ALMADELIC
Journey of the Soul Healing of the Mind

Informed Medical Consent and Agreement for At-Home Ketamine Treatment

About Ketamine: Ketamine is a new psychiatric treatment that has shown potential in treating mood disorders such as major depressive disorder, bipolar depression, and substance use disorders. It is also being studied for its efficacy in treating pain. Before deciding to undertake this therapy, it is important that you understand the risks and benefits to make an informed decision. This process is known as informed consent.

FDA Status of Ketamine: Ketamine has been approved by the Food and Drug Administration (FDA) for use as an anesthetic agent for many years. The use of ketamine in lower, subanesthetic and "micro" doses to treat pain and/or depression is a newer, off-label use. This means the FDA does not endorse these uses of ketamine and classifies them as investigational. Ketamine is not a first-line treatment for pain or depression and is usually used after other treatments have been unsuccessful.

The FDA has approved one form of ketamine – esketamine, or S-ketamine – for the treatment of treatment-resistant depression (TRD) and depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior. Sold under the brand name SPRAVATO®, esketamine must be administered via nasal spray in a doctor's office and used in conjunction with an oral antidepressant medication. **Esketamine is not offered at Almadelic Medical Groups and affiliated medical groups, but may be available at another doctor's office and potentially covered by your health insurance.**

The form of ketamine available by prescription through Almadelic Medical Groups is generic ketamine, also known as racemic ketamine or ketamine racemate. This type of ketamine is available worldwide and can be formulated by a compounding pharmacy into syrup, lozenge, nasal spray, or another format.

Health insurance plans typically do not cover at-home ketamine. You may be able to bill your HSA or FSA account, though coverage is not guaranteed. Be prepared to pay out-of-pocket for your prescription and services.

While not formally approved by the FDA, some studies demonstrate that ketamine may be an effective and rapid treatment option for mood disorders and pain.

At-Home Ketamine Dose Ranges: At-home ketamine can be administered in one of the following ranges:
• Sub-anesthesia dose: This dose is high enough to cause a change in motor coordination and requires that you lay down after taking the medication. You may experience visual imagery or "trip" at this dose.
• Microdose: This is a very low dose taken daily, sometimes a few times per day, and is not psychoactive.
• Low dose ketamine: These doses are between a sub-anesthesia dose and a microdose, and are typically only done during therapy sessions.
• Topical ketamine: This entails using creams or gels prepared with ketamine and applying them topically to the skin over an area of pain.

Benefits may occur after only one sub-anesthesia dose treatment or after a few days of microdosing. Typically, an initial course of several treatments spaced out or several weeks of daily microdosing are required for a more robust response. If your symptoms respond to this initial course, you may receive further prescriptions for at-home ketamine. You may still elect to be treated with other medications and ongoing psychotherapy to reduce the possibility of relapse. Over time, you may need additional periodic ketamine treatments or other therapies to maintain remission. **Ketamine works best as part of an integrated treatment program including**

psychotherapy, lifestyle changes and other medication prescribed by your treating prescriber. It may not permanently relieve depression or pain.

Preparation & Forms of Medicine: At-home ketamine may be prescribed in various formats, including troche (lozenge), sublingual (under-the-tongue) syrup, nasal spray, oral capsule, topical cream or gel, or rectal suppository.

Using the troche involves holding the lozenge in your mouth for approximately 5-7 minutes to allow it to fully dissolve and become absorbed and then all saliva is spit out. **Try not to swallow the ketamine, as it is not very active orally and swallowing may increase and prolong side effects such as nausea, dizziness and loss of coordination.**

Do not drive, operate heavy machinery, or sign legal documents while sedated or under the influence of ketamine.

You may ask your Almadelic Medical Prescriber any questions concerning the procedure or effects of ketamine at any time. **Your consent to receive ketamine may be withdrawn, and you may discontinue your participation at any time up until the actual dose has been administered.**

Eligibility for Ketamine At-Home Therapy

Before participating in ketamine therapy, you will be carefully screened to determine eligibility, including a medical history, psychiatric history, and possibly psychological testing.

