Institutional Handbook of Operating Procedures Policy 09.13.05	
Section: Clinical Policies	Responsible Vice President: Executive Vice President and CEO Health System
Subject: General Clinical Policies and Procedures	Responsible Entity: Health System

I. Title

Procedural Sedation (Moderate and Deep Sedation)

II. Policy

A. The following policy sets uniform requirements and minimum standards for the use of moderate and sedation for therapeutic, diagnostic, or surgical procedures performed at the University of Texas Medical Branch (UTMB).

B. All UTMB patients who receive procedural sedation for a procedure will be provided a safe and comparable level of care consistent with, or in excess of, the minimum recognized standards for such procedures.

C. UTMB respects the diverse cultural needs, preferences, and expectations of the patients and families it serves to the extent reasonably possible while appropriately managing available resources and without compromising the quality of health care delivered.

III. Definitions

Minimal Sedation (Anxiolysis): A drug-induced state during which a patient responds normally to verbal commands. Cognitive functions and coordination may be impaired, but ventilatory and cardiovascular functions are unaffected.

Moderate Sedation (Conscious Sedation): A drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway and spontaneous ventilation is adequate. Cardiovascular function is maintained. Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

Deep Sedation: A drug-induced depression of consciousness during which a patient cannot be easily aroused but responds purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. The patient may require assistance with maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

General Anesthesia: A drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Rescue: Rescue of a patient from a deeper level of sedation than intended is an intervention by a practitioner proficient in airway management and advanced life support. The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation (such as hypoventilation, hypoxia and hypotension) and returns the patient to the originally intended level of sedation. It is not appropriate to continue the procedure at an unintended level of sedation.
Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended. Individuals administering Moderate Sedation/Analgesia ("Conscious Sedation") should be able to rescue patients who enter a state of Deep Sedation/Analgesia, while those administering Deep Sedation/Analgesia should be able to rescue patients who enter a state of General Anesthesia.

Licensed Independent Practitioners (LIP) , any individual permitted by law and UTMB Bylaws to provide care and services without direction or supervision within the scope of the individual's license and consistent with individually granted clinical privileges. Refer to UTMB Policy Term Definition for Privileges.

Monitoring Assistant (MA) is a RN, MD, DO, DDS, Podiatrist, APRN, or PA responsible for providing sedation monitoring during the procedure. The MA is directed and supervised by the LIP.

Anesthetic agents: Propofol, etomidate, ketamine. These medications are the agents referred to in the deep sedation portion of this policy and their use is restricted to LIPs who are specifically privileged to administer them (refer to section 6).

IV. Exclusions

A. This policy does not apply to:

- **a)** Sedation provided by an anesthesiologist/Certified Registered Nurse Anesthetists (CRNA). (Anesthesiologists/CRNAs are privileged to provide all levels of sedation including moderate sedation with no additional requirements.)
- **b)** Mechanically ventilated patients in the Intensive Care Unit (ICU), ER, or Post-Anesthesia Care Unit (PACU) with ECG, blood pressure, and SaO_2 monitoring.
- **c)** Administration of anxiolytic or analgesic agents when administered routinely to alleviate pain and agitation (e.g., sedation for treatment of insomnia, pre- or post-operative analgesia).
- **d)** Patients not undergoing diagnostic or therapeutic procedures
- **e)** Otherwise healthy patients receiving local and/or topical anesthesia and no other sedative of analgesic agents per any route
- **f)** Patients requiring emergency tracheal intubation or emergency cardioversion

B. The use of anesthetic agents for non-procedural sedation by continuous drip is addressed in Pharmacy Policy 07.49 Preparation and Administration of Medications via Continuous Intravenous Infusion (Adult).

V. Licensed Independent Practitioner for Moderate Sedation

A. Licensed Independent Practitioners (LIP), for moderate procedural sedation include MD, DO, DDS, or Podiatrist. The LIP is a member of the Medical Staff and has been granted privileges by UTMB to direct and administer moderate procedural moderate sedation based on UTMB Moderate Sedation Education Requirements, as follows:

1. The LIP must maintain at least one current Advanced Cardiac Life Support (ACLS), Pediatric Advanced Life Support (PALS), Advanced Trauma Life Support (ATLS), or Neonatal Resuscitation Program (NRP) certification, as appropriate to the population served.

