A. PURPOSE

Sedation and analgesia are used alone or in combination to facilitate the performance of medical or surgical procedures, for diagnostic or therapeutic purposes, while providing anxiolysis, sedation, amnesia and/or pain relief for patient comfort. This protocol provides guidelines for the administration of sedation/analgesia to adult patients in all locations throughout the Health System (a separate protocol covers Moderate or Deep Sedation/Analgesia in Children and Adolescents) in association with the performance of procedures for diagnostic or therapeutic purposes. Other purposes or uses of sedation and analgesia that are specifically exempt from this protocol are defined in Medical Center Policy No. 0153.¹ This protocol applies when the plan of care is for a moderate or deep level of sedation. Minimal sedation (anxiolysis) is exempt from this protocol. This protocol applies for all procedures, and in all patient populations not covered by a specialized protocol formally approved as described in Policy 0153.

Use of sedation/analgesia for procedures in continuously-monitored, intubated patients (endotracheal or tracheostomy), when completed in a critical care or intermediate care unit or the Emergency Department, may not require specific separate evaluation or informed consent; however, the medical record should reflect awareness of the patient's medical status prior to the procedure and the minimum monitoring standard outlined below is still required.

Because the level of a patient’s sedation is defined by the patient’s psychologic and physiologic state, and the ability to maintain a patent airway and spontaneous ventilation, this protocol does not delineate what constitutes the levels of sedation based solely on the route, dose or specific drug used. Therefore, providers are directed to the definitions below for use in determining when the intended plan for sedation/analgesia can be expected to render a patient sedated at the minimal (anxiolysis), moderate (conscious), or deep level.

It is the responsibility of the Clinical Chairs, Center and Program Directors, Attending Physicians, House Staff physicians, Administrators and Managers, and Nurse Clinicians to ensure that departmental, unit, and clinic policies and practices comply with the established criteria in this or an equivalent approved protocol.

B. DEFINITIONS

Sedation/analgesia associated with procedures will be conducted using the definitions outlined in the Continuum of Depth of Sedation - Definition of General Anesthesia and Levels of Sedation/Analgesia adopted by the American Society of Anesthesiologists:²

Minimal Sedation (Anxiolysis) is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

Moderate Sedation/Analgesia (“Conscious Sedation”) is a drug-induced depression of consciousness during which patients respond purposefully² 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 usually maintained.

Deep Sedation/Analgesia is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully² following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

¹ Medical Directors from clinical areas may submit for approval procedures to be exempted from this protocol. Any such proposal will include frequency of the procedure, drugs and dosages commonly used for the procedure, and the designation(s) of providers routinely performing the procedure (MD, NP, etc).
General Anesthesia is 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.

“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.”

<table>
<thead>
<tr>
<th>Minimal Sedation (Anxiolysis)</th>
<th>Moderate Sedation/Analgesia (Conscious)</th>
<th>Deep Sedation/Analgesia</th>
<th>General Anesthesia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responsiveness</td>
<td>Purposeful* response to verbal or tactile stimulation</td>
<td>Purposeful* response following repeated or painful stimulation</td>
<td>Unarousable even with painful stimulus</td>
</tr>
<tr>
<td>Airway</td>
<td>Unaffected</td>
<td>Intervention may be required</td>
<td>Intervention often required</td>
</tr>
<tr>
<td>Spontaneous Ventilation</td>
<td>Unaffected</td>
<td>Adequate</td>
<td>May be inadequate</td>
</tr>
<tr>
<td>Cardiovascular Function</td>
<td>Unaffected</td>
<td>Usually maintained</td>
<td>May be impaired</td>
</tr>
</tbody>
</table>

* Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

** Rescue of a patient from a deeper level of sedation than intended is an intervention by a practitioner proficient in airway management and resuscitation. 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.

