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INFORMED CONSENT FOR KETAMINE THERAPY

Welcome to your Ketamine Journey. As you begin your journey with Ketamine Therapy it is important to understand what it is. This form will help explain what ketamine therapy is, why it's done, how it might help you, and the potential risks. Feel free to discuss the information with family and friends and ask your practitioners for clarification or more information at any time. It is important to follow the instructions provided in the days before and on the day of ketamine administration, including fasting for 2-4 hours prior, taking your regular blood pressure medications, and not driving afterwards.

About Ketamine

Ketamine is a dissociative anesthetic approved by the FDA for anesthesia and for sedation during medical procedures. Since its first FDA approval in 1970, it has been widely used for surgical and emergency department procedures. Ketamine's use in mental health is *off-label*, meaning it has not been approved by the FDA for the treatment of depression, anxiety, chronic pain, OCD, PTSD, drug or alcohol abuse, or other mental health or pain disorders or symptoms. Many medications are used off-label safely and effectively and many studies have shown ketamine to be effective in treating mental health disorders and symptoms.

Ketamine works as a dissociative, which means, it can quickly induce a state where people feel detached from their body and from their everyday awareness and perception; everyday awareness and perception is often called "ordinary consciousness". "Non-ordinary consciousness", the dissociated consciousness that can be induced through ketamine, meditation, holo-tropic breath work, and other means, gives us time away from our normal way of thinking, including ruminating, obsessing, or depressing thought patterns and emotions. Getting away may bring about new ways of experiencing the world (or the universe) and how you move through it. Ketamine can be combined with psychotherapy to create a powerful mechanism for healing by letting go of ordinary consciousness. Ketamine is neuroplastic, meaning it helps create new connections and structures in the brain. Ketamine has significant research suggesting that with repeated dosing it can have an antidepressant, anti-suicide, and anti-anxiety effect, though not everyone may experience this.

Ketamine Therapy Process

There are four types of sessions: evaluation, preparation, journey, and integration sessions.

1. Evaluation: The first meeting is an evaluation by a prescriber to get a sense of whether you can safely receive ketamine and whether there would be a potential for benefit. We

can also explain the process and provide informed consent for treatment. Evaluations are typically a one hour session, but sometimes can be done over 2 sessions.

2. Preparation: A preparation session can sometimes be included in a longer evaluation session, where we can get to know you better and:
 - can talk in more detail about what you want from the treatment, the problems you have been experiencing, and salient life experiences that may be important during your ketamine journey
 - set intentions or goals
 - ask questions about what to expect or what typically happens in a session

Sessions are typically one hour and some people prefer to meet for several session before starting ketamine.

3. Journey or Medicine Session: What to expect during the journey. First, make yourself comfortable and relax into the sofa with a blanket and eye mask. If you have important objects you would like close by, you can set these up as well. We'll prepare the music and keep you safe during your journey. We'll be right next to you the entire time.

The journey or medicine session (receiving ketamine) is typically about 2 hours, sometimes longer. During the journey session you will receive ketamine as an injection in the arm (called an intramuscular (IM) injection). We typically start with a standard dose of ketamine (0.5mg/kg) divided in 2 injections 10 minutes apart in order to get a sense of the effect of the medicine on you- in future sessions we can gradually increase, or decrease, the dose as needed. The medicine has a rapid onset and you may feel the effects within about 1-5 minutes, typically about 3 minutes. People are usually in the medicine for about 30-50 minutes, depending on sensitivity to the medicine. We measure your vitals prior to starting and intermittently if we need to. Once the medicine starts to wear off, it is a beautiful time to begin integration, or to talk about your experience in the medicine or about anything else you want to work on through the medicine.

What people experience during the ketamine journey depends greatly on the dose of medicine and session preparation. Because ketamine creates a dissociative experience that is dose dependent, meaning dissociation increases as the dose is increased, you can have very different experiences at different doses and in different session preparations. During the session, some people are talkative, move a lot, dance, or yell even, others are silent or quiet, still, and inward focused. All experiences are fruitful and there is no right way to experience ketamine.