2. The LIP must successfully complete the online Moderate Sedation course and final assessment fiscal year.

3. The LIP must be familiar with this policy.

4. The LIP must be granted the moderate sedation privilege by the UTMB Credentialing Office.

5. Those who have met these criteria are privileged to direct and administer moderate sedation with no additional supervision requirements.

6. Physician Assistants (PA), Advanced Practice RNs, physicians in fellowship training and resident physicians working with the LIP can, under the direction and with attestation when applicable of the LIP, perform the tasks described in section V.B.2. and V.B.3. as described below. PAs, APRNs, physicians in fellowship training and resident physicians working with the LIP cannot serve in the role of LIP but require direction and supervision by the LIP. The LIP physician/DO/DDS/podiatrist who works with a PA, APRN, physicians in fellowship training and/or resident physician must be recorded as the LIP in the patient's record.

7. The LIP working with a PA, APRN or physician in fellowship training must be immediately available for the duration of the procedure for rescue or other necessary interventions. A LIP working with a resident must stay present at the bedside for the duration of the sedation.

B. Responsibilities of the LIP privileged to direct moderate sedation

1. The LIP is responsible for the safety and wellbeing of the patient. The prescribing LIP's intent is to produce a depression of consciousness that exceeds a simple reduction of anxiety or simple relief of pain.

2. The LIP is responsible for completion of patient's electronic medical record of history and physical (H&P), the pre-sedation assessment, and for obtaining informed consent for both the procedure and the use of sedation.

3. The LIP is responsible for ordering medication (including dosage and route of administration).

4. The LIP is responsible for directing and providing emergency interventions and rescue as necessary.

5. The LIP will ensure that this policy is observed. In either elective or emergent procedures, if circumstances warrant deviation from this policy, the reason must be documented in the patients' medical record.

VI. Deep Sedation Qualified Licensed Independent Provider:

A. Credentialing

1. Deep sedation privileges are granted by the Department of Anesthesiology to non-anesthesiologist physicians. The requirements for privileging and the process are detailed in the UTMB Department of Anesthesia Policy and Procedures.

2. Deep sedation qualified physicians must be competent in advanced airway management.

3. Deep sedation qualified physicians must be also credentialed in moderate sedation based on UTMB Moderate Procedural Sedation Education Requirements, as described in section V.A.

4. Deep sedation qualified physicians are approved by the UTMB Department of Anesthesiology to order an anesthetic agent. Privileges granted will be drug specific and will specify the drugs propofol, etomidate and/or ketamine.

5. The deep sedation credentials may be verified online using iPrivileges.

B. Deep sedation physicians must fulfill the responsibilities as described in section V.B.

C. Responsibilities of the deep sedation qualified physicians different from moderate sedation:

1. The priority of the deep sedation qualified physician is the monitoring of sedation and maintaining a patent airway.

2. Therefore, he/she cannot be involved in any other activity that cannot be instantly abandoned including participation in the medical/surgical procedure. The deep sedation qualified physician shall not be the principal proceduralist unless the procedure can be instantly abandoned to attend to the patient's airway.

3. The deep sedation qualified physician administers the anesthetic agent or in his/her place a physician resident, a PA, a Registered Nurse (RN), or an APRN may administer the anesthetic agent under the direction of and in the immediate presence of the deep sedation qualified physician.

4. Due to the potential for rapid, profound changes in sedative/anesthetic depth and the lack of antagonist medications for propofol, etomidate and ketamine, patients receiving these agents should receive the monitoring and attention required for deep sedation even if only moderate sedation is intended.

5. The deep sedation qualified physician is the primary person responsible for procedural monitoring during deep sedation until the patient has recovered to a level of consciousness (LOC) of 3 or less on the Modified Ramsay Scale. At this time the Monitoring Assistant can assume primary responsibility for sedation monitoring.

6. The deep sedation qualified physician should remain immediately available until the patient has met the discharge criteria (described below in section XVII).

VII. Personnel

A. Moderate sedation directed by a LIP requires use of a Monitoring Assistant (MA). During deep sedation, the primary person responsible for procedural monitoring is the deep sedation qualified

physician. See section VI.C for the role of the MA.

B. The MA is a RN, MD, DO, DDS, Podiatrist, APRN, or PA responsible for providing sedation monitoring during the procedure. Respiratory Therapists and Radiological Technicians are excluded as Monitoring Assistant.