You may not qualify for ketamine therapy for at-home use if you have any of the following conditions:

- Untreated or Uncontrolled Hypertension
- Hear, Liver or Bladder Disease
- Ongoing Alcoholism or Substance Use Disorder*
- Congestive heart failure or other cardiac problems
- Severe breathing problems or COPD
- Active psychotic, manic or mixed symptoms*
- History of psychotic or manic symptoms *
- Active suicidal ideation with method, intent or plan within the past month or suicide attempt within the last year*
- Pregnancy, nursing, or currently trying to become pregnant
- Any other serious medical condition or illness*

Pregnant women, nursing mothers, and women of child-bearing age who are not using an effective method of birth control should not receive ketamine. If you become pregnant while participating in this program, notify your medical providers immediately as the effects of ketamine on the unborn child are undetermined.

Suicidal Ideation: Patients experiencing active suicidal ideation with method, intent or plan within the past month or suicide attempt within the last year are not candidates for at-home ketamine treatment and should seek immediate help through in-person treatment options, report immediately to a hopsital or call 988 for assistance.

Estimate of Expected Recovery Time: Sub-anesthesia dose ("trip" dose): The non-ordinary state of consciousness produced by ketamine usually lasts under two hours. The reduced sense of balance, dizziness,

and possible nausea when moving your head gradually subside over three to six hours. Sometimes people feel generally "out of it" for a few hours after a treatment. Plan not to drive or work the rest of the day.

• Microdose: By definition, a microdose of ketamine should not noticeably affect your motor skills or cognition. Nevertheless, avoid driving, operating heavy machinery, or signing legal documents when you begin ketamine microdosing until you have found the right dose that allows you to feel relief without affecting your physical or mental functioning. Most people find that once they find the dose that gets them benefits without side effects, they can go about their daily routines without interruption.

Potential Risks & Side Effects of Ketamine Therapy: Sub-anesthesia doses: You will be asked to lie still during and after ketamine administration because your sense of balance and coordination will be impaired until the effect has worn off. It is possible you may fall asleep. Other potential adverse effects include:
• Blurred and uncomfortable vision
• Slurred speech
• Mental confusion
• Excitability
• Diminished ability to see things that are actually present
• Diminished ability to hear or 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 seem out of the ordinary. Synesthesia, a mingling of the senses, may occur, and your sense of time may be altered. Ketamine may also cause tachycardia (elevated pulse), diplopia (double vision), nystagmus (rapid eye movements), elevation of intraocular pressure (feeling of pressure in the eyes), and anorexia (loss of appetite). These reactions are more likely to occur with the high doses of ketamine used for anesthesia – much higher than the doses prescribed for at-home use. Because of the risk of nausea and vomiting, please refrain from eating and drinking for at least 6 hours before the session. If you are unduly nauseated, you might require a prescription for anti-nausea medication. During the experience itself, some people have reported frightening and unusual experiences. These frightening experiences, however, may be of paramount value in your transition to recovery with the help and ongoing guidance from your provider and/or psychotherapist.

Microdoses of ketamine: When taken inappropriately or over time, ketamine may cause:
• Sleepiness or drowsiness
• Nausea
• Lightheadedness
• Dizziness
• Confusion
• Allergic reaction
• Slowing of reaction time
• Kidney or liver disease
• Interstitial cystitis (bladder irritability)
• Cognitive decline
• Addiction
• Dependence
• Possibility that the medicine will not provide complete relief

The overuse of ketamine can result in serious health risks, including tachycardia, hypertension, hallucinations, liver failure, and the aforementioned conditions.

Physical risks of ketamine and contraindications: Ketamine should not be taken if you have untreated hyperthyroidism. There have been reports of some decrease in immune function in patients receiving surgical doses of ketamine, but this has not been seen in subanesthetic doses. Ketamine has an extensive record of safety and has been used at much higher doses for surgical anesthesia without respiratory depression. Untreated hypertension (high blood pressure) is a contraindication to ketamine use, as the substance may cause a rise in blood pressure. Similarly, a history of heart disease may make you ineligible to participate. Repeated, high dose, chronic abuse of ketamine has been shown to cause urinary tract symptoms and even permanent bladder dysfunction, though this is rare in medical use. In terms of psychological risk, ketamine has been shown to worsen certain psychotic symptoms in people who suffer from schizophrenia or other serious mental disorders. It may also worsen underlying psychological problems in people with severe personality disorders.