Some people can have a journey where they re-experience past trauma, which can have a variety of effects, such as it could be healing or it could be unnerving, painful, and overwhelming. Having a plan for how to work with a painful or difficult journey is important. Breathing, comforting mantras or statements, or touch can be helpful in getting you through a difficult

experience. Someone will be with you throughout your journey and we are here to support and care for you during your journey, whatever happens.

As you begin and move through the ketamine experience many people like to have an intention for the session. Simple intentions, such as gratitude, healing, calm, or peace seem to work best with ketamine, but you can bring any intention you want to the medicine. Mantras such as ‘let it be, let it happen’ or ‘let it go’, or ‘go towards it’, ‘be open’, or even ‘no’ if you’re not ready to go somewhere yet can be helpful-use any phrase that is supportive of moving through your journey and healing process.

Many psychedelic healers or practitioners believe we have an internal healer. That each of us has our own ability to emotionally heal in the same way that our body heals its physical wounds and that part of experiencing ketamine is trusting yourself to guide your own healing. That whatever comes up, may be what you needed to come up as part of healing in the supportive environment of the ketamine journey. Trust yourself in your journey.

A note about touch: Some people feel comforted by touch during the medicine session. We can offer to hold your hand, or touch your arm, shoulder, or feet to help comfort you. We will ask you if you are comfortable with touch and what touch is okay. If before the session you don’t give consent for touch, we won’t provide it and will default to your pre-medicine preferences and consent, and then afterwards we can talk about whether you would like to change your preferences for future sessions.

Some people may have sexual feelings come up in session, however no sexual touch is allowed by either the patient or practitioners at any time, though it is a safe place to talk about what you are experiencing. Physical violence is exceedingly uncommon, but is also not allowed at any time, either towards people or objects and we will help you work with or redirect feelings in a non-violent way if they come up. Keeping you and everyone in the room safe is most important to us.

4. Integration: Integration sessions are a chance to work with the experience. Sometimes they are at the tail end of the medicine (journey) session or they can be sometime after the medicine session. These sessions are a time when you can talk about the journey experience, what or how you experienced it, emotions that came up, connect to past experiences, connect with your body, create meaning, or process the experience or other life experience that were touched by the ketamine. Some people may have more than one integration session(s) before another journey session. Integration sessions are usually 60 minutes.

Risks, Benefits, and Side Effects

All treatments have potential risks, side effects, and benefits. The benefits are what we want to have happen and why we seek treatments. Side effects or risks are things that may happen that

we typically don't want, or that may cause harm or discomfort. Most side effects with ketamine resolve on their own with no further treatment required. We have medication available to help manage physical side effects, such as clonidine for elevated blood pressure or heart rate and ondansetron to help with nausea or vomiting, though they are rarely needed. You should not drive the day of a ketamine session and can resume driving the following day or after you have slept 7-8 hours because it continues to have an effect on your thinking for many hours afterwards.

Risks with ketamine: Side effects normally depend on the dose and form (eg: injection, IV, or dissolvable lozenge). The dose being used for mental health treatment is lower than anesthetic doses and side effects often go away on their own in a short amount of time as the medication wears off. The incidence of side effects is higher with more prolonged use and higher doses.

Ketamine is not used during pregnancy, but may be used in the post-partum time and during breastfeeding under some circumstances.

Experiences people may have that may feel uncomfortable or scary, but typically dissipate on their own:

- Most people have a feeling of dizziness or movement when the medicine first starts.
- Many people have a feeling of slowed or sped up time, slowed movement, distorted sounds, visuals, unusual physical sensations, memories coming up, increased heart rate, or more rapid or slowed breathing.
- Many people have tingling or numbness, hot or cold in areas of the body or the entire body, more or less intense feelings and sensations in your body, or feeling disconnected from the body, or completely out of the body and no longer aware of themselves or the room/circumstances.
- When coming out of the ketamine dissociation or as the medication is wearing off, you may have some nausea, you may not be able to move or talk immediately, or may feel muscle contractions or twitching (usually with higher doses), this will go away as the medication wears off.
- Some people may not remember any or all of what they experienced during or soon after the ketamine journey, especially with higher doses. It may be helpful to write down, or in some way express your experience soon after the journey.

