



KETAMINE ASSISTED PSYCHOTHERAPY INFORMED CONSENT

The information contained in this form is meant to provide a solid outline of the efficacy, uses, risks, and benefits of Ketamine Assisted Psychotherapy (KAP) to aid you in your decisions about this treatment. Please note that it is important that you understand and feel comfortable with KAP and that we want to ensure that all of your questions are answered. You will be asked to sign this form before participating in this treatment and we ask that you do not do so until you thoroughly understand and are comfortable with the process. Please read this form carefully and thoroughly, review the information and resources that are provided on our website, and openly and freely ask us to clarify and expand on any part that is unclear or on which you want more information. We want to make sure that the “informed” part of this consent form is true for *you*, and will work with you to help you decide whether this form of treatment is potentially a right fit for you and your goals.

What is ketamine?

Ketamine, which was first developed over 50 years ago, is synthetic pharmaceutical compound classified as a dissociative anesthetic medication. As an anesthetic (at doses much higher than ever used in KAP, where administered doses are only about 10% to 25%) it is listed on the World Health Organization’s global list of “essential medications” and is used the globe over as a general anesthetic for many types of procedures (including pediatric surgery) because of its rapid onset, proven safety, and short duration of its effects. It was approved for use by the FDA in 1970 and classified as a Schedule III medication (along with such commonly used medications as Tylenol with Codeine and anabolic steroids).

While all medications approved by the FDA are provided with a “label” by the manufacturer (an explanation of its proven benefits and uses as understood at the time of submission), with study and use over time many further uses and benefits are discovered. Given the involved and rigid structure of the FDA approval process and the financial realities of the pharmaceutical companies that develop our medications, it is infrequent that these further uses and benefits are ever officially added to a given medications label. Instead, it is common that these uses and benefits, as long as they are based on solid medical evidence, become known as what are termed “off-label” by physicians.

With close to 60 years of use, it is no surprise that ketamine has been shown to have great promise as an off-label treatment medication. In fact, over the course of the last twenty years ketamine has shown promise as an off-label treatment medication to for treatment resistant depression (TRD), anxiety (GAD), bipolar disorder, eating disorders, the effects of traumatic stress (PTSD), obsessive behaviors (OCD), drug and alcohol addiction, and other psychiatric diagnoses. It can be administered by intravenous (IV), intramuscular (IM), sub-lingual, oral, and intra-nasal routes.

I am aware and understand that despite increased use by medical professionals and positive study results, the Food and Drug Administration (FDA) has not yet established the appropriateness of KAP and this specific use of ketamine is considered “off-label.” Please initial: _____

What are the effects of ketamine?

While ketamine is not classified as a classic psychedelic medication, some of the effects experienced by those utilizing ketamine for therapy can feel similar. As mental health professionals we embrace and

celebrate those effects for the insight and leverage for change that they can provide. The name psychedelic itself is derived from the combination of the Greek words “psykhe” (mind) and “deloun” (make visible, reveal); a pretty solid definition of the goal of psychotherapy itself! But what exactly will the ketamine experience be like for you? Here we have to answer with the powerful truth that each and every person’s experience is, indeed, uniquely their own. However, there is a lot that we can tell you about what it may be like for you based on the actual physiological effects of the medication and on the experiences of thousands.

At a low dose of ketamine, you will likely first experience the anesthetic (distancing from pain), anxiolytic (relief from anxiety) and anti-depressant and anti-suicidal effects of the medication. This alone has been found by many to be beneficial and research data has demonstrated the possibility of a lasting positive effect on those who utilize sustained and repeated low-level ketamine treatments. This, in effect, is the logic behind the many ketamine infusion treatment clinics that have proliferated in recent years, to provide the potential cumulative effect of the medication alone. Research has shown that the psychedelic/mystical experiences may well be instrumental in providing a more robust benefit. The KAP philosophy not only offers the client these potentially immediate physiological benefits of ketamine as a medicinal agent, but goes much further by tapping into the potentially long-term transformative power of personal psychotherapy through the relaxed and insightful lens of the ketamine experience.

At the therapeutic dose administered in KAP (carefully determined by your individual factors), those early “calming” effects will then allow you to move towards that insightful space. As mentioned above, ketamine is classified as a dissociative anesthetic and in that “dissociative” effect comes a sense of relaxation from day-to-day concerns and from one’s usual mindset and sense of self. This “time-out of usual experience” (while still maintaining consciousness) will vary in length but usually lasts between a half hour to an hour and a half. During that time your visual, tactile and auditory senses will feel different, heightened, or undergo a “mingling” (termed synesthesia). While the full physiological effects of ketamine on the brain are extremely complex (interacting with multiple “systems” simultaneously) the effects of ketamine side-stepping the brain’s “default mode” while enhancing its neuroplasticity can offer a new way of thinking, in particular about one’s own life, patterns, and the bigger picture of our very existence in relationship to the world. For many, ketamine (combined with therapy) can lead to unique avenues for disrupting negative thoughts and feelings and the reduction of obsessive preoccupations. In this way, ketamine can offer a profound alteration of consciousness that can be revelatory. And in this way, ketamine can offer not only a “refreshed” glimpse of the journey of life but also a powerful and leveraged platform from which to plan for and affect lasting change in one’s life.

