## 834 SW Saint Clair Ave., Suite 206 Portland OR 97205

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#### **INFORMED CONSENT FOR KETAMINE ASSISTED PSYCHOTHERAPY (KAP)**

This document is long; it is also very important. Unlike many consent forms, it contains a great deal of information that will help maximize the benefits of KAP, if you decide to engage in it. Please read it carefully, all the way through, and ask your therapist if you have any concerns or questions.

#### What is Ketamine?

Ketamine was synthesized in 1962 and was approved for use as an anesthetic agent in 1970. In the last ten years, researchers at the National Institute of Mental Health have been studying and promoting the use of lower, sub-anesthetic doses to treat pain, depression and other psychiatric diagnoses. Ketamine is now increasingly being used as a treatment for depression (Ryan, Marta, and Koek, 2016), anxiety (Kolp et al. 2007), addiction (Sullivan, 2018), PTSD (Feder et al. 2014) and other psychiatric diagnoses, as well as for existential, psychological and spiritual growth (Krupitsky and Grinaneko, 1997). Research suggests it may be effective for various chronic mental health conditions considered "treatment-resistant" (Dore et al. 2019). Ketamine can be administered by intravenous (IV), intramuscular (IM), sublingual, oral, and intranasal routes.

#### **How Does Ketamine Work?**

Ketamine is classified as a dissociative anesthetic (dissociation means a sense of disconnection from one's ordinary reality and usual self). At the dosage level administered during KAP, you will most likely experience mild anesthetic, anxiolytic (anti-anxiety), antidepressant and potentially mild to moderate psychedelic effects.

Neuropsychologists currently believe that ketamine works primarily through the glutamate neurotransmitter system in the brain (Wallach 2018). Note that this is a very different pathway than that of other psychiatric drugs such as SSRIs, SNRIS, anti-psychotics and benzodiazepines. This may be why ketamine treatment is providing benefit to many patients who have not been adequately helped by SSRIs and related psychotropic medications.

Recent research conducted in FDA clinical trials of MDMA and psilocybin indicate a temporary disabling of the Default Mode Network (the network of habitual neuron firing patterns) in subjects' brains, which then allows them to perceive things in novel ways (Scheidegger 2012). It is thought that ketamine may have the same effect (but more research is necessary in this area). A recent study of ketamine effects in the brains of mice showed neurogenesis (Soumier et al. 2016) which is the creation of new neural networks; this may further explain the apparent benefits to humans (but again, further research is needed).

## Why Ketamine Assisted Psychotherapy (KAP)?

The purpose of KAP is to create a non-ordinary, altered state of consciousness in order to facilitate the working through of limiting beliefs, dysfunctional thinking, maladaptive behavioral patterns, trauma and/or attachment-related distress. Ketamine can facilitate the loosening of psychological defenses, which can clear the way for the accessing and healing of dysfunctional states and limiting beliefs. KAP can include profound transpersonal experiences which, for many, have been beneficial in resolving existential problems, accelerating psycho-spiritual growth and leading to deep personal transformation. Such change is best facilitated within a structured, supportive process of psychotherapy with a therapist who has knowledge of your issues, struggles, hopes and desires.

Following your experience, you may feel improvement in your emotional state and reduction in symptoms of depression, anxiety, and/or post-trauma. You may notice that you move through the world in a different way after KAP; often participants report changes such as increased hopefulness, empathy, awareness, loving-kindness to self and others, and greater self-acceptance and peacefulness. Your experience will be unique to you, and each of your sessions will be different.

#### **Preparation for KAP Therapy**

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Eligibility for KAP work requires both psychological/emotional assessment by your KAP therapist <u>and</u> medical assessment by a medical provider/prescriber. You and your KAP therapist will discuss your psychological eligibility and readiness for KAP. Before scheduling KAP, you will also need to meet with a licensed medical provider/prescriber to determine if you are medically eligible, and to obtain a prescription. This assessment will likely include a medical history, review of your medical/psychiatric records, a psychiatric history, and a physical exam. Dosage amounts and frequency will be determined by your prescriber. Your signature on this consent form indicates that you have undergone these processes, are medically cleared and have gotten approval to participate in KAP (as well as a prescription for the medicine) from your prescriber.

#### **Structure of KAP Treatment**

Most psychedelic psychotherapy is conducted in sets of three sessions: a preparation session, a psychedelic "journey" session (during which the medicine is taken), and an integration session. Some clients feel their goals have been met after just one set of three, while others may elect to engage in additional sets over time. Information about each of the three sessions is given below.

