

Informed Consent

When creating an informed consent form for ketamine treatment for depression, it is essential to cover both medical, ethical, and legal aspects of treatment. Below are the key elements that should be included:

- 1. Off label nature of treatment.
- 2. There is a lack of long-term safety data, however, there is the potential for interstitial cystitis/ hemorrhagic cystitis.
- 3. Ketamine is a treatment, not a cure, and maintenance is often required. Ongoing treatment may be costly due to the lack of insurance coverage.
- 4. Short term side effects (nausea/ dizziness, altered levels of consciousness, etc.).
- 5. Potential for abuse or misuse.
- 6. Treatment alternatives (TMS, medications, psychotherapy, ECT).
- 7. Potential Benefits (improvements in pain and mental health).
- 8. Indications (e.g. MDD, bipolar depression, GAD, PTSD, OCD, pain, substance use disorders, suicidal ideation, eating disorders).
- 9. Contraindications (examples include uncontrolled HTN, unstable coronary disease, active psychosis, hx of intracerebral aneurysm, active mania).
- 10. A link to the following statement from the FDA should be included: https://www.fda.gov/drugs/human-drug-compounding/fda-warns-patients-and-health-care-providers-about-potential-risks-associated-compounded-ketamine.

This informed consent guidance is for **informational purposes only and does not constitute legal or medical advice**. Laws and regulations regarding the administration of ketamine for depression and pain vary by state. Practitioners are strongly advised to consult with legal counsel and review the specific regulations and guidelines in their state or region. Additionally, practitioners should ensure compliance with local boards and licensing requirements, as well as any federal regulations governing the use of ketamine in clinical practice.