I understand that the effects of ketamine can be powerful in the moment and life- and perception-changing, especially when paired with psychotherapy. Please initial:_____

What is KAP?

While the mood-boosting effects of the medication and the heightened consciousness experience themselves can be powerful and even lasting for some clients, the goal of KAP is to work with you to leverage those feelings and those profound personal (perhaps even mystic, transcendental, spiritual) peak experiences into real self-acceptance, change, and goal attainment in your life.

This therapy work begins during your intake sessions prior to your actual ketamine sessions. It is our aim that you be fully comfortable with the process itself and, most essentially, with the therapist who will be “holding space” with you during your ketamine sessions and will be working with you to explore your insights, questions, and experiences in scheduled therapy after your ketamine use. It is essential to the process that both sides of this relationship are in place: that you have a trusting relationship with your

psychedelic therapist and that they are aware of your important issues, desires, hopes, and struggles.

During the actual ketamine administration sessions your KAP therapist will stay with you in the room and be available to take notes, make observations, and to provide you with a sense of security and safety. There is, however, no pressure or expectation for you to “work” with the therapist at this time. Some clients may find themselves talkative and wish to share their ongoing experience with the therapist while others may not wish to speak at all and just “be.” Either path (or any in-between) is perfectly fine. As the major effects of the medication wear off, again individual clients may wish to share or not what they have thought or experienced. You will be asked to journal about your experiences the evening of your ketamine sessions so as to have fresh impressions and notes from which to draw at your next day’s integration session.

Monitoring: It is essential that you be followed very closely during and after your treatment. This may include blood pressure and pulse measurements—as appropriate, and mood rating scales administered before your first and subsequent sessions to measure effects. Follow-up integration will be by telephone and in-person. To the best of our abilities and your scheduling realities, we do like to plan for post-ketamine integrative therapy sessions within a few days of the ketamine administration, at least for the first time you experience ketamine. These sessions may vary in length based on what you are working on, what came up in your experience, and what you and your therapist have agreed upon. While the ketamine experience itself may offer a path to your own beneficial healing wisdom, it is through these integrative sessions that we can aid you in making that experience even more valuable and understandable to you. It is here that we may endeavor to assist you with changes to patterns of mind and behavior that you have been seeking to achieve.

While each individual’s therapeutic journey is unique to them, we do ask that you commit to a minimum of three ketamine sessions and their immediate (next day is advised) integrative follow-up therapy sessions as this has been shown to be an average “minimum” treatment commitment of value. Of course, your consent to receive ketamine may be withdrawn by you, and you may discontinue your participation, at any time up until the actual injection has been given. We urge you to fully discuss your treatment at all points with your therapist(s).

How Long Will It Take Before I Might See Beneficial Effects?

You may experience changes in emotions, mood and thinking during treatment, in the aftermath, and in the days and weeks that follow. Some experiences may be temporarily unsettling to you. The ketamine experience itself is designed to enable your own inner healing wisdom to be accessed by you. The psychotherapy 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.

At our clinic, ketamine is administered via intra-muscular injection(s). The purpose of the intra-muscular ketamine experience is to create a non-ordinary (“altered”) state of consciousness in order to facilitate profound transpersonal (“transcendental”, “mystical”, “spiritual”, “religious”) peak experiences. These may prove to be beneficial in resolving your existential problems, 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 psychotherapeutic milieu in connection with therapists who have a view of your issues, hopes, desires, and struggles. 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 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.

The research literature indicates a 70% response rate to ketamine; and a remission rate for patients with

treatment resistant depression of 40-50% with continued care. Ketamine assisted psychotherapy is meant to help clients get to the root cause of their difficulties and the psychotherapeutic support aids in sustained transformation. Relapses do occur and may require periodic additional sessions. Over time, a certain number of patients may become un- responsive to further ketamine sessions. We believe that combining ketamine with intensive psychotherapy enhances these response rates.

I understand that in the very nature of therapy there is always the possibility that discussing psychological and emotional issues may at times be distressing. However, I understand that this process is intended to help me personally and with relationships. I understand and commit to the minimum recommended treatment plan as discussed by my therapist and myself. Please initial:_____

Is KAP appropriate for me?