C. A MA will be credentialed by UTMB through completion of the UTMB Moderate Sedation Education Requirements:

1. The MA must maintain at least one current certification described below as appropriate to the population served.
   a. ACLS
   b. PALS or ENPC (Emergency Nursing Pediatric Course)
   c. NRP certification.

2. The MA must successfully complete the online Moderate Sedation course and final assessment annually.

3. The MA must be familiar with this policy.

D. The Monitoring Assistant's responsibility:

1. To monitor physiologic parameters.
2. Know how to monitor required parameters, recognize abnormalities in the required parameters, and intervene as needed.
3. Administration of medication(s) as permitted to do so by their licensure and UTMB.
4. Be familiar with the effects of the drugs used.
5. Know how to recognize an airway obstruction and correct it.
6. Be able to manage ventilation with a self-inflating bag valve mask.
7. To assist in any supportive or resuscitative measures, as required.
8. To make sure that all equipment (see below) is immediately available and functioning properly.

VIII. Equipment

All necessary equipment will be available and checked for proper function prior to administration of sedative medications. The equipment must be appropriate for the patient's weight and height. Monitoring equipment detailed herein will be available, in the procedure room. The monitor with the patient's vital signs needs to be easily visible to both LIP and MA. Equipment includes:

1. Device to measure blood pressure.
2. Pulse oximeter.
3. Continuous ECG will be used for patients requiring continuous ECG monitoring.
4. Oxygen, including delivery system with appropriate supplies and a positive pressure oxygen delivery system.
5. End tidal CO_2 monitor unless patient conditions make it unadvisable.
6. A functional suction apparatus.
7. Emergency medication and equipment, including emergency airway equipment.
8. Thermometer of other means to objectively assess temperature.
9. Appropriate reversal agents located in the procedure room; and
10. A crash cart, defibrillator/AED with emergency medications must be readily available. If not present in the locations the procedure is performed, the staff must know the nearest location and be able to immediately access these items if needed.

IX. Informed Consent

A. Each patient, parent, or guardian must receive an explanation regarding the risks and alternatives of moderate sedation.

B. Appropriate informed consent for both the procedure and sedation will be obtained prior to sedation. Refer to the following related policies: IHOP Policy 9.3.17, *Patient Consent - Overview and Basic Requirements* and IHOP Policy 9.3.18, *Consent – Treatment of a Minor*.

X. Dietary Precautions

A. Sedation may reduce airway protective reflexes, thus allowing pulmonary aspiration of gastric contents in the event of emesis. The use of sedation will be preceded by an evaluation of food and fluid intake.

B. Elective Procedure: Before elective sedation, oral intake will be curtailed as appropriate for age.

Clear liquid:	2 hours
Breast milk:	4 hours
Infant Formula:	6 hours
Non-human milk:	6 hours
Light meal:	6 hours
Fatty meal:	8 hours

C. Administration of intravenous fluids should be considered for patients experiencing prolonged fasting or who are at risk for dehydration.

D. Certain radiological procedures require the administration of oral fluids in conjunction with sedation and analgesia. Risk of aspiration during these procedures must be weighed against the benefits of sedation and analgesia.

E. Emergency: For non-elective sedation when proper fasting has not been assured, the risks of sedation will be weighed against its benefits and against the risk of delaying the procedure. Administering pharmacologic treatment to reduce gastric volume and increase gastric pH may be considered. Some patients may require protection of the airway and/or anesthesia consultation.

XI. Pre-Procedure Assessment and Plan

A. Because sedation carries risks, administration of sedation must be planned. A sedation plan should be developed to meet each patient's needs identified through a pre-sedation assessment. A pre-sedation assessment by the LIP is required prior to administration of sedation. The pre-sedation assessment will be documented in the patient's medical record.

B. The pre-sedation assessment must be reviewed prior to administration of sedation by both LIP and Monitoring Assistant. A pre-sedation assessment includes but is not limited to:

1. Physical status assessment (vital signs, airway, cardiopulmonary reserve, past and present drug history including drug allergies, review of systems).
2. Previous adverse experience with sedation and analgesia, as well as with regional and general anesthesia.
3. Results of relevant diagnostic studies.
4. Verification of patient NPO status; and
5. Assignment of physical status classification using American Society of Anesthesiologist (ASA) Scoring.

