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INFORMED CONSENT FOR KETAMINE THERAPY

Welcome to your ketamine journey. As you begin your journey with Ketamine Therapy or Ketamine Assisted Psychotherapy it is important to understand the treatment. This form will help explain what the treatment is, why it's being done, how it might help you, and its potential risks. Feel free to discuss the information with supportive family and friends and ask your providers 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 and taking your regular blood pressure medications.

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 in operating rooms and emergency departments. 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 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 may bring about new ways of experiencing the world (or universe), your self and your thought patterns, and your relationships. Ketamine can be combined with psychotherapy to create a powerful mechanism for healing when letting go of ordinary consciousness and when letting down the guard of the mind, also known as the Default Mode Network (DMN), which can be the origin of critical or anxious thoughts and defenses. Ketamine is neuroplastic, meaning it helps create new connections and structures in the brain. Ketamine has significant data suggesting that with repeated dosing it can have an antidepressant, anti-suicide, and anti-anxiety effect, though not everyone may experience this.

Ketamine Treatment

In Ketamine Assisted Psychotherapy, or KAP, you will meet with a prescriber (and possibly a therapist) to evaluate to see if this type of treatment would be safe and potentially effective (they

may be the same person). You can meet for four types of sessions: evaluation, preparation, journey, and integration sessions.

1. Evaluation: An evaluation by the therapist and an evaluation by the prescriber, (sometimes they are the same person and same session) to get a sense of whether you can safely receive ketamine, whether there would be a potential for benefit, and to explain the process and provide informed consent for treatment. This can be from 1-2 hours for each evaluation.
2. Preparation: A preparation session can sometimes be included in a longer evaluation session, where we can get to know you better and:
 - you can talk more about what you want from the treatment, the problems you have been experiencing, salient life experiences that may help make meaning of your ketamine journey,
 - set intentions or goals,
 - ask questions about what to expect

Preparation is often 1 hour and some people have several preparation sessions before receiving ketamine. You will receive additional information about how to prepare for your journey, in the “KAP Preparation Checklist”.

3. Journey: The journey session (receiving ketamine) is typically about 2 hours, sometimes 3. During the journey session you will receive ketamine either as an injection in a muscle, usually in the arm, (called an intramuscular (IM) injection). You will be given a standard dose of ketamine for your first dose to get a sense of the effect of the dose. The injection form has a rapid onset and you may feel its effects almost immediately, or within about 5 minutes. Sometimes people will receive a second dose about 10-20 minutes later. Your blood pressure, heart rate, and oxygen saturation will be monitored at various times and staff will be here to keep you safe and take care of you during your journey.

What to expect during the journey. Welcome to your first journey. Make yourself comfortable, relax into the sofa, with a blanket, and have your eye cover ready. If you have 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.

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 with the increased doses of ketamine, 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, while others are silent or quiet, still, and inward focused during the journey. All experiences can be fruitful and there is no right way to experience ketamine.

Some people can have a journey where they re-experience past trauma, which can be healing, as it can reframe the experience or connection with a person, or it could be unnerving, painful, and overwhelming, or both. Having a plan for how to cope with a painful or difficult journey is important. Breathing exercises or comforting mantras or statements can be helpful.

As you move through the experience some people like to have an intention around the experiences, such as ‘let it be, let it happen, or let it go’. Maybe think, “go towards it”, “be open”, or even “no” if you’re not ready to go somewhere yet-use any phrase that is supportive of your journey and inner healer.

Many ketamine practitioners believe we have an internal healer. That each of us has our own ability to emotionally heal in the same way that the 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.

A note about touch: Some people feel comforted by touch during the ketamine session. In your preparation session we will discuss what type of touch, if any, you are comfortable with. The most common types of touch are holding your hand, or touching your shoulder or feet. Some people may have sexual feelings come up in session, however no sexual touch is allowed by either the patient or providers at any time. Keeping you and the providers safe is our utmost priority. If before the session you don’t give consent for touch, we won’t provide touch and will default to your pre-ketamine preferences and consent, and then afterwards we can talk about whether you would like to change your preferences for future sessions. Physical violence is very 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.

4. Integration: Integration session(s) occur after the journey and they are a chance to work with the experience to create long lasting healing and change in your life. Sometimes they are immediately after the ketamine session on the same day, but more commonly they are the next or the following day. They 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, creating meaning, or processing the experience. Some people may have more than one, or even many, integration session(s) before another journey session. Integration sessions are usually 60 minutes.

Risks 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 effect 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.

Side effects normally depend on the dose and form (eg: injection or SL troche). The dose being used for this purpose 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.

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

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

- Feeling of dizziness, movement, slowed movement, distorted sounds, visuals, physical sensations, or slowed sense of time.
- Tingling or numbness or feeling hot or cold in areas of the body or the entire body.
- Feeling disconnected from your body
- Increased heart rate or pounding heart or more rapid or slower breathing
- 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, 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.