Common side effects

- hallucinations (visuals)
- vivid dreams and nightmares
- nausea is common and vomiting is less common, though occurs
- increased saliva production
- increased urination immediately after (diuretic effect)
- dizziness
- blurred vision
- increased heart rate and blood pressure, usually during treatment

- out of body experience or dissociation
- change in motor skills, feeling unsteady, not able to sit up, or not able to move immediately

Uncommon side effects

- rash
- double vision
- pain and redness at the injection site
- increased pressure in the eye (eg: glaucoma)
- jerky movements resembling a seizure
- addiction or dependence to ketamine

Rare side effects

- allergic reaction
- irregular heart rate or arrhythmia or slow heart rate
- low blood pressure
- ringing in the ear or tinnitus-can be permanent
- laryngospasm
- cystitis of the bladder: inflammation, ulcers, and fibrosis of the bladder-mostly with frequent ketamine use
- Even more severe side effects up to and including death are possible, but extremely unlikely, such as a fatal allergic reaction to one of the medications, or suicidal thoughts and actions.

Other Risks:

- Ketamine can cause various symptoms including but not limited to the very things we are trying to treat: flashbacks, hallucinations, feelings of depression, restlessness, anxiety, insomnia, disorientation, existential fears, and very rarely, even suicidal thoughts or behaviors.
- The uncommon risk of a dosing error, or an unknown drug interaction that may require medical intervention including intubation (putting in a breathing tube), or hospitalization.
- Getting an injection may cause temporary discomfort from the needle stick; bruising, infection, or fainting can happen.
- Risk of other medications interacting with ketamine. It is very important that you disclose all medications (both prescription and over the counter) and supplements that you are taking as they may interact with ketamine.
- Ketamine may not help your depression, bipolar disorder, PTSD, anxiety, or other mental health condition or symptoms or some people may feel worse after ketamine, including having suicidal thoughts. Please get help immediately if this occurs.

Benefits and Alternative Treatments

Ketamine has been associated with a decrease (sometimes rapid decrease) in depression, PTSD, OCD, suicidal thoughts, and with alleviating the cravings for drugs and alcohol related symptoms in some people; more frequent ketamine sessions may be needed to provide a stronger and longer response and not all people will benefit from ketamine.

Ketamine isn't the only option for patients with treatment-resistant depression or other mental health disorders. There are other alternatives, including electroconvulsive shock therapy (ECT), transcranial magnetic stimulation (TMS) for multiple disorders; specific types of psychotherapy such as ERP or CBT for OCD; EMDR, CBT, DBT, IFS, and somatic therapies for trauma/PTSD or depression, including treatment resistant depression. Ketamine is also not the only option for alcohol and drug abuse, naltrexone or other medications, or psychotherapies or settings such as residential treatment, may be very helpful.

While the goal is improvement of symptoms and quality of life, results cannot be guaranteed, and there is no way to predict how any individual will respond to ketamine therapy. The beneficial effects may or may not be long lasting and will most likely require multiple treatments. Talk to your providers about how you are doing in treatment and how much it is helping to determine if treatment should be continued or if another option could be pursued.

What I agree to do:

- I agree to stay in the treatment room for the duration of treatment and until the medical staff has said it is safe for me to leave and to follow instructions from practitioners regarding my safety.
- I agree to not eat for at least 2-4 hours before each of the ketamine sessions. I may sip clear liquids.
- I agree to tell my providers about all medications, over the counter medication, and herbal or vitamin supplements I am taking.
- I will take all of my usual morning medications EXCEPT for Lamictal, any benzodiazepines, any stimulants, including caffeine, any NSAIDs such as ibuprofen or naproxen, and any sedating drugs including narcotic pain medication.
- **I agree to NOT drive a car, operate hazardous equipment, or engage in hazardous activities until the following day, or longer if impairment persists longer, after each treatment as reflexes may be slow or impaired and decision making may be impaired. Another adult will need to drive me home.**
- I agree to not conduct business or make any important decisions the remainder of the day after a ketamine treatment and will try to have a calm environment afterwards.
- I agree to refrain from alcohol or other substances for 48 hours prior to, and for 24 hours after a ketamine treatment.
- If I experience a troublesome side effect after I leave the clinic, I should contact my providers. If I cannot reach them directly, I should call my primary care provider, call 911 or 988, or go to my local emergency department.
- **For ketamine therapy, unless otherwise stated, I am only under my provider's care for the ketamine treatment sessions and my regular provider(s) will continue to care for my non-ketamine psychiatric or mental health and physical health care needs.**