C. PATIENT SELECTION, ASSESSMENT, and PREPARATION

1. Presedation Assessment: In addition to the regular medical history and physical examination, there must be a presedation assessment of the patient documented in the medical record on the same day of any therapeutic, diagnostic, or surgical procedure requiring sedation/analgesia. This assessment shall be performed to determine whether the patient is an appropriate candidate for the procedure and for the administration of sedation/analgesia or anesthesia.3 This assessment must include the plan of care* and identification of any post-procedure/post-sedation care needs and will include:4

- completion of, or review of recent, history and physical examination*
- medication allergies
- previous reaction to sedative, analgesic or anesthetic
- pregnancy status
- dietary status
- airway exam*
- ASA classification* (see Appendix A)


3 Decision on appropriateness to proceed with the procedure and with sedation/analgesia is the responsibility of a licensed independent practitioner (LIP). For the purposes of sedation/analgesia, LIP includes physicians, dentists, certified registered nurse anesthetists, nurse practitioners and physicians assistants. Non-physician credentialed providers may direct moderate sedation/analgesia (and CRNAs may direct deep sedation) within the limits of their practice agreements and under the direction of their supervising physician(s). Other non-credentialed providers may direct and administer sedation/analgesia only when covered by care protocols and/or medical command such as exists for the NETS and Pegasus patient transport programs. Assessment of the patient and the decision on appropriateness to proceed may be completed by the same LIP for both procedure and sedation/analgesia, or by separate practitioners, depending upon the responsible parties for the procedure and the sedation.

4 An appropriate history and physical examination will be conducted within a maximum of 7 days prior to the procedure and sedation. Review of systems and physical examination may be focused to the nature of the planned procedure and sedation but will, at minimum, include those elements necessary to document the patient’s neurologic, ventilatory, and cardiovascular status.
A separate re-evaluation of the patient’s status and readiness for the procedure and for sedation/analgesia will be performed and documented immediately prior to the start of the procedure and administration of the initial dosing of any sedative/analgesic drug(s). This may be incorporated into the “time-out” pre-procedure verification process. Elements marked with an asterisk (*) must be completed by an appropriately credentialed licensed independent practitioner (LIP).

2. **Anesthesia Consultation:** Patients who are American Society of Anesthesiologists (ASA) Class I, II, and some in class III may be candidates for procedural sedation/analgesia. Patients in ASA Classes IV or V present special challenges that require additional and individual consideration outside the guidelines provided by this document and will usually require the involvement of an individual trained in anesthesiology. Prior consultation with an anesthesiologist should be strongly considered for sedation/analgesia in patients who have a co-existing disease or other conditions that when combined with sedation may result in a high probability of immediate life-threatening complications. Practitioners are expected to consult with a member of the Anesthesiology Department when there is a question regarding the appropriate delivery of sedation/analgesia. (Within their scope of practice, emergency physicians provide airway management and other lifesaving procedures in ASA Class IV and V Emergency Department patients. This section is not intended to require consultation with an anesthesiologist prior to these emergent procedures.)

3. **Consent:** Consent shall be obtained from the patient or surrogate decision maker in accordance with the requirements of Medical Center Policy No. 0024. The standard **Consent for Medical/Surgical Procedures and/or Administration of Anesthesia or Sedation** form shall be used and placed in the patient’s permanent medical record. If it is known that similar sedation will be required on multiple occasions, one consent form may suffice if the patient’s risks do not change and the consent is obtained at least every six months.

4. **Dietary Status:** The use of sedation must be preceded by an evaluation of food and fluid intake. Food should generally be withheld for a minimum of six hours and clear liquid intake for a minimum of two hours, except as needed for administration of medication.

D. **PATIENT MANAGEMENT**

1. **Supervision:** Sedation/analgesia associated with medical procedures shall be performed by or under the immediate direction of a physician or dentist with documented competency. Licensed nurses may administer sedative/analgesic medications under supervision. A specified, responsible physician or dentist must be available within the immediate clinical area, unit, or clinic where sedation is being performed.

2. **Personnel Requirements:** The minimum number of available personnel for any procedure employing sedation/analgesia shall be two: the operator (person performing the procedure) and the monitor (an assistant trained to monitor appropriate physiologic parameters and to assist in any supportive or resuscitative measures required). These personnel will be available from the time of administration of sedation through recovery, or until the patient is transferred to equivalently qualified personnel performing recovery care. They may not have other duties or responsibilities that would prevent appropriate monitoring of the patient. Procedures requiring intended deep sedation will require the presence of a practitioner with skills in advanced airway management.