These symptoms dissipate when the medication wears off. If they are more severe, another medication can be used to treat the symptoms:

1. Common side effects
 - hallucinations/visuals
 - vivid dreams and nightmares
 - nausea or vomiting
 - increased saliva production
 - dizziness
 - blurred vision
 - increased or decreased heart rate or blood pressure
 - out of body experience or dissociation
 - change in motor skills, feeling unsteady, or unable to move.
2. Uncommon side effects
 - rash
 - double vision
 - pain and redness in the injection site

- increased pressure in the eye
- jerky arm or other movements resembling a seizure
- headaches

3. Rare side effects

- allergic reaction
- irregular or significantly slow heart rate
- arrhythmia
- low blood pressure
- Ringing in the ear or tinnitus
- laryngospasm
- cystitis of the bladder: inflammation, ulcers, and fibrosis-can be permanent with prolonged exposure to ketamine
- Severe side effects up to and including death are possible, but extremely unlikely, such as a fatal allergic reaction to one of the medications.

Other Risks:

- Ketamine can cause various symptoms including, but not limited to, flashbacks, hallucinations, feelings of unhappiness/depression, restlessness, anxiety, insomnia, disorientation, existential fears, and very rarely, even suicidal thoughts or reactions.
- 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.
- 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 depression, bipolar disorder, PTSD, anxiety, or other mental health condition or symptoms or some people may feel worse after ketamine.

Benefits and Alternatives

Ketamine has been associated with a decrease (sometimes rapid) in depression, PTSD, OCD, suicide, 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. Ketamine is not a panacea

Ketamine isn't the only option for patients with treatment-resistant depression or other mental health disorders. There are other options, including electroconvulsive shock therapy (ECT), transcranial magnetic stimulation (TMS) for multiple disorders, psychiatric medication; 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 person will respond to ketamine therapy. The beneficial effects may or may not be long lasting and most people require multiple treatments and even ongoing treatment longterm. Talk with 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 should be pursued.

Safety:

- Patients will need to stay in the treatment room for the duration of treatment and until the medical staff has said it is safe to leave and follow instructions from staff regarding safety.
- Patients will need to fast, not eat or drink for at least 2-4 hours before each of the ketamine sessions, though may sip liquids for before ketamine therapy.
- Patients **will 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 impaired. **Another adult will need to drive me home.**
- Patients agree to not conduct business or make any important decisions for the remainder of the day after a ketamine treatment as decision making may be impaired (or longer if impairment persists).
- Patients agree to refrain from alcohol or other substances for 24 hours before and after a ketamine treatment.
- If you experience a troublesome side effect after leaving the clinic, you should contact your providers. If you cannot reach them directly, you should call your primary care provider, call 911 or 988, or go to the local emergency department.

Ketamine Treatment is not a Comprehensive Treatment Plan

Ketamine therapy is meant to be part of a comprehensive mental health treatment plan. We recommend you to be under the care of a qualified mental health professional (or an internal medicine or family physician with experience and skill in treating psychiatric illnesses) while receiving ketamine, and for the duration of your psychiatric symptoms. Follow up medications may be suggested but these will be the responsibility of your treating provider.

Suicidal Thoughts

Psychiatric illnesses (especially, depression), chronic pain, and addictions carry the risk of suicidal thoughts (thoughts of ending one's life). If you have such thoughts at any time during the weeks of your ketamine sessions, or at any point in the future, which cannot be addressed by contacting a mental health professional, then you should seek emergency care at an Emergency Department or call 911 or 988.

Voluntary Nature of Treatment

You can decide whether or not you want ketamine treatment at any time prior to the administration of the medicine. Please tell your providers if you do not wish to receive ketamine, prior to its administration.

Termination of Treatment

Your providers have the right to stop treatment at any time. They can stop treatment with or without your consent for any reason.

IN ADDITION:

- **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.**
- I agree to be under the care of a qualified mental health or primary care provider with mental health experience while receiving ketamine therapy.
- I agree to allow my ketamine treating providers access to all information pertaining to my mental and physical healthcare and allow permission to speak to all provider, including mental health providers, to discuss my condition and the administration of ketamine therapy.
- I understand that ketamine therapy may **not** help my mental health symptoms, including depression, PTSD, OCD, substance use or other mental health disorder or other symptoms symptoms.
- I affirm no guarantees or assurances have been made or given to me about the possible results of treatment with ketamine and understand some people may feel worse, feel worse before they feel better, or not get better with treatment.
- I understand ketamine is an off label treatment and is not FDA approved for mental health disorders or treatment (except for Spravato, an intranasal form of ketamine).
- I affirm the alternative treatments, the risks involved, and the possibility of complications or side effects have been explained to me.

By signing below, I attest I have read, understand fully, agree to the contents, have had all my questions answered, have provided information accurately, and provide consent for treatment with ketamine. A copy of this form shall have the same force and effect as the original.

X _____
Patient or Guardian Signature Printed Name Date

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:

- No alcohol or other substances.
- 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.
- Pack anything you'd like to bring.
- Connect with your intention for tomorrow's session
- Practice slow, deep breathing for a few breathes and observe you breathe for a 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.
- Get adequate sleep and rest, try for 8-10 hours sleep the night before the ketamine session.

The morning of your session:

- Take your regular blood pressure medications as prescribed, if you usually take them in the morning.
- Take your regular medications, **except extra or as needed doses** of 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.
- Pack a snack for after the session if you would like something to eat afterwards.
- Confirm your ride home.
- 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 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 a few minutes early.

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.
- 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.