines of the group and that all participants are obligated to agree to strict confidentiality and anonymity. However, your provider is not responsible for the other members of the group. If you are not comfortable with the group arrangement, private sessions can be booked instead.

## **Voluntary Nature of Participation**

Please be aware that the Food and Drug Administration (FDA) has not yet established the appropriateness of ketamine therapy and its use is considered off-label. Although medical studies have shown benefit in depression and in other areas, the only official indication for use of ketamine is anesthesia. Your awareness of this situation is key to understanding any liability associated with your use of ketamine. Your informed consent indicates you are aware of this situation.

Ketamine is a new treatment modality, the primary studies have been with depression, bipolar disorders, alcoholism, and heroin addiction. It is not yet a mainstream treatment, although there are now many studies that demonstrate that it may be an effective treatment. There is an expanding array of ketamine clinics across the country and worldwide primarily administering ketamine without a counseling component. That therapeutic effect generally occurs with more than one treatment and is more robust when part of an overall treatment program. It may not permanently relieve depression. If your depressive symptoms respond to ketamine therapy, you may still elect to be

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treated with medications and ongoing psychotherapy to try to reduce the possibility of relapse. Over time, you may also need additional ketamine treatments or other therapies to maintain your remission.

Your decision to undertake ketamine therapy is completely voluntary. Before you make your decision about participating in ketamine therapy, you may ask and will be encouraged to ask, any questions you might have about the process.

### **WITHDRAWAL FROM KETAMINE THERAPY IS ALWAYS YOUR OPTION!!!!**

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

**I understand that I am to have no food or drink 4 hours prior to my ketamine session.**

**I understand that I need to have someone drive me home from the sessions and not engage in any driving or hazardous activity for at least 4 hours or more after the end of the session depending on the continued presence of effects of the medicine.**

### **Eligibility for Ketamine Therapy**

This consent form contains information about the use of sub-anesthetic dosages of ketamine for mental health purposes including depression. Ketamine was approved by the FDA for use as an anesthetic agent several decades ago. The administration of ketamine in lower, sub-anesthetic doses to treat pain, depression, or other psychiatric diagnoses is a newer, off-label use of ketamine. Use of ketamine has become relatively wide-spread in recent years, has been studied and promoted by researchers at the National Institute of Mental Health. Ketamine has been administered by intravenous, intramuscular, sub-lingual, oral and intra-nasal routes. Often it has been used after other treatment approaches have been unsuccessful.

Once you indicate that you have understood the benefits and risks 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 for your records. This process is known as informed consent.



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**By signing this document you indicate that you understand the information provided and that you give your consent to the medical procedure 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.**

**Informed Consent**

By signing this form, I agree that:

1. I have fully read this informed consent form describing ketamine therapy and agree to its terms holding harmless the practitioner(s) involved in my care. I am waiving, releasing and discharging all claims, rights and/or causes of action which may arise out of or in connection with my participation in ketamine therapy. No oral or written statements, representations, or inducements have been made to cause me to enter into this agreement.
2. I have had the opportunity to raise questions and have received satisfactory answers concerning ketamine therapy in all regards.
3. I fully understand that the ketamine session(s) can result in profound change in mental state but that this is not guaranteed. I also fully understand that ketamine may result in unusual or difficult psychological and physiological effects.
4. I give me consent to the use of lorazepam or midazolam if deemed necessary for agitation, to ondansetron for nausea, and clonidine for high blood pressure.
5. I have been given a signed copy of this Informed Consent form, which is mine to keep.
6. I understand the risks and benefits. I freely give my consent to participate in ketamine assisted therapy as outlined in this form and under the conditions indicated in it.
7. I understand that I may withdraw from ketamine therapy at any time up until the actual injection or lozenge has been given.

I voluntarily sign my name and thereby give evidence of my acceptance of the provisions of this agreement.

SIGNATURE \_\_\_\_\_

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

DATE \_\_\_\_\_



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