3. **Staff Competency:** Practitioners responsible for the therapeutic, diagnostic or surgical procedure and the administration of drugs for sedation shall be appropriately trained. The Medical Directors and Administrators and Managers of the care units or services performing the procedures shall certify that all practitioners administering sedation/analgesia are trained in airway management and the safe use of drugs causing sedation. Individuals performing or monitoring sedation/analgesia must be currently certified in basic life support for health care providers or its equivalent as confirmed by hospital policies and procedures. A BLS-HCP certified individual with additional training in airway management including use of ventilation bag and mask and the defibrillator shall be present in the clinic, treatment area, or unit in which procedural sedation is employed.
All clinicians engaged in procedural sedation will complete an institutional competency program including online training module(s) (adult, pediatric, or both depending upon practice population) and mentored experience during actual patient procedures. During the initial competency training, house staff, nurses, physician’s assistants and others will be monitored for a minimum of four (4) sedation procedures prior to performing independently. Operators directing sedation/analgesia will be observed by senior house staff or an Attending physician with documented competency; patient monitors by a competency-validated, experienced nurse or other licensed provider. Performance will be documented in department records. Privileges for the use of moderate and deep sedation/analgesia shall be subject to the customary reviews of the Medical Staff Credentialing Committee and the Allied Health Credentialing Committee and approval by the Medical Staff Executive Committee. Administration of sedation/analgesia by residents must be in accordance with their departmental housestaff supervision policy and under the direction of an appropriately credentialed attending physician.

Recognizing that sedation exists on a continuum, and that patients may unavoidably or unintentionally slip into a deeper-than-intended level of sedation or analgesia:

a. All providers (operators and monitors) of moderate/conscious sedation will be qualified to rescue patients from deep sedation and competent to manage a compromised airway and to provide adequate oxygenation and ventilation.

b. Intended deep sedation carries an increased risk for ventilatory and cardiovascular compromise and therefore requires the presence of a practitioner (physician, dentist or certified registered nurse anesthetist) with the ability to establish an artificial airway and provide full ventilatory and cardiovascular resuscitation. Providers with appropriate credentials who are permitted/credentialed to perform intended deep sedation will be qualified to rescue patients from general anesthesia and will be competent to manage an unstable cardiovascular system as well as a compromised airway and inadequate oxygenation and ventilation.

Training of all sedation providers (operators and monitors) will be consistent with the requirements in Medical Center Policy No. 0265.

c. Staff responsible for drug administration and patient monitoring will demonstrate knowledge of medications used for sedation/analgesia and will maintain competence in patient assessment and monitoring, CPR, and basic airway management.

4. **Drug Selection:** In view of the diversity of procedures, and of the age and drug sensitivity of individual patients, these guidelines cannot fully address the specific drugs or dosages to be used for individual circumstances. Drug choices and dosages must be individualized to the patient. The responsible physician/dentist selects appropriate medications to produce the intended degree of sedation/analgesia. Sedative/analgesic drugs and dosages will be titrated to achieve optimal patient comfort and outcomes with a minimal risk of untoward effects. Individual care centers and clinics where procedural sedation is used should prepare standard drug protocols for their service. The appropriate pediatric or adult sedative/analgesic drug charts should be used as references.

5. **Equipment:** The following minimum equipment must be present, in working order and ready for use:

In the room:
- Oxygen, including a positive pressure delivery system capable of administering a five liter flow rate for at least 60 minutes
- Suction
- Emergency airway equipment (bag and mask)
- Non-invasive blood pressure monitor or manual blood pressure cuff
- Pulse oximeter

In the immediate procedure area, clinic, or unit:
- Cardiac monitor*
- Emergency ventilation and drug boxes*
- A cardiac arrest cart with defibrillator

* The cardiac monitor and emergency ventilation and drug boxes must be in the room when providing intended deep sedation.
6. **Oxygen Supplementation:** All patients undergoing procedural sedation shall be provided augmented inspired oxygen during the procedure, as indicated by the duration of the procedure and the patient’s medical condition. Any supplemental oxygen use will be documented (percentage, route, duration) and monitoring of O$_2$ saturation will be performed.

7. **IV Access:** As sedation/analgesia is customarily provided by the use of intravenous drugs, and as resuscitation from untoward incidents during sedation/analgesia will require the use of intravenous drugs, patients undergoing sedation/analgesia should generally have a patent IV with continuous administration of IV fluids per physician’s order. Patent saline (or heparin) locks are acceptable for patients with contraindications to IV fluids. IV fluids for resuscitation shall be readily available. At the discretion of the responsible physician, IV access is not mandatory when oral, nasal, or rectal routes and dosages are used for sedation/analgesia and it is expected that only Minimal Sedation or Moderate/Conscious Sedation will be achieved.

