



KRI **KETAMINE
RESEARCH
INSTITUTE**
Clinical Professional Education
and Development Programs

KRI Mini-Fellowship Intensive Ketamine Training Program

*A Comprehensive Curriculum Overview
for Clinicians & Medical Staff*

Revised Edition — Aligned with All Federal, State & Professional Society Standards

AT A GLANCE

Location	Ketamine Research Institute — 5969 Cattlebridge Blvd., Suite 104, Sarasota, FL 34232
Format	3-Day In-Person Intensive Thursday – Saturday, 9:00 AM – 5:00 PM
Dress Code	Casual and comfortable — this is a hands-on, informal setting
Materials	A comprehensive Course Workbook is provided — no notetaking required
Regulatory Alignment	FSMB • APA • ASA • ASRA/AAPM • AANA/APNA • FDA • DEA • Spravato REMS • State Medical Boards (AL, TX, UT, PA, CA, KY)

Before the Course Begins

Please complete and return your Patient Registration and Brief Medical History forms by email or fax as soon as possible. If you will be participating in the optional Ketamine Experience on Day 2 or Day 3, you will need to arrange transportation (Uber or similar) for that day — you will not be able to drive following your infusion.

DAY 1

Ketamine Fundamentals, Compliance & Practice Setup

Thursday | 9:00 AM – 5:00 PM

Day 1 establishes the scientific and regulatory foundation of the course — where ketamine came from, why the standard protocol falls short, and what it takes to run a safe, compliant, and effective infusion practice from day one.

MODULE 1 The Scientific Journey of Ketamine

- From anesthetic origins (1960s) to FDA approval
- The 1994 Krystal Study & birth of the 0.5 mg/kg protocol
- Landmark antidepressant studies (Berman 2000, Zarate 2006)
- The 6-infusion standard and its real-world limitations
- Stereochemistry: racemic ketamine vs. esketamine (Spravato) vs. arketamine — pharmacological and regulatory distinctions
- FDA-approved vs. compounded ketamine: quality, safety, and regulatory differences — including FDA Safety Alerts (2022, 2023)

MODULE 2 Clinical Excellence & Regulatory Compliance

- APA, ASA, FSMB, and DEA frameworks
- ASRA/AAPM/ASA Consensus Guidelines (2018): chronic pain and acute pain standards for indications, contraindications, personnel, and monitoring
- AANA/APNA Joint Position Statement (2023): interdisciplinary collaboration model, CRNA and PMHNP scope-of-practice boundaries, referral process requirements
- Spravato REMS program: certified healthcare setting requirements, patient enrollment, 2-hour monitoring mandate, prescriber onsite requirement — as a model framework for off-label ketamine protocols
- State medical board regulations: state-by-state prescriber requirements, clinic registration mandates (TX), prohibited practices, and scope-of-practice boundaries (AL, TX, UT, PA, CA, KY)
- Patient selection: ideal candidates vs. contraindications

- Expanded contraindication screening per ASRA: elevated intracranial/intraocular pressure, severe hepatic disease (cirrhosis), poorly controlled cardiovascular disease, active psychosis
- Mandatory baseline testing: ECG for cardiovascular risk patients, LFTs for hepatic dysfunction or anticipated high dose/frequent infusions (ASRA 2018)
- Anesthesiology-standard documentation across all three infusion phases
- Standardized intake forms, PHQ-9, BDI-II, GAD-7, PTSD, and DEA log requirements
- Pain outcome instruments: Numeric Rating Scale, Brief Pain Inventory, Oswestry Disability Index, and ASRA positive treatment response criteria ($\geq 30\%$ pain reduction)
- Comprehensive Informed Consent, Formal Ketamine Consultation and Collaborative Care Agreement
- Informed consent enhancement: explicit off-label disclosure, FDA non-approval for psychiatric indications, compounded formulation risks, realistic outcome expectations, and identity/credentials of administering clinicians (per APA, FSMB, state boards)

MODULE 3 DEA Compliance & Controlled Substance Management

- Controlled substance logbook mastery
- Vial serialization, inventory, and secure storage (21 CFR 1301.75)
- Waste management: two-person integrity rule and DEA Form 41
- Procurement, account setup, and the SORS reporting system
- DEA enforcement landscape: recent prosecution cases involving illegal ketamine administration, distribution, and fraudulent billing (DEA 2024) — risk mitigation strategies
- PDMP integration: mandatory query at intake and quarterly thereafter, doctor-shopping identification, coordination with state prescription monitoring programs (TX, FSMB)