Ketamine Session Checklist and Instructions **Preparing for Your Journey**

Starting 48 hours before your session:

- Avoid alcohol, cannabis, and extra doses of pain medications or muscle relaxers (regular doses are ok). Avoids other psychedelics or ‘street drugs’ for 7 days prior.
- Arrange for your ride home from the session.

The night before your session:

- Take your medications as prescribed, especially blood pressure medication.
- Pack the medications you might need for the session or in an emergency, such as: an inhaler, blood pressure, or nausea medication.
- Get adequate sleep and rest, try for 8-10 hours sleep the night before the ketamine session.
- Pack your supplies, such as a journal, pen, socks, blanket, eyeshades, music if you want to use your own, and important objects.
- Connect with your intention for tomorrow’s session
- Practice slow, deep breathing for a few breathes-observe your breathe for those few breathes.
- Identify relaxing and calming things you can do in case you feel triggered during or after the session.
- Identify a support person you can contact in case you need to after the session.

The morning of your session:

- Confirm your ride.
- Take your regular blood pressure medications as prescribed
- Take your regular medications, **except** any benzodiazepines (such as Xanax, Ativan, or klonopin), stimulants (such as caffeine, Adderall, or Ritalin), or pain medications (such as NSAIDS or opioid pain pills) as these can reduce the effect of ketamine.
- Don’t take your Lamictal (lamotrigine) dose until after the session. You may take it 3-4 hours after the session.
- Pack a snack for after the session if you would like something to eat afterwards.
- Do some calming and relaxing activities, such as walking, journaling, yoga, movement or light exercise, listen to music, talk with supportive people in your life, and avoid negative media. If you have important activities to attend to (such as work or caring for children or elders), try to do them calmly and with intention.

2-4 hours before your session:

- **Fast for 2-4 hours prior to the ketamine session, you can sip or drink fluids during this time. If you are prone to nausea, please fast for 4 hours, otherwise 2 hours is usually adequate.**
- Wear loose, comfortable clothing and dress in layers as your body temperature may change during the session.
- Avoid stress and rushing on the day of the appointment. Arrive on time, no need to be early.

- Have your session supplies, medications, and snack ready to go.

After session care and Discharge Instructions:

- Many people are hungry after a session and you can eat soon after the session. If you have nausea or vomiting, the medication ondansetron may be used to help reduce these side effects.
- You may take Lamictal (lamotrigine) 3-4 hours after the session, if you didn't take it on the morning of your session.
- You may resume your regular medications, unless your provider has instructed you not to.
- Allow for a calm, relaxing day focused on caring for your physical and emotional needs and feeling safe and comfortable.
- Ketamine can leave you feeling more open and you may feel more sensitive, vulnerable, or permeable to emotional experiences and influence; be mindful of the media you consume after the session and of the experiences you participate in as they may feel more intense or meaningful. For this reason, avoid conflict if possible.
- Don't make any major decisions, drive, or operate machinery for the rest of the day and for 24 hours after the session, or at a minimum until you have slept for 6-7 hours and the medication has had time to wear off and your mind to reset.
- Journal, create art, or share your experiences with people who are supportive of your journey. Journaling or sharing your experiences soon after can help you recall the experience more vividly and be useful during the integration sessions.

Some people may feel worse, or more depressed or anxious, for a few hours to several days after receiving ketamine. This may mean ketamine isn't a good medication for you, or it may take more time for your mind and body to adjust to the ketamine experience. Some people have reported worse symptoms for up to a week, followed by improved symptoms, so even if you don't feel better right away, it may still help. Talk to your providers about worsening symptoms should they happen.

Call your providers at 503-640-3009 (Kerstin) or _____ if you have effects that you are uncertain or concerned about.

Go to the nearest emergency department or call 911 if you are having a medical or mental health emergency.

Welcome to your Ketamine Journey, may you heal along the way.