Potential for Ketamine Abuse & Physical Dependence: Ketamine belongs to the same group of chemicals as phencyclidine (Sernyl, PCP, "Angel dust"). Collectively, this group is classified as arylcyclohexylamines and hallucinogens ("psychedelics"). Ketamine is a controlled substance and is subject to Schedule III rules under the Controlled Substance Act of 1970. Medical evidence regarding drug abuse and dependence suggests that ketamine's abuse potential is low and equivalent to that of phencyclidine and other hallucinogenic substances. However, cravings have been reported by some individuals, and there are documented cases of overuse of illicitly obtained and diverted ketamine. In addition, ketamine can have effects on mood (feelings), cognition (thinking), and perception (imagery) that may make some people want to use it repeatedly. Therefore, ketamine should never be used except under the direct supervision of a licensed physician.

Consent for Remote Monitoring or Telemedicine: As part of your ketamine therapy, you may participate in remote monitoring or telemedicine consultations. By agreeing to this treatment plan, you consent to the use of telemedicine technologies, which may include:

- Video Consultations: Virtual appointments with your Almadelic Medical Prescriber to discuss your progress and any concerns.
- Remote Monitoring: In some cases, you may be asked to use devices or apps to monitor your vital signs or symptoms at home. This data may be shared with your healthcare provider for ongoing assessment.

Please note that while telemedicine offers convenience, it may have limitations compared to in-person consultations. Discuss any concerns with your Almadelic Medical Prescriber.

Confidentiality: Your privacy and all therapy records will be kept confidential. They will be maintained with the same precautions as ordinary medical records. The results of this ketamine therapy may be published in clinical literature. Published reports will not include your name or any other information that would identify you.

As with any medication prescription, the prescribing physician has permission to discuss all diagnostic and treatment details with dispensing pharmacists or other professionals who provide your health care for the purpose of care coordination.

If the responsible legal authorities have questions concerning your treatment, all confidentiality is waived and these authorities may be given full access to your records as required by law.

Voluntary Nature of Participation: Your decision to undergo ketamine treatment is completely voluntary. Before you make your decision about participation, you may ask and will be encouraged to ask any questions you may have about the process.

Withdrawal from ketamine treatment is always an option available to you, even after agreeing to undergo treatment. You may decide to withdraw at any time.

Patient Responsibilities: For your own safety – and because ketamine is a controlled substance – all patients are required to adhere to the following requirements:

- Take ketamine only as prescribed. Do not increase, decrease, or change your dose or frequency of dosing without first discussing it with your Almadelic Medical Prescriber.
- Have an adult support person with them at all times during an active session of ketamine and will provide Almadelic with the person's name and contact information.
- Follow all preparation guidance for the self-administration of ketamine
- Do not get ketamine from another doctor's office, clinic, or pharmacy without informing your Almadelic Medical Prescriber beforehand and getting approval.
- Inform the clinic of any changes to medical history, allergies, drug reactions, medications, or pregnancy status.
- Do not use illicit "street drugs" while taking ketamine. Submit to random drug screens upon the Almadelic Medical Prescriber's request.
- Treat the Almadelic Medical Prescriber and all clinic staff with respect.
- Tell the Almadelic Medical Prescriber your complete and honest personal drug/medication usage and history. Even common medications like pain relievers or cold medicines can interact with ketamine, and even natural supplements and herbal remedies may also affect how ketamine works in your body. **Failure to disclose all medications could result in serious side effects or diminished effectiveness of ketamine therapy. Note that it is a felony to obtain controlled substances under false pretenses, including getting medication from more than one doctor, misrepresenting yourself to obtain medications, using medications in a manner other than as prescribed, or diverting them (e.g., sharing with friends, selling, etc.).**
- Keep your medication safe and secure, away from the reach of children, pets, and others.