MODULE 4 Setting Up Your Infusion Practice

- Infusion center layout and suite design (120 sq ft per suite)
- Staffing requirements: qualified practitioner + RN, ACLS certification
- Required equipment: monitors, syringe pumps, crash carts, oxygen
- Mandatory monitoring equipment per most stringent standards: continuous pulse oximetry with audible alarms, end-tidal CO₂ capnography (TX mandate), ECG/cardiac monitoring, automated BP at 5–15-minute intervals
- Emergency equipment inventory per ASA standards: BVM (adult/pediatric), oral/nasal airways, suction (Yankauer), AED/defibrillator, advanced airway equipment (laryngoscope, ETT, LMA), pharmacologic antagonists (naloxone, flumazenil), emergency medications (epinephrine, atropine, vasopressin, amiodarone, nitroglycerin, corticosteroids)
- Personnel requirements: physician onsite throughout administration; dedicated monitoring nurse continuously in room with patient (may not leave or perform competing tasks); at least one person with advanced airway/intubation skills immediately available (ASA, CA, KY)
- Start-up cost estimates and operational readiness checklist
- Clinic registration and state compliance: mandatory registration with state medical boards where required (TX), biennial renewal, audit/inspection readiness

MODULE 5 The Future of Ketamine Therapy — Why Standards Matter

- Real-world outcomes vs. clinical trial success rates
- The risks of commercialization, telehealth prescribing, and regulatory backlash
- FDA warnings on compounded ketamine and telehealth: adverse event case reports including respiratory depression at twice anesthetic blood levels, risks of unsupervised at-home use
- Why 0.5 mg/kg fails as a one-size-fits-all solution
- The shift toward plasma concentration targeting and precision medicine
- Positioning for state medical board recognition: how meeting every regulatory standard creates the foundation for board endorsement and referral partnerships

◆ Clinical Session: Introduction to the Infusion Room

The infusion room is the operational core of a ketamine practice. How it is designed, equipped, and managed directly shapes clinical outcomes, patient safety, and the therapeutic experience. This session establishes the foundational competencies every KRI-trained clinician must master before administering their first independent infusion.

- Full walkthrough of the infusion encounter — from pre-visit intake to next-day follow-up
- IV access, pump programming, and infusion management hands-on
- Airway assessment & emergencies, airway devices – BVM ventilation, LMA, ETT etc.

- ASA formal airway evaluation: Mallampati classification, thyromental distance, neck anatomy, jaw mobility, BMI assessment, history of difficult intubation — documented as mandatory pre-procedure component
- Patient monitoring: pulse oximetry, capnography, cardiac monitoring, sedation scoring
- Level-of-consciousness assessment: Ramsay Sedation Scale (RSS), Modified Observer's Assessment of Alertness/Sedation Scale (MOAA/S) — with ketamine-specific considerations (eyes may remain open during deep sedation)
- ASA sedation continuum mastery: definitions of minimal, moderate, deep sedation, and general anesthesia; rescue competency requirement (must be able to rescue one level deeper than intended); absence of pharmacologic antagonist for ketamine
- Pre-infusion time-out procedure: patient identity confirmation, dosing parameter verification, informed consent completion check, allergy and medication review (APA, TX)
- NPO status verification protocols (case-by-case per ASA; mandatory at higher dose ranges per ASRA)
- Set and setting as clinical variables: lighting, music, positioning, staff behavior
- Discharge criteria, documentation, and post-infusion instructions
- Enhanced discharge protocol: Aldrete scoring for discharge readiness (TX), two BP readings 10 minutes apart (TX), psychiatric safety screen including suicidal ideation assessment before discharge (APA), 30-40 minimum post-infusion monitoring, written post-procedure instructions covering medications, alcohol, driving restrictions, and emergency contacts

DAY 2

Advanced Practice, Pharmacokinetics & Supervised Clinical Training

Friday | 9:00 AM – 5:00 PM

Day 2 moves into the pharmacological science that separates a KRI-trained clinician from the standard clinic — including the critical variables that determine whether a patient responds or drops out. The afternoon includes supervised clinical training and the optional personal infusion experience.

