

Ketamine/Esketamine Consent Grading Form

0/1/2 = missing/incomplete/complete

0/1 = missing/complete

*non-graded items of interest

1. Clinical Content

Risks

- *Short-term adverse reactions*
 - 0 = missing
 - 1 = incomplete
 - 2 = includes one sign/symptom from 3 of the 5 following systems:
 - cardiovascular (changes in blood pressure, heart rate, cardiac index)
 - respiratory (respiratory depression, apnea, laryngospasm)
 - *please note if risk of death is mentioned (typically listed in the context of concomitant use of benzodiazepines, opioid analgesics, or other CNS depressants)
 - gastrointestinal (nausea, vomiting, anorexia, liver injury)
 - neuro/psychiatric (“emergence phenomenon”/delirium, confusion, impaired cognition, anxiety, dissociation, lethargy, dizziness, vertigo, hypoesthesia)
 - *please note if worsening suicidality is mentioned anywhere in document
 - *please note if discusses psychedelic/mind-altering properties of ketamine/esketamine in some context other than as an adverse effect- eg. “you may experience changes in cognition that may be pleasant or will pass”
 - immune (hypersensitivity, anaphylaxis)
- *Long-term adverse reactions*
 - 0 = missing
 - 1 = incomplete
 - 2 = includes 2 of the following 3:
 - addiction/abuse potential
 - *please note specifically if mentioned
 - renal/urinary: dysuria, frequency, urgency, incontinence, hematuria, or cystitis
 - neurotoxicity: concern for long-term cognitive impairment, particularly in pediatric population
- *Safety/contingency protocols*
 - 0 = missing

- 1 = incomplete
- 2 = includes 2 of the following 3:
 - no driving or operating machinery following drug administration
 - anticipation and management of any of short-term adverse reactions above (eg. “We may give ____ medication if _____”)
 - management of worsening mood or suicidal thoughts after treatment (eg. call your physician, 911, ER, etc.)

Benefits

- *Noted*
 - 0 = missing
 - 1 = complete (proposes effect/goal of treatment)
- *Success factors*
 - 0 = missing
 - 1 = incomplete
 - 2 = includes both of the following:
 - contextualizes reasonable expectations of benefit +/- clinical data (e.g. “condition may be temporarily, permanently or not improved,” “results not guaranteed,” etc.)
 - discusses factors involved in maintenance or optimization of outcome
 - *please note if there is comment that benefits may be transient, curative, etc.

Alternatives

- *Noted*
 - 0 = missing
 - 1 = complete (proposes at least one alternative treatment)
- *Associated risks and benefits*
 - 0 = missing
 - 1 = incomplete
 - 2 = complete (discusses risks AND benefits of alternative/s)

Voluntary nature of treatment

- *Noted*
 - 0 = missing
 - 1 = complete (proposes voluntary nature of treatment or that patient may decline/withdraw from treatment- note, this is sometimes found at the end of the consent, where the patient signs)
- *Associated risks and benefits*

- 0 = missing
- 1 = incomplete
- 2 = complete (discusses risks AND benefits of no treatment)

2. Procedures

- *Discusses the role of medical evaluation prior to ketamine treatment*
 - 0 = missing
 - 1 = incomplete
 - 2 = emphasizes importance of both:
 - historical data: comprehensive medical history
 - objective data: vital signs, physical exam, laboratory studies
 - *please note if there is language about specialty consultation for complex medical decision-making, or discussion of special populations (pregnant, geriatric, etc.)
- *Discusses the requirement for on-site medical support during treatment*
 - 0 = missing
 - 1 = incomplete
 - 2 = complete (discusses vitals monitoring capacity AND on-site medical professional)
- *Discusses the role of psychiatric evaluation prior to ketamine treatment*
 - 0 = missing
 - 1 = incomplete
 - 2 = complete (discusses need for comprehensive psychiatric evaluation by treatment team prior to initiating treatment)
 - *please note if there is language about specialty consultation for complex psychiatric decision-making, or discussion of special populations (psychosis, substance use, dissociative disorders, etc.)
- *Discusses the requirement for on-site psychological support during treatment*
 - 0 = missing
 - 1 = complete (discusses on-site availability of mental health professional)
- *Administration protocols*
 - 0 = missing
 - 1 = incomplete
 - 2 = includes 2 of the following 3:
 - approximate number of doses
 - dosage
 - rationale for adjustments in dosing
- Psychotherapy as possible adjunct to treatment
 - 0 = missing
 - 1 = complete (discusses value of psychotherapy as adjunct- before, during, or after treatment)
 - *please note specifically how this is engaged

3. Syntax

- *Name of clinic*
 - 0 = missing
 - 1 = complete
- *Indication for ketamine*
 - 0 = missing
 - 1 = complete
- *Acknowledges difference between ketamine and esketamine*
 - 0 = missing
 - 1 = complete
- *Mentions that use of drug +/- route may be off-label*
 - 0 = missing
 - 1 = complete
- *Date of consent*
 - 0 = missing
 - 1 = complete
- *Patient name/signature*
 - 0 = missing
 - 1 = complete
- *Witness signature*
 - 0 = missing
 - 1 = complete
- *Person explaining IC-Doc signature*
 - 0 = missing
 - 1 = complete
- *Readability scores at or below 8th grade reading level*
 - 0 = missing
 - 1 = complete

*as measured by Flesch-Kincaid, Gunning Fog, and Simple Measures of Gobbledygook (SMOG) readability