#### **The Preparation Session**

During the preparation session, you and your therapist will discuss and agree upon a treatment plan including (but not limited to) purpose and intentions for KAP, preparation guidelines for journey sessions, self-guided integration methods, and follow-up sessions. We will go over the information contained in this document and you will have the opportunity to ask any questions you have about KAP. You will be given additional details about ways to prepare and what you might bring to the journey session; intentions and preferences for the journey session will be discussed.

While it is often helpful to consider intentions for your KAP session, know that your session may or may not unfold in the direction of your intention; therefore, it is helpful to remain open to whatever arises in the course of your journey.

#### **Prior to the Medicine Journey**

Because of the risk of nausea and vomiting, you will need to refrain from eating for at least 4 hours preceding the journey session, and to refrain from liquids for at least 1 hour prior. On the day of treatment, if you eat prior to the 4-hour fasting period, eat lightly. Hydrate well prior to the fasting period. You will need to **arrange for transportation** home after the session.

You will be given a detailed handout of additional guidelines, recommendations and "things to bring" during your preparation session.

#### **The Medicine Journey**

The scheduled length of the journey session is 3 hours. Initially the journey session begins with a check-in and grounding in the purposes and intentions of the session. When you are ready, you will sub-lingually (under the tongue) self-administer oral ketamine (lozenges) at doses of 100 to 300 mg. The dose will depend on prior exposure to ketamine and other psychedelics, and also upon discussions and agreements made between you and the prescriber. It is always better to start with a lower dose to minimize anxiety and become familiar with the experience of the medicine. (Remember that you can always make a choice to increase the dose in a future session, if desired and appropriate.)

After you ingest the medicine, you will place an eye mask on and recline in a manner comfortable for you. Music will be playing, and you will usually experience 60 – 120 minutes of time under the direct influence of the ketamine. The length of the effects of ketamine varies from person to person and from experience to experience.

While in the medicine state, a relaxation of ordinary concerns and usual mindset will occur. Experiences may be emotional, physical/somatic, visual, existential, or just plain impossible to describe. Some sessions are enjoyable and filled with awe, and some are difficult. Clients are

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encouraged and supported by their KAP therapist to **not resist, but allow** any difficult experiences to move through. Ketamine creates an unusual experience of formlessness and a dissolving of physical and spatial boundaries with novel effects on the mind. During this time, some clients are drawn to be wholly in their own internal experience; others are drawn to interact with the therapist as the experience unfolds. Either (or both) of these are just fine; your therapist will take cues from you. As you return to normal consciousness, further verbal processing, psychotherapeutic interventions, integration and guided grounding/re-orienting will usually take place.

Note: some therapeutic psychedelic models utilize two therapists in the room for each session. This KAP model uses one therapist, which enables clinical customization and increased accessibility (by keeping client costs down). Know that if you prefer, it may be possible to have two therapists in your KAP sessions, but that the cost per session will be much higher.

## After the Medicine Journey

Ideas for self-directed integration methods will be discussed before you leave your journey session. You and your therapist will determine together whether you are safe to leave the office, and at that point you can connect with your arranged transportation. You may feel mild effects of the medicine even after you leave; this is why it is recommended that you plan time and space to rest after your session, and it is imperative that you not operate any mode of transportation (car, bike, scooter, etc.) for the rest of the day.

If your arranged ride does not show up, you will need to arrange to have someone else pick you up or to use public transportation. You are welcome to remain in the waiting area as long as you need to in order to make arrangements and/or feel grounded and safe.

#### The Integration Session

Integration is the act of processing and incorporating the material that arose during a journey into a non-ordinary state of consciousness once you have returned to your ordinary state of mind. This process will begin as soon as your journey is completed, and will continue to unfold over time. KAP integration sessions are generally scheduled within 1 to 2 weeks after a journey session; this allows some time for you to do some of your own short-term processing, and to notice what shifts might have occurred. KAP experiences often ripple outward into participants' lives for months and even years afterwards; it can be very helpful to be connected to ongoing therapy, and to use this as needed to support continued integrating and processing over time. In psychedelic medicine, it is said that "the final stage of integration is that you live your life differently."

## Potential Side Effects, Risks, and Contraindications of KAP

You will be asked to lie down during the KAP session, as your sense of balance and coordination will be adversely affected until the medicine has cleared. Other possible adverse effects include: blurred and altered vision, 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 (in rare cases) vomiting. If nausea/vomiting is a concern for you, you can talk with your prescriber about anti-nausea medicines to use during the journey sessions.