MODULE 6 Pharmacokinetics & Plasma Concentrations

- Why weight-based dosing produces unpredictable plasma levels
- Volume of distribution, metabolism, and elimination variables
- Defining Cmax, MEC, and MTC — the therapeutic “sweet spot”
- Transitioning from mg/kg dosing to targeted plasma concentrations (ng/ml)
- Adjusted Body Weight vs. Ideal body weight vs. total body weight dosing: mandatory adjustment for BMI ≥ 30 (APA, KY) — evidence for reduced hemodynamic complications

MODULE 7 Mechanism of Action — The Master Molecule

- Racemic ketamine: (S)- and (R)-ketamine enantiomers and active metabolites
- NMDA receptor blockade, the glutamate surge, and neuroplasticity cascades (BDNF, mTORC1)
- Ketamine as a “dirty drug” — activity at 23+ receptor sites
- Depression as a disconnection syndrome: DMN, SN, and CEN network dysfunction
- Analgesic mechanisms: central sensitization reversal, descending modulatory pathway enhancement, spinal cord pain transmission modulation (ASRA framework)

MODULE 8 Mastery of Delivery & Risk Management

- IV, IM, intranasal, and oral routes — bioavailability and clinical trade-offs
- Neurological, cardiovascular, respiratory, and hepatic risk profile
- Hepatic monitoring protocol: baseline and post-infusion LFTs for patients with liver dysfunction, chronic hepatitis, alcohol abuse history, or anticipated high dose/frequent infusions (ASRA 2018)
- Cardiovascular screening: baseline ECG for high-risk patients to exclude uncontrolled ischemic heart disease (ASRA 2018)
- Managing dissociation and sympathomimetic effects in real time
- Preemptive and rescue medication protocols: benzodiazepines for anxiety/dysphoria, antiemetics, antihypertensives — evidence basis and limitations (ASRA Grade C)
- Airway issues, recognition and management
- Long-term risks: differentiating therapeutic use from ketamine abuse

- Chronic exposure safety monitoring: cognitive function assessment, lower urinary tract symptom screening (cystitis risk), substance misuse surveillance, ketamine use disorder identification (APA)
- KIRT-S Ketamine Infusion Risk Assessment Tool/PMP review
- Substance abuse risk stratification: KIRT-S formalized risk assessment modeled after Opioid Risk Tool, urine toxicology screening, PDMP integration, monitoring for multi-provider ketamine seeking (FSMB, APA)

MODULE 9 Advanced Pharmacokinetics & Target-Determined Infusions

- The 3-compartment pharmacokinetic model: distribution, accumulation, elimination
- KRI's 800-infusion dataset: identifying ED50 and ED75 plasma sweet spots
- Correlation between infusion rate, receptor occupancy, and C_{max}
- Introduction to the KRI Clinical Companion for real-time plasma targeting
- ASRA pain-specific dosing parameters: bolus doses up to 0.35 mg/kg, infusion rates 0.5–2 mg/kg/hr, minimum 80 mg over 2+ hours for chronic pain; condition-specific evidence grades (CRPS: moderate; SCI pain: weak; others: limited)

◆ Clinical Session: Supervised Infusion Training

Supervised clinical sessions bridge didactic knowledge and real-world practice. Under the direct oversight of experienced ketamine clinicians, trainees execute every phase of the infusion encounter — developing the procedural fluency, clinical judgment, and patient management skills that define safe, effective ketamine therapy.

- Hands-on management of the complete infusion sequence under expert supervision
- Dose selection, rate titration, and real-time monitoring
- Adverse event recognition: hypertension, tachycardia, emergence reactions
- Airway assessment & emergencies, airway devices – BVM ventilation, LMA, ETT etc.
- Defined infusion stopping criteria: BP >180/100 or HR >110, respiratory distress, SpO₂ decline, severe behavioral disturbance, cardiac rhythm changes (AL, APA)
- Behavioral emergency management: acute agitation, severe dissociation, psychotic symptoms — de-escalation techniques and pharmacologic intervention
- Therapeutic presence: knowing when to intervene vs. when to hold space
- Documentation, procedure notes, and post-infusion patient debriefing
- Contemporaneous documentation drill: real-time recording of all monitored parameters before, during, and after infusion per ASA/TX standards

◆ Optional: The Ketamine Infusion Experience (Day 2 or Day 3)

A defining component of KRI clinical training. Clinicians who have personally undergone a supervised ketamine experience are demonstrably better equipped to guide, prepare, and support their patients through one.

Why This Matters Clinically

The ketamine experience is not simply sedation — it is a non-ordinary state of consciousness that can be disorienting, emotionally intense, and for many patients, profoundly meaningful. Clinicians who have never experienced this state are working with a significant perceptual gap. Firsthand experience closes that gap.