C. The ASA Physical Status Classifications as follows:

1. Class I a normal healthy patient
2. Class II a patient with mild systemic disease
3. Class III a patient with severe systemic disease
4. Class IV a patient with severe systemic disease which is a constant threat to life
5. The addition of "E" denotes emergency surgery

D. Candidates for sedation should be in good general medical health and have adequate ventilatory reserve. For patients who have significant medical problems (e.g., ASA Class 3 and above, morbid obesity, sleep apnea, upper or lower structural airway abnormalities) consultation with an anesthesiologist or attending physician specializing in the primary disease process affecting the patient is strongly recommended but not required.

XII. Intravenous Access

Administration of medications intravenously for moderate and deep sedation requires continuous IV access until the patient has recovered. This can be accomplished with an indwelling catheter or needle, with or without IV fluid administration. For patients receiving procedural sedation by non-intravenous routes or whose intravenous access has become nonfunctional, the LIP directing the moderate sedation will determine the advisability of establishing or reestablishing intravenous access. In all circumstances, an individual capable of establishing intravenous access should be readily available.

XIII. Intra-Procedure

A. The patient must be reevaluated immediately prior to administration of sedation. Immediately prior to procedural sedation, baseline values of blood pressure, heart rate, respiratory rate, oxygen saturation, and responses to verbal stimuli or level of consciousness must be recorded.

B.

B. The MA must be present to continuously assess patient wellbeing and facilitate patient safety and comfort. Sedated patients must never be left alone during or immediately after sedation. The MA will have no other responsibilities that will leave the patient unattended or compromise continuous monitoring.

C. Medications will be administered only under the direction of a LIP privileged to order and direct moderate sedation.

D. For patients undergoing moderate procedural sedation loss of consciousness should not be the goal.

E. Heart rate and oxygen saturation will be monitored continuously. Continuous ECG monitoring will be considered for patients who are ASA Physical Status Class II or higher. Use of supplemental inspired oxygen should be considered. Continuous end tidal CO_2 monitoring during moderate sedation is required for every patient unless patient conditions make this unadvisable. Continuous end-tidal CO2 must be monitored during deep sedation.

F. The following items will be monitored and recorded at five-minute intervals or more frequently, if indicated, on a time-based record:

1. Blood pressure, heart rate, respiratory rate, oxygen saturation, and the presence of end-tidal CO_2.
2. Responses to verbal stimuli or level of consciousness; and
3. Medications and dosages.

G. Documentation Requirements: Any unusual, unanticipated, or adverse events must be described. The patient's condition at the conclusion of the procedure must also be assessed and documented using the Modified Aldrete Score. Fluid types and total fluid volume will be recorded.

XIV. Warning on the use of Reversal Agents

The routine use of narcotic antagonists and/or benzodiazepine antagonists is not recommended. The duration of action of the sedatives and/or narcotics may exceed that of the antagonist(s). Patients who receive narcotic antagonists and/or benzodiazepine antagonists require extended post-procedure observation, as determined by the LIP.

XV. Post Procedure

A. During the immediate post procedure period, the patient will not be left alone. A Modified Aldrete Score will be obtained at the end of the procedure. A medically qualified individual will monitor and record the following items immediately post-procedure and frequently until stable and adequate function is restored:

1. Blood pressure, heart rate, respiratory rate, oxygen saturation, etCO2.
2. Responses to verbal stimuli or level of consciousness.
3. Medications and dosages, fluid types and volumes; and
4. Unusual, unanticipated, or adverse events.

B. Procedural monitoring will be continued until the following criteria are met:

1. Modified Aldrete score of ≥ 9 or a return to the patient's baseline.
2. Protective reflexes are intact.
3. No evidence of procedural complications (including bleeding from the wound site);
4. Pain adequately controlled; and
5. A minimum of 15 minutes has elapsed after the end of the procedure.

C. Postprocedural monitoring takes place in the procedure room. Alternatively, if the area where the procedure takes place has a nearby designated post procedure recovery unit equipped and staffed according to UTMB policy for post-procedure care the patient can be moved to this area. The LIP determines if and when the patient's status allows for moving the patient to the recovery unit. Post procedural monitoring will continue there until criteria described in XV.B. are met. EtCO2 monitoring in the recovery unit is optional.

D. During this immediate post sedation period, in addition to the MA or recovering RN, there will be at least one other staff member in the unit. This additional staff member should be able to directly hear a call for assistance in the case of an emergency.