Explanation of Alternatives: Before proceeding with at-home ketamine therapy, it is important to understand that there are alternative treatments available for conditions such as depression, bipolar disorder, and pain management. These alternatives include but are not limited to:
Traditional antidepressants (e.g., SSRIs, SNRIs)
Psychotherapy (e.g., cognitive behavioral therapy, dialectical behavior therapy)
Other psychiatric medications (e.g., mood stabilizers, antipsychotics)
Non-pharmacological treatments (e.g., transcranial magnetic stimulation, electroconvulsive therapy)
Pain management strategies (e.g., physical therapy, other medications)
Each alternative treatment carries its own set of risks and benefits, which should be discussed with your healthcare provider. By understanding these options, you can make an informed decision about whether ketamine therapy is the right choice for you.

Emergency Contact Information: In case of an emergency during at-home ketamine treatment, please follow these guidelines:

- Immediate Danger: If you or someone else is in immediate danger, call 911.

- Non-Emergency Concerns: Contact your Almadelic Medical Prescriber directly if you experience unexpected side effects or complications. Ensure you have the contact information readily available during your ketamine sessions.
- Support Person: Your designated support person should also have all emergency contact information and instructions on when to call for help. They should not hesitate to seek medical assistance if they believe you are in distress.

Specific Instructions for Aftercare: After a ketamine session, please follow these aftercare instructions:

- Rest and Recovery: Plan to rest for several hours after a session, especially after a sub-anesthetic dose. Avoid driving, operating heavy machinery, or engaging in complex tasks until you feel fully recovered.
- Managing Side Effects: Common side effects such as nausea, dizziness, and lightheadedness can often be managed at home. Drink plenty of water, eat light meals, and avoid sudden movements. If side effects persist or worsen, contact your Almadelic Medical Prescriber.
- When to Seek Help: If you experience severe or prolonged side effects, such as intense confusion, hallucinations, or unmanageable nausea, contact your Almadelic Medical Prescriber immediately. In the case of an emergency, call **911.**

Clarification on Support Person's Role: Your designated support person plays a critical role in your ketamine therapy. Their responsibilities include:

- Observation: The support person should closely monitor you during and after the ketamine session, watching for any signs of distress or unusual behavior.
- Assistance: They should be ready to help you with basic needs, such as getting water, helping you move safely, and ensuring you do not attempt any activities that could be dangerous.
- Emergency Response: The support person should know when and how to seek medical help if necessary. They should have access to emergency contact information and be prepared to call 911 if required.

Duration of Treatment and Follow-Up: The duration of your ketamine treatment will depend on your response to therapy. Typically, an initial course may involve several treatments over a period of weeks, followed by maintenance doses as needed.

- Follow-Up: Regular follow-up appointments with your Almadelic Medical Prescriber are required to monitor your progress, adjust dosages, and assess the ongoing need for ketamine therapy.
- Evaluation of Success: The success of your treatment will be evaluated based on symptom relief and improvement in your overall functioning. If ketamine therapy is not providing the desired benefits, alternative treatments may be considered.

Explicit Patient Consent for Risks: I acknowledge that I have been informed of the potential risks and side effects of ketamine therapy, including but not limited to:

- Physical risks (e.g., dizziness, nausea, tachycardia)
- Psychological risks (e.g., confusion, hallucinations)
- Risk of addiction or dependence

I understand these risks and agree to proceed with treatment with full knowledge of the potential consequences.

To ensure the safety of your ketamine medication:

- Secure Storage: Store ketamine in a secure location, out of reach of children, pets, and unauthorized individuals.

- Proper Handling: Follow all instructions for storing and handling the medication, including keeping it at the correct temperature and away from light or moisture.
- Disposal: If you no longer need your ketamine prescription or it has expired, dispose of it properly according to local regulations. Do not share or sell your medication.

Withdrawing Consent: You have the right to withdraw your consent at any time. This section explains the process for discontinuing treatment safely, including tapering schedules if applicable and follow-up care.

Communication: Keep open lines of communication with your healthcare team throughout the process of tapering and after cessation of ketamine treatments. It is vital to report any adverse effects, concerns, or changes in your condition promptly.

Tapering Schedules: For patients receiving regular ketamine treatments, especially those on a more frequent dosing schedule, a gradual tapering of the dose may be necessary to minimize the risk of withdrawal symptoms or the sudden return of depressive or anxiety symptoms. The specific tapering schedule will be tailored to your individual treatment regimen and response, as follows:

- Reducing Dosage: Gradually reduce the dose of ketamine over a period determined by your clinician, typically over several weeks.
- Extending Intervals: Increase the interval between treatments gradually while monitoring symptom control and overall mental health.