- A supervised low-dose ketamine infusion in a controlled clinical setting
- Firsthand exposure to dissociation, time distortion, and altered perception
- Overseen by a senior KRI clinician with full safety protocols in place
- Structured post-infusion reflection on clinical implications and empathic insight
- Practical training in debriefing and integration techniques for use with your own patients

DAY 3

Precision Medicine, Targeted Infusions & Putting It All Together

Saturday | 9:00 AM – 5:00 PM

Day 3 brings everything together with the precision medicine methodology that defines KRI-trained practice — covering the clinical variables that most programs ignore entirely and providing the practical tools you'll use on Day 1 in your own infusion suite.

MODULE 10 Transforming Your Approach: The Critical Variables

- From total body weight to adjusted body weight dosing
- The “Five Moving Parts”: mass, metabolism, medications, morbidities, mindset

- Medication reconciliation in treatment-resistant depression: polypharmacy realities
- Key pharmacological roadblocks: benzodiazepines, lamotrigine, antipsychotics, opioid antagonists
- Drug-drug interaction management: opioid co-administration risks (oversedation), MAOI considerations, sympathomimetic potentiation, CNS depressant synergy

MODULE 11 Metabolism, Genetics & Comorbidity Management

- CYP450 modulators, genetic variants (BDNF, MTHFR, COMT), and dosing adjustment
- Genomind pharmacogenomic testing in clinical practice
- Metabolic comorbidities: MTHFR, hypotestosteronemia, hypomagnesemia, carnitine deficiency
- The KRI Clinical Companion: automated safety checks and pre-infusion optimization

MODULE 12 Precision Medicine in Practice — The SOMA Framework

- Selection, Optimization, Monitoring, Adjustment — the full clinical workflow
- Standard vs. advanced eligibility matrices and red flag identification
- Step-by-step patient optimization: correcting MTHFR, medications, hormones, nutrients
- Understanding tolerance, tachyphylaxis, and ketamine-induced glutamate excitotoxicity
- Treatment continuation and discontinuation decision framework: non-responder protocols (discontinue after 4–6 infusions per AL/APA), frequency tapering schedules (twice-weekly → once-weekly → discontinuation per APA), ongoing risk-benefit documentation
- Concurrent psychotherapy integration: evidence for greatest efficacy when combined with CBT (FSMB), coordination with patient's existing mental health team

MODULE 13 Ketamine Therapy Improved: Personalized Dosing & Treatment Trajectories

- Diagnosis-specific plasma concentration targets: anxiety/PTSD, depression/bipolar, neuropathic pain
- Navigating the four levels of consciousness from anxiolysis to reorientation
- The three-stage treatment trajectory: Induction, Reinforcement, and Maintenance phases
- Using real-time biometrics (HR, HRV, respiration) to guide and refine the series
- Treatment response measurement: validated depression scales (PHQ-9, BDI-II, MADRS) at every session; pain outcome criteria ($\geq 30\%$ reduction, ODI) per ASRA; systematic documentation of cumulative response for ongoing risk-benefit analysis

MODULE 14 Putting It All Together: Tools for Clinical Success

- Point-of-care rapid reference guides and standardized clinical protocols
- Setting realistic patient expectations and explaining the ketamine journey
- The KRI Clinical Companion: personalized dosing, medication safety, and real-time clinical intelligence
- The KRI Mentorship Program: ongoing case review, urgent support, and professional development
- Standard operating procedure development: site-specific protocol creation as both clinical best practice and medicolegal defense strategy
- Quality improvement framework: outcome tracking methodology, complication rate monitoring, patient satisfaction metrics, and protocol refinement cycles

MODULE 15 Clinical Ethics, Medical-Legal Standards & Professional Accountability

- Informed consent beyond the form: off-label disclosure obligations, realistic outcome representation, and patient autonomy in vulnerable psychiatric populations
- Scope of practice boundaries for non-psychiatrist practitioners and recommended psychiatric clearance criteria
- Coordination of care standards: formal protocols for communicating with the patient's existing mental health team
- Malpractice exposure in ketamine practice: off-label prescribing liability, standard of care documentation as legal defense, and critical incident reporting
- Adverse event reporting requirements: content specifications, retention periods (minimum 3 years per TX), reportable events (airway intervention, EMS transport, hospitalization, death), FDA MedWatch reporting for serious events
- Quality assurance frameworks: adverse event reporting, outcome tracking methodology, and peer review standards
- Business compliance in cash-pay practice models: anti-kickback statute awareness and appropriate financial disclosures to patients
- Marketing compliance: evidence-based advertising only, avoiding misleading claims about ketamine efficacy (FDA/FTC guidelines), appropriate representation of off-label status
- Continuing competency: CME requirements, credentialing considerations, and maintaining currency as clinical standards evolve