Visual, tactile and auditory processing are affected by this medicine. Familiar music may appear quite different to you, even unrecognizable. Synesthesia, a mingling of the senses, may occur. Ordinary sense of time may become distorted. Ketamine generally causes a significant increase in blood pressure and in some cases elevated pulse rate (tachycardia), and agitation and anxiety may occur. Some clients experience headaches after the sessions, and Ketamine has in some cases caused and/or stopped migraines. Diplopia (double vision), nystagmus (rapid eye movements), feeling an elevation of pressure in the eyes, and loss of appetite may also occur. [Note that these reactions have been observed to occur after rapid intravenous or intramuscular administration of doses greater than 5 mg/kg. Doses used in this sub-anesthetic, sub-lingual KAP are much lower (2 mg/kg or less).]

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You may experience changes in personality, mood and cognition during treatment, in the aftermath, and in the days and weeks that follow. Ketamine 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 personality disorders and/or dissociative disorders. If you have been or are presently diagnosed with these disorders, you may not be a candidate for KAP. Repeated, high dose, chronic use/abuse of ketamine has caused urinary tract symptoms and even permanent bladder dysfunction. Pregnant women and nursing mothers are not eligible because of potential effects on the fetus, or nursing child (the effects of ketamine on pregnancy and fetus are undetermined). Untreated hypertension is a contraindication to ketamine use, as it causes a rise in blood pressure. Similarly, a history of heart disease may make you ineligible to participate. Ketamine should not be taken if you have hyperthyroidism. There have also been reports of some decrease in immune function in patients receiving surgical-level doses of ketamine. You prescriber will assess you for any medications you are already taking and any possible adverse interactions. You should never discontinue the use of medications that you are already taking, or add any new medications without first consulting with your KAP prescriber. Your KAP therapist is in no way qualified to determine medical appropriateness for KAP; this determination must be made by your prescriber.

## How Long Might It Take to See Beneficial Effects?

Some clients report feeling immediate beneficial results after a first KAP session; for others, it takes longer. You may not be able to identify shifts or learnings right away. Some of what arises may feel temporarily distressing. The ketamine experience itself is designed to open you, while at the same time to enable and access your own healing wisdom. The psychotherapy support you will receive will aid you in making your experience(s) more valuable and understandable to you. As with traditional psychotherapy, results can vary widely and there are no guarantees.

#### Potential for Ketamine Abuse and Dependency

Ketamine and other hallucinogenic compounds do not meet official criteria for potential 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/emotion, thinking and perception that may make some people want to use it repeatedly. Therefore, ketamine should never be used except under the supervision of a prescribing physician.

Repeated use of very high doses of ketamine over time has caused urinary tract symptoms and even permanent bladder dysfunction in individuals abusing the drug. (These effects have only been seen with doses substantially higher than those used in KAP.)

#### **Voluntary Nature of KAP Participation**

Please be aware that the Food and Drug Administration (FDA) has not yet established the appropriateness of Ketamine Assisted Psychotherapy (KAP) and its use is considered "off-label." The only uses of ketamine officially approved by the FDA are as an anesthetic and (more recently) a nasal spray for depression. This awareness is important in understanding any liability associated with your use of ketamine. Your informed consent (below) indicates you are aware of this.

*Your decision to undertake KAP is completely voluntary.* Before you make your decision about participating in KAP, please ask any questions you may have about the process. Even after deciding to undertake KAP, you may decide to withdraw from treatment at any time prior to ingesting the lozenge.

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#### **Use of Therapeutic Touch**

Research shows that trauma is stored in the body/nervous system. Since body and mind are inseparable, by incorporating the body into psychotherapy healing can be accelerated. Your KAP therapist is trained in mindfulness-based experiential and somatic psychotherapy, which can include the use of safe non-sexual touch as a therapeutic intervention. Your therapist will <u>always</u> ask your permission before such an intervention is made. Touch is <u>never</u> required and will not be initiated or continued if you are at all uncomfortable with it. You are encouraged to ask your therapist for examples if you have any questions about what safe touch could include. You are asked to express boundaries if touch is not okay with you at any time during KAP sessions. Understand that your consent given for therapeutic touch, if given below, may be revoked verbally by you <u>at any time</u>. Please **check and sign next to one option below** indicating whether you consent or do not consent to use of therapeutic touch during KAP sessions.

\_\_\_\_\_ I consent to the therapeutic use of touch during KAP (but can change my mind at any time).

Signature	Date
I <b>DO NOT</b> consent to the therapeutic use of touch during KAP.	
Signature	Date

#### **Fees and Cancellation Policy**

#### **Preparation and integration sessions:**

- Minimum of 3 preparation sessions and 2 integration sessions at \$205/ 50 minutes with insurance, \$170 for credit card, \$150 cash
- Preparation and Integration sessions can be adjusted if you have a therapist.