Before participating in ketamine treatment and KAP, you will be carefully screened to determine if you are eligible and whether this type of therapy is indicated. This will include a medical and psychiatric history interview, a review of your medical/psychiatric records if necessary, a series of basic medical tests (such as blood pressure), and administration of brief psychological tests to assess your state of mind. Further, you will be asked to meet with the therapist/ physician on our staff who will be working with you as many times as you feel is necessary to gain a relationship of trust and an assurance that you feel that they understand your goals in seeking this treatment. We believe that a sense of connection between you and your therapist facilitates the ketamine experience. Together, we are creating a state of mind (set) in a safe and supportive setting.

As mentioned previously, a large portion of the research done on ketamine and KAP has concentrated on its efficacy as a treatment aid with treatment resistant depression. For those clients who have had several prior psychiatric treatments or therapies (medications, therapy, combinations) that have been unsuccessful in reducing your symptoms (ketamine is not a first-line treatment for depression), KAP may offer an attractive new option. Because of the widely varied specifics of the many studies done on the use of ketamine and KAP we are reluctant to quote specific response rates and/or statistics on symptom remission rates etc. We urge you to explore the literature that is available and are more than willing to help you do so. Our bottom line is this; if we did not fully believe in the safety and efficacy of this treatment we would not be here offering it!

This holds true for the large and growing list of off-label use studies and evidence for treatment of everything from OCD to trauma to eating disorders to addictions to personal growth and transformative symptom reduction of all kinds. There are studies and there is evidence and we are happy to help you understand these, but in the end the decision is one that needs to be driven by you with the help of our team. Throughout the process we can discuss with you other treatment options and continuously assess the viability of KAP for you. Our ultimate goal is to help you find the path that works for you.

While the proven safety record of ketamine makes it physically viable for most, pregnant women, mothers who are nursing, and women who are actively planning on becoming pregnant in the short term should not receive ketamine. If a client becomes pregnant while participating in our program, they should notify us immediately as the effects of ketamine on an unborn child are undetermined.

Other specific reasons that you might not be eligible for ketamine treatment include a recent myocardial infarction (heart attack), stroke, recent psychosis (delusions or hallucinations) or recent bladder inflammation. 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 (high dose) of ketamine. It is important to note that ketamine has an extensive and consistent record of safety available to us from

it's long history of use at much higher doses for surgical anesthesia.

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

1. You agree to follow any direct instructions given to you by the therapist(s) until it is determined that the session is over, and
2. You agree to remain at the location of the session until the therapist(s) decides you are ready to leave.

The length of ketamine sessions varies from person-to-person and from experience- to-experience. You will be mostly internally focused for the 40 minutes to one hour or more. We layer our ketamine dose with 1-3 injections based on a variety of factors that pertain to your physical and emotional state in order to curate the experience we think would maximize benefits for you. Following each IM (intramuscular) administration of ketamine, the experience deepens and yet you remain fully conscious of your experience and present in a profound way. The choice of dose will depend on prior exposure to ketamine and other psychedelics, body weight, and sensitivity. We dose in the range of 0.5-1.2mg per kilogram body weight. Ketamine IM creates an unusual experience of formlessness and a dissolving of boundaries and has unique effects on the mind. We aim to ease you into this novel experience. Please remember that 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 administered.

I understand that my medical evaluation and further evaluations may preclude me from ketamine therapy at this time. I understand the various factors that can have an effect on eligibility and have honestly and openly discussed these with the ketamine therapy team. Please Initial:_____

What are the potential downsides of KAP?

As mentioned, ketamine has a long and proven record of safety when used for surgical anesthesia. The dosages administered for KAP sessions are, of course, very much smaller and the safety of the medication at these levels is well established. However, as with any medication and as with any therapeutic treatment there are risks and considerations that must be understood.

You will be asked to lie still during the ketamine administration because your sense of balance and coordination will be adversely affected until the drug's effect has worn off (generally two and up to four hours after the injection). You will be able to walk and use the bathroom after the session. Other possibilities for adverse effects include blurred and uncomfortable vision (you are advised to keep your eyes closed and or wear an eye mask until the main effects have worn off), slurred speech, mental confusion, excitability, diminished ability to see things that are actually present, diminished ability to hear or to feel objects accurately including one's own body, anxiety, nausea and vomiting. Visual, tactile and auditory processing are affected by the drug. Music that may be familiar may not be recognizable. Synesthesia—a mingling of the senses may occur. Ordinary sense of time may morph into time dilation. Agitation or anxiety may occur during the course of a ketamine session. This is a rare event in our experience. You will never be alone. Your therapist will always be there and offer as much support as you consent to. The administration of Ketamine at anesthetic doses may occasionally 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). **Driving an automobile or engaging in hazardous activities should not be undertaken until all effects have stopped—and for this reason you will be required to have someone pick you up from each ketamine session. You agree not to drive until at least 7 hours after your ketamine dosing in the office.**