8. **Patient Monitoring and Documentation:** The patient monitor must be able to observe and respond appropriately to the patient’s clinical condition and response to medication, including, at a minimum: a) changes in vital signs, level of consciousness, oxygen saturation; b) compromise of a patent airway; and c) adverse drug reaction. Minimum monitoring and documentation throughout the sedation period shall include:
   - Baseline blood pressure, pulse and respiratory rates, level of consciousness, O$_2$ saturation (on room air unless the patient arrives with O$_2$ or O$_2$ supplementation is used during the procedure), and Aldrete score.
   - Ongoing pulse rate, respiratory rate, O$_2$ saturation, and level of consciousness at least every five minutes and more frequently as indicated by the patient’s clinical needs and the expected effects of the drug(s) and dosage(s) in use.
   - Blood pressure will be monitored and documented minimally at pre- and post-procedure, and at intervals throughout the procedure as indicated by the patient’s clinical needs and the expected effects of the drug(s) and dosage(s) in use.
   - Electrocardiographic monitoring should be used whenever possible in patients undergoing intended deep sedation and also during moderate sedation in patients with significant cardiorespiratory disease or those who are undergoing procedures where dysrhythmias are anticipated.
   - A pain score will be obtained at the beginning and end, and at appropriate intervals during, any procedure anticipated to result in patient discomfort or pain. An age- and developmentally-appropriate pain scale will be used for this assessment.

The standard UVAHS Sedation/Analgesia Flowsheet (or Anesthetic Record or approved procedure flowsheet incorporating the following elements) shall be completed for all patients. Documentation must include:

- Informed consent signed
- Prior adverse drug reactions (including allergies)
- Presedation assessment including dietary status, airway exam, ASA classification, and baseline parameters as outlined above
- Plan of care, including intended level of sedation, selected drug(s), and any individual patient needs
- Patient re-evaluation immediately prior to start of procedure and administration of initial dosing of any sedative/analgesic drug(s)
- Premedication, time and effect
- Name, dose, route, time of all drugs given
- Oxygen, if delivered; liters/minute via mask or nasal route
- All monitoring parameters as outlined above
- Note of patient response to all drugs given
- Any adverse drug reactions or untoward/significant responses, including management and outcome
- Beginning and end time of procedure
- Type and amount of IV fluids (if administered)
- Name of responsible physician (physician of record)
- Signatures of operator and monitor
E. POST PROCEDURE

1. Monitoring: Patients who receive sedation/analgesia associated with medical procedures shall be monitored post-procedure in an area where continuous monitoring and resuscitation equipment is available. The ratio of patients to caregivers in the post-procedure observation area shall be appropriate to the patient's age, pre-procedure condition, procedure performed and amount of sedation/analgesia administered. Full hospital bed/stretching rails may be used until recovery and do not constitute patient restraint. The duration and frequency of monitoring should be individualized depending upon the level of sedation achieved, the overall condition of the patient, and the nature of the intervention for which sedation/analgesia was administered. The level of consciousness, vital signs, and oxygenation will be recorded at regular intervals. A patient may not leave the monitored area prior to full recovery unless accompanied by a qualified professional caregiver. In the event of post-procedure patient transfer, appropriate monitoring will continue until recovery criteria are met. The names of the transferring and receiving clinics/units and individuals responsible for patient monitoring will be documented in the patient’s medical record.

2. Recovery/Discharge/Transfer: Patients will be deemed recovered when specific criteria, indicating a return to safe physiologic and psychologic levels, have been achieved. Specifically, vital signs, O₂ saturation, airway protective reflexes, and level of consciousness will be stable and within pre-procedure limits. The Aldrete score will be completed at the beginning of the recovery period, and again before transfer or discharge from the post-procedure recovery area, and will be within 1 (one) point of the pre-sedation baseline score prior to patient discharge or transfer. No patient is to be discharged sooner than 30 minutes following a dose of any sedative or narcotic, nor sooner than 90 minutes following a dose of any antagonist to sedatives or narcotics such as flumazenil or naloxone.