XVI. Criteria for Discharge Post Sedation

A. Prior to discharge, the responsible physician will reexamine the patient and enter a note in the chart documenting post-procedure recovery status and the patient's physiological status return to pre-procedure baseline. Alternatively, specific discharge criteria may be applied by qualified personnel to facilitate safe discharge.

B. The patient may be discharged once discharge criteria are met. If discharge criteria are not met, exceptions may be made by a qualified LIP.

C. Discharge criteria:

1. Modified Aldrete score of ≥ 9 or a return to the patient's baseline.
2. Protective reflexes are intact, and the patient exhibits no signs of respiratory distress.

3. Vital signs have returned to the patient's normal baseline.
4. The patient is not suffering from nausea, vomiting, or dizziness.
5. Pain adequately controlled.
6. A minimum of 30 minutes has elapsed since the end of the procedure
7. Any infant who is either a full term infant (EGA at birth ≥ 37 weeks) and less than 6 weeks of age, or who is a premature infant (EGA at birth <37 weeks) and less than 52 weeks post-conceptual age, because of the risk of post-sedation apnea, needs to be monitored for 12 hours post procedure when any sedatives are given.

D. If the patient is transferred to an inpatient location, the designated nurse on the receiving floor with receive a report about the patient containing information about the procedure including but not limited to the procedure, the course of the sedation, medications administered, any intra-procedure events, post-procedure treatment, adverse events and post-procedure patient status.

XVI. Post-Discharge Instructions

If the patient is to go home the day of the procedure, the patient will be accompanied at discharge by a responsible adult, with written post-discharge instructions. Written post-discharge instructions will be provided to the patient and the responsible adult accompanying the patient. Information will include:

1. Relevant dietary and medication instructions.
2. Post-discharge activity instructions.
3. Requirement that a responsible adult accompany the patient home post-discharge.
4. Steps to follow in the event of a complication, including a phone number to call; and
5. What to do in event of an emergency.

XVII. Additional References

The Joint Commission Comprehensive Accreditation Manual for Hospitals (August 2014). Practice Guidelines for Preoperative Fasting and the Use of Pharmacological Agents to Reduce the Risk of Pulmonary Aspiration: Application to Healthy Patients Undergoing Elective Procedures. *Anesthesiology,* V 114, No 3, 495-511:2011.

American Society of Anesthesiologists: Continuum of Depth of Sedation (October 2019)

American Society of Anesthesiologists: Statement on Safe Use of Propofol (October 2019)

American Society of Anesthesiologists: Practice Guidelines for Moderate and Procedural Sedation and Analgesia 2018 (Anesthesiology 2018; 128: 437-79)

American Society of Anesthesiologists: Statement on Granting Privileges for Administration of Moderate Sedation to Practitioners Who Are Not Anesthesia Professionals (Oct, 29, 2016)

American Society of Anesthesiologists: Advisory on Granting Privileges for Deep Sedation to Non-Anesthesiologists (October 2017)

Board of Nurse Examiners for the State of Texas, Position Statement #15.8 The Role of the Nurse in Moderate Sedation. (verified May 8, 2020).

American Society of PeriAnesthesia Nursing- Nursing Standards, Practice Recommendation 1 -Patient Classification/ Staffing Recommendations (Reviewed and updated 2019-2020).

Benefits and harms of capnography during procedures involving moderate sedation. (JADA 2018; 149(1): 38-50)

Board of Nurse Examiners for the State of Texas, Position Statement #15.8 The Role of the Nurse in Moderate Sedation.

"LVNs cannot administer pharmacologic agents for the purpose of achieving moderate sedation to or monitor patients receiving moderate sedation.

The administration of drugs and monitoring of patients for moderate sedation may be within the RN's scope of practice. If an RN elects to engage in administration of pharmacologic agents classified as "anesthetic" agents to induce moderate sedation, the RN should either be skilled in, or have immediate availability of other practitioners skilled in advanced airway management along with appropriate equipment that might be necessary to rescue a patient from unintended deep sedation. The facility or physician's office needs to have policies and procedures to guide the RN. See evidence-based practice standards of professional anesthesia association guidelines listed in the position statement."

XVIII. Dates Approved or Amended

Originated: 07/01/1995	
Reviewed with Changes	*Reviewed without Changes*
06/20/2014	04/20/2018
03/20/2015	09/20/2018
12/16/2020	
07/01/2021	

XIX. Contact Information

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