#### KAP Medicine Session (3 to 4 hours)

\$450 cash up to \$545 (based on ability to bill 1 hour of insurance)

Any cancellations or rescheduling requests should be made at least 48 hours prior (with the exception of cancellation due to illness, which can be done at any time with no penalty). Late cancellations of journey sessions will result in a fee equal to half of the normal medicine journey rate. Late cancellations of preparation or integration sessions will be charged at the full rate.

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# You should never feel pressured to take ketamine for any reason. Therefore, if you decide you do not want to ingest the medicine and you are within the 48-hour window, you have the option of changing to a 3-hour intensive therapy session (which will not include medicine).

#### **KAP Agreements**

You are asked to make 6 agreements with your KAP therapist to ensure your safety and well-being:

1. You agree to follow any safety-related instructions given to you by the therapist until it is determined that the session is over. Initials \_\_\_\_\_

2. You agree to remain at the location of the session until the therapist determines you are ready to leave. Initials \_\_\_\_\_

3. You agree to not engage in any driving or hazardous activity for the rest of the day after your KAP session. Initials

4. You agree to not ingest ketamine until you are directed to do so by your KAP therapist during the session. Initials

5. You agree to schedule and complete integration session(s) and to engage in self-directed integration work in between sessions, as planned with your therapist. Initials \_\_\_\_\_

6. You agree to payment plan of \$\_\_\_\_\_ per prep and integration and \$\_\_\_\_\_ for medicine session. Initials \_\_\_\_\_

#### **INFORMED CONSENT**

#### By signing this form, I agree that:

1. I have fully read this informed consent form describing Ketamine Assisted Psychotherapy (KAP) and agree to its terms, holding harmless the practitioner(s) involved in my care--waiving, releasing and discharging all claims, rights, and or causes of action, which may arise out of or in connection with my participation in KAP. 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.

3. I fully understand that the ketamine session(s) can result in a profound change in mental state and may result in unusual psychological and physiological effects.

5. I have been offered a signed copy of this Informed Consent form, which will be mine to keep.

6. I understand the risks and benefits, and I freely give my consent to participate in KAP as outlined in this form, and under the conditions indicated in it.

7. I understand that I may withdraw from KAP at any time up until the time at which I ingest the medication.

8. I understand that my KAP therapist is bound by mandatory reporting and duty-to-warn statutes, just as they are in other therapy sessions.

9. I agree to adhere to any previously-determined fee and cancelation policies explained in my KAP therapist's general psychotherapy informed consent forms.

10. I understand that this consent form does not replace or supersede any other treatment consent forms I may have signed with my therapist previously.

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I voluntarily sign my name evidencing acceptance of the provisions of this agreement.

<b>Printed Na</b>	me	 	
Signature _			

Date \_\_\_\_\_

#### **Therapist Statement**

I, Mark Henry, have trained with the Ketamine Training Center in Ketamine Assisted Psychotherapy (KAP) and have carefully explained the nature of Ketamine Assisted Psychotherapy (KAP) to \_\_\_\_\_\_\_. I hereby certify that to the best of my knowledge, the individual signing this consent form understands the nature, conditions, risks and potential benefits involved in participating in KAP. To the best of my knowledge, neither a medical problem nor a language, cognitive, or educational barrier has precluded a clear understanding of the subject's involvement in KAP or his/her/their ability to give informed consent.

I am a Licensed Professional Counselor #C1433 with a Master's of Arts in Counseling Psychology (1999) from Lewis and Clark College and a Master's in Education (1984) from Linfield College. I am governed by and follow the Code of Ethics of the State of Oregon Board of Licensed Professional Counselors and Therapists. The board can be contacted at 3218 Pringle Road SE, #250, Salem, OR 97302-6312, at (503) 378-5499, or by email: <u>lpc.lmft@state.or.us</u>.

I have training in Internal Family Systems, <u>https://selfleadership.org/</u>, focused on guiding people towards wholeness, connection with their deep self, and foster a stronger connection in their relationships.

In order to stay current with new understanding in my field and maintain my license, I am required to participate in annual continuing education in classes that I believe will help me develop my practice and be beneficial to my clients. I maintain membership in the following associations: the Oregon Counselors Association, the Amsterdam Psychedelic Research Association, and the Ketamine Psychotherapy Associates.

Signature of KAP	therapist	Date	

#### **Additional Resources:**

Psychedelic Support Ketamine Treatment Guide

Third Wave Ketamine Guide

Youtube talk: Ketamine for Depression and Reconnection // Lowan Stewart MD