Patient discharge must be at the discretion of an appropriately credentialed licensed independent practitioner. If the responsible individual is not personally present, the name of that individual must be recorded in the patient's medical record and discharge criteria approved by the medical staff must be rigorously applied to determine the patient's readiness for discharge.

Patients who have received sedation/analgesia or anesthesia in the outpatient setting will be discharged in the company of a responsible, designated adult. Patients will be informed of this requirement during pre-procedure evaluation. On any occasion when a designated accompanying adult is not available, staff will assist the patient in identifying and contacting an individual to perform this role. The patient will be informed that the post-sedation monitoring period will be extended if an accompanying adult is not present at the time of readiness for discharge. In the rare instance that this occurs, the patient will be monitored for a further period until the following criteria are achieved:

- At least 30 minutes have elapsed after completion of initial recovery period and return to pre-procedure status;
- Vital signs, O₂ saturation, airway protective reflexes, and level of consciousness remain at pre-procedure, baseline level;
- Pain type and level is assessed at pre-procedure baseline, or is anticipated post-procedure pain and a treatment plan has been addressed; and
- After review, the patient can repeat back from memory all elements of the discharge instructions.

Post-procedure written discharge instructions must be provided. Home discharge instructions should include specific post-sedation cautions and instructions in addition to post-procedure instructions. These should include diet and activity restrictions; restrictions on driving, making critical decisions or operating dangerous machinery; medications to be taken or avoided; possible side effects; conditions requiring notification of a physician and means of doing so; and return visits or other follow-up care needed.

F. QUALITY IMPROVEMENT PROCEDURES

Each unit/clinic/department in which sedation/analgesia/anesthesia is performed must regularly review patient care outcomes. Quality indicator thresholds should be identified and a clear corrective process established for when these thresholds have been exceeded. A Quality Report will be completed and
forwarded to the Quality and Performance Improvement Office if any of the pre-determined adverse outcome criteria are met. At minimum, outcomes criteria to be monitored will include the occurrence of any of the following:

- apnea for >15 seconds
- unplanned tracheal intubation or positive pressure ventilation
- oxygen desaturation for >90 seconds to <90% O2 Sat (or ≥ 8% O2 Sat drop from baseline)
- vomiting (for non-GI procedures)
- unexpected change in HR, BP, RR to 30% above or below baseline
- unplanned use of a reversal agent
- emergency anesthesia consultation after procedure begun

Review and analysis of the aggregate data will be forwarded to the Chair, Department of Anesthesiology, or designee, for review. Additionally, whenever a new agent or therapy for sedation/analgesia is introduced, there shall be a focused review of outcome events directed jointly by the Department of Anesthesiology and the Quality and Performance Improvement Program. Compliance with the policy and protocols governing the use of sedation/analgesia shall be monitored at intervals. The Patient Care Committee will regularly review the monitoring of these policies, their outcomes and compliance with these procedures.

APPENDIX A
American Society of Anesthesiologists
Physical Status Classification

Class I  A normally healthy patient. The patient has no organic, physiologic, biochemical, or psychiatric disturbance. The pathologic process to be treated is localized and does not entail a systemic disturbance.

Class II  A patient with mild to moderate systemic disease, caused either by the condition to be treated or by other pathophysiologic process.

Class III  A patient with severe systemic disease from whatever cause, even though it may not be possible to define the degree of disability with finality. Examples: limiting organic heart disease; diabetes with vascular complications; moderate to severe degrees of pulmonary insufficiency; obesity to the extent of greater than 50 per cent excess over ideal weight which may limit airway and respiratory management.

Class IV  A patient with severe systemic disorders that are a constant threat to life. Examples: cardiac failure, persistent anginal syndrome, advanced degrees of pulmonary, hepatic, renal, or endocrine insufficiency.

Class V  The moribund patient in whom a procedure is attempted in the hope that it may save life. Examples: profound shock, massive pulmonary embolus, ruptured blood vessels, cerebral trauma with increasing intracranial pressure.

Guidelines are general and cannot take into account all of the circumstances of a particular patient. Judgment regarding the propriety of using any specific procedure or guideline with a particular patient remains with that patient’s physician, nurse, or other health care professional, taking into account the individual circumstances presented by the patient.

Approved by the Patient Care Committee, March 2005
Approved by the Clinical Staff Executive Committee, June 2005

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