Physically, Ketamine causes a significant but not dangerous increase in blood pressure but usually not pulse rate. Initial screening will determine if this creates any undue risk for you and may preclude you from ketamine work. During your ketamine sessions, in the unlikely event that blood pressure monitoring reveals that your blood pressure is becoming too elevated, you may be offered a medication to such as clonidine address the situation. Likewise, medication like ondansetron (zofran) may be offered to combat nausea should it occur during your session. **Because of the risk of nausea and vomiting, please refrain from eating for at least the 3-4 hours preceding the session. And eat lightly when you do. Hydrate lightly in the last 2 hours before your session.** Please do hydrate well the previous day and up until the window prior to your appointment.

Like other hallucinogenic compounds, ketamine does not meet the criteria for chemical dependence since it does not cause tolerance or withdrawal symptoms. "Cravings" for the effects of hallucinogens have been reported by some individuals but again, only after a history of heavy use, making even the risk of psychological dependence extremely unlikely within in the KAP setting. Frequent/daily use of ketamine has been shown to potentially cause urinary tract symptoms and even permanent bladder infection in some, however this seems to be a risk only from chronic, repeated high doses. We and our colleagues doing clinical ketamine work have not had patients become dependent on ketamine.

Ketamine is a legal medication approved by the FDA subject to Schedule III rules and there is nothing illicit nor stigma-inducing about its use. However, as with any controlled substance, record of use of medication is kept on file with the Board of Pharmacy in the event when ketamine is prescribed as lozenges to the patient directly and these records may be accessed by some employers. As the only "on label" use of ketamine is for the treatment of Treatment Resistant Depression, this is something to be aware of for certain professions (pilots, military, etc.). Therapeutic IM ketamine administered in our office is not tracked by the Board of Pharmacy, but we keep detailed records as per DEA requirements of administering this medication.

During the ketamine experience itself, the medication can result in profound changes in your mental state and may result in unusual physiological and psychological states. Some have reported frightening or unusual psychological or cognitive experiences. These experiences, however, can often prove of paramount value within the work that you are doing towards reaching the goals that brought you to KAP in the first place. They are temporary and you will not be alone. We will provide psychotherapeutic help and guidance throughout should you need. In the case of severe agitation or distress that we are unable to adequately address together, you may be offered lorazepam to help.

As with any therapy there are risks inherent in the profound and powerful journey of working with one's own life and psyche. You may experience profound changes in personality, thoughts, and mood during treatment and beyond. Sometimes these changes can seem disturbing at first. On the other side of the coin, no therapy or medication can offer itself as a "silver bullet" that will work for all and some may find that KAP did not provide them with the path for change that they were seeking. All of these possibilities should be understood and discussed with your KAP therapist before deciding to proceed.

I understand and accept the physical and psychological risks involved in entering into any new treatment modality and those associated specifically with KAP. Please Initial:_____

ALTERNATIVE PROCEDURES AND POSSIBILITIES

No other procedure is available in medicine that produces ketamine's effects. Major Depression (MDD), 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 comprehensive treatment programs.

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.

VOLUNTARY NATURE OF PARTICIPATION

In 2019 a ketamine derivative, esketamine was approved to treat treatment resistant depression by the the Food and Drug Administration (FDA), but they have yet to establish the protocol of Ketamine Assisted Psychotherapy and its use is considered off- label. 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 psychiatric treatment—the primary studies have been with depression, bipolar disorders and alcoholism. The benefits generally occurs with more than one treatment and are most robust when part of an overall treatment program. It may not permanently relieve depression. If your depressive symptoms respond to Ketamine, you may still elect to be 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 is completely voluntary. Before you make your decision about participating, you may ask and will be encouraged to ask any questions you may have about the process. Withdrawal from ketamine treatment is always your option. Even after agreeing to undertake Ketamine Treatment, you may decide to withdraw from treatment at any time.

☐ *I have discussed the risks and benefits of ketamine-assisted psychotherapy with my treatment team. I understand and agree that this Agreement contains the entire understanding between the parties and cannot be changed except by mutual written Agreement. If any provision of this Agreement is found by a court to be void and unenforceable, the other provisions will be unaffected. By signing below I signify that I have read, understand, and agree to the terms and conditions of this agreement.*

Patient Name: _____

Date: _____

Client Signature

Date