- Malpractice insurance verification: ketamine-specific coverage confirmation, scope-of-practice alignment, interdisciplinary referral process documentation (AANA 2023)

MODULE 16 Precision Psychedelics & REMS Readiness

To ensure our clinicians remain at the absolute forefront of psychiatric medicine, our Mini-Fellowship now includes strategic preparation for the expanding psychedelic pipeline, including:

- REMS-Compliant Infrastructure: How to structure your physical clinic, staffing, and emergency protocols to meet the anticipated FDA Risk Evaluation and Mitigation Strategies (REMS) for incoming Schedule III therapies including MDMA, Psilocybin, and Ibogaine
- KIRT — Ketamine Institute Risk Evaluation Tool: A comprehensive, multi-system risk assessment that goes beyond standard PMP review — evaluating psychiatric, neurological, cardiovascular, respiratory, and hepatic factors to build a complete patient safety profile before a single infusion begins
- Navigating “Right to Try” Pathways: Practical guidance on the legal, ethical, and operational frameworks for providing eligible patients access to investigational drugs prior to full FDA approval
- Advanced Pharmacology & Contraindications: Expanding our metabolic optimization protocols to understand drug-drug interactions, SSRI tapering, and cardiovascular screening for classic psychedelics
- Real-World Data Generation: How to implement compliant EHR tracking today to position your clinic for state-level grants, VA partnerships, and federally matched ARPA-H funding initiatives

MODULE 17 Competency Assessment & Certification Standards

A formal competency assessment ensures every KRI graduate can demonstrate proficiency across all regulatory domains — creating documentation that satisfies state medical board credentialing requirements and establishes the KRI certification as a recognized standard of training.

- Written examination: pharmacology, regulatory frameworks, protocols, emergency management, and documentation requirements
- Clinical skills demonstration: airway assessment performance, patient evaluation competency, monitoring proficiency, emergency response capability
- Case-based evaluation: patient selection decisions, dose calculation, informed consent process execution, discharge readiness determination using Aldrete scoring
- Documentation competency: medical record review, adverse event log completion, contemporaneous recording accuracy
- Formal competency documentation package: individualized certificate of completion with competency attestation, suitable for submission to state medical boards, hospital credentialing committees, and malpractice insurance carriers

◆ Clinical Session: Supervised Infusion Training (continued)

- Continued hands-on supervised infusion experience
- Applying precision medicine principles to real patient scenarios
- Series progression planning: adjusting subsequent infusions based on response data
- Discharge criteria, documentation, and next-visit scheduling
- Complete discharge protocol execution: Aldrete scoring, dual BP readings, psychiatric safety screen, written post-procedure instructions, responsible adult transport confirmation

WHAT YOU TAKE HOME

Clinical Resources

- ✓ Comprehensive Course Workbook
- ✓ All forms, consents, and DEA documentation
- ✓ Assessment tools (PHQ-9, GAD-7, PTSD Index, Beck Depression, Oswestry Disability Index)
- ✓ Ketamine infusion records, DEA-compliant logbooks, Adverse Events Logbook, and REMS Protocol
- ✓ Certified Ketamine Clinician logo for your website or practice materials
- ✓ State medical board compliance checklist and registration guidance

Ongoing Support

- ✓ KRI Certification as a qualified ketamine therapy clinician
- ✓ Formal competency attestation for state medical board submission
- ✓ Access to the KRI graduate referral network
- ✓ Year-long personal mentorship with Dr. Grass
- ✓ Access to the KRI Clinical Companion app (2026)
- ✓ KIRT-S: Ketamine Infusion Risk Assessment Tool
- ✓ Invitation to the KRI graduate discussion board
- ✓ KRI Business Guide and Marketing Manual

<ul style="list-style-type: none">✓ Standard Operating Procedure templates for every phase of treatment✓ ASA airway assessment documentation templates [NEW]✓ Aldrete discharge scoring forms	<ul style="list-style-type: none">✓ Regulatory update alerts as new state guidelines are adopted
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REGULATORY ALIGNMENT STATEMENT

This curriculum satisfies the most stringent training requirements from all current federal, state, and professional society guidelines governing ketamine therapy, including:

FSMB • APA • ASA • ASRA/AAPM • AANA/APNA • FDA Safety Alerts • DEA • Spravato REMS
State Medical Boards: Alabama • Texas • UTAH • Pennsylvania • California • Kentucky

Questions? Ready to Apply?

Contact Charlene at [800-850-6979](tel:800-850-6979) or visit ketamineinstitutetraining.com

Class openings fill several months in advance — early application is strongly encouraged.