Patient Agreement for At-Home Ketamine: I understand that any medical treatment is initially a trial and that continued prescription is based on evidence of benefit. I understand that the goal of using ketamine at home is to decrease my ailments and increase my functional level. If my ailments do not significantly decrease and/or my function does not increase, the medication will be stopped.

I am aware that the use of such medicine has certain risks associated with it, including but not limited to sleepiness or drowsiness, nausea, lightheadedness, dizziness, confusion, allergic reaction, slowing of reaction time, kidney or liver disease, interstitial cystitis (bladder irritability), cognitive decline, addiction, dependence, and the possibility that the medicine will not provide complete relief. The overuse of ketamine can result in serious health risks, including tachycardia, hypertension, hallucinations, liver failure, and the aforementioned conditions.

This medication will be strictly monitored and should be filled at the same pharmacy every month. I understand that health insurance typically does not cover compound medications and that I will be paying for my ketamine prescriptions out of pocket. (I may be able to use a health savings account or flexible spending account; my Almadelic Medical Prescriber does not guarantee this, however.)

I am responsible for making and keeping scheduled appointments. Early refill requests will not be honored. I understand that I must have a clinical follow-up and medical evaluation with an Almadelic medical provider to continue receiving refills of this prescription.

I will take ketamine only as prescribed. Any changes must first be discussed and agreed upon with my Almadelic Medical Prescriber.
Medications will not be replaced if they are lost, destroyed, left on an airplane, etc. If my medication has been stolen and I complete a police report regarding the theft, an exception might be made. I will take the highest

possible degree of care with my medication and prescription. I will not leave my medication where others might see or otherwise have access to them, or where children or pets may reach them.

I agree that only my Almadelic Medical Prescriber will prescribe my ketamine unless we discuss otherwise. I will instruct my other physicians to confer with my Almadelic Medical Prescriber for any changes to the ketamine prescription. If it is brought to the attention of the clinic that other providers are prescribing medications for me, my Almadelic Medical Prescriber and staff reserve the right to discontinue prescribing medications and/or discharge me from the clinic.

I will inform my Almadelic Medical Prescriber of any changes in my medical condition, any changes in any prescription and/or over-the-counter medication that I take, and any adverse effects that I may experience from any of the medications that I take.

I agree to tell my Almadelic Medical Prescriber my complete and honest personal drug/medication usage and history.

I will not use any illegal "street drugs" while receiving ketamine prescriptions. Routine blood work and random drug screens may be a part of my treatment plan. I agree to have them done on the day the Almadelic Medical Prescriber requests it.

The prescribing Almadelic Medical Prescriber has permission to discuss all diagnostic and treatment details with dispensing pharmacists or other professionals who provide my health care for purposes of maintaining accountability.

If the responsible legal authorities have questions concerning my treatment, all confidentiality is waived and these authorities may be given full access to my records.

It is a felony to obtain controlled substances under false pretenses. This could include getting medication from more than one doctor, misrepresenting myself to obtain medications, using them in a manner other than prescribed, or diverting the medications in any other way (selling).

I know that controlled substances will be stopped if any of the following occur:

- I trade, sell, or misuse the medication
- The clinic finds that I have broken any part of this agreement
- I do not go for a blood or urine test when asked
- My blood or urine test shows the presence of medications that the staff is not aware of, the presence of illegal drugs, or does not show medications that I am receiving a prescription for
- I get ketamine from sources other than from this clinic
- Any member of the professional staff of this clinic feels that it is in my best interest that the controlled substance is stopped
- Any aggressive behavior toward the Almadelic Medical Prescriber or staff
- I consistently miss scheduled appointments

It is understood that failure to adhere to this agreement may result in cessation of therapy with controlled substance prescription by the Almadelic Medical Prescriber.

Please inform your Almadelic Medical Prescriber of any pre-existing conditions, and discuss how ketamine may impact your health.

Patient Signature: _____

Printed Name:_____

Date: _____

My signature acknowledges that I have read this document in full and without question understand all of this agreement.