I. **SUBJECT:** Sedation and Analgesia during Diagnostic and Therapeutic Procedures by Non-anesthesiologists.

II. **SCOPE:** This policy applies to those patients receiving sedation/analgesia.

III. **PURPOSE:**

To provide specific recommendations for the safe care of adult patients, while minimizing the associated risks, during the delivery of IV medications for sedation/analgesia, and pediatric patients receiving medication by any route, by non-anesthesiologists during medical/surgical procedures.

**Sedation/analgesia provides two general types of benefit:**

1. Sedation/analgesia allows patients to tolerate unpleasant procedures by relieving anxiety, discomfort, or pain.

2. In children and uncooperative adults, sedation/analgesia may expedite the conduct of procedures that are not particularly uncomfortable but that require that the patient not move.

   Such procedures typically consist of...

   - endoscopic examinations;
   - vascular or cardiac catheterization;
   - radiologic studies such as magnetic resonance imaging, cat scan, and interventional procedures;
   - other procedures routinely performed in emergency department, in-patient or ambulatory setting.

**The guidelines specifically exclude the following:**

1. Minimal sedation (anxiolysis) entails minimal risk,
   a) minimal sedation include peripheral nerve blocks, local or topical anesthesia, and either less than 50% nitrous oxide (N2O) in oxygen with no other sedative or analgesic medications by any route, or
   b) a single, oral sedative or analgesic medication administered in doses appropriate for the unsupervised treatment of insomnia, anxiety, or pain.

2. Patients who are not undergoing a diagnostic or therapeutic procedure.
3. Situations where it is anticipated that the required sedation will eradicate the purposeful response to verbal commands or tactile stimulation.

4. Peri-operative management of patients undergoing general anesthesia or major conduction anesthesia (spinal or epidural/caudal blockade).

IV. DEFINITIONS:

“Sedation and analgesia” comprise a continuum of states ranging from minimal sedation (anxiolysis) through general anesthesia. Definitions of levels of sedation-analgesia, as developed and adopted by the ASA, are given below:

These Guidelines specifically apply to levels of sedation corresponding to moderate sedation (frequently called conscious sedation) and deep sedation.

**Minimal sedation (anxiolysis)** 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”)** A drug-induced depression of consciousness during which patients respond 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. CV function is usually maintained.

**Deep sedation/analgesia** A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilator function may be impaired. Patients may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. CV 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 may be 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. CV function may be impaired.

V. OBJECTIVES: To offer general guidelines for:

A. The use of sedating medications to facilitate patient comfort during the performance of diagnostic and therapeutic procedures, minimizing risk.

B. Patient assessment prior to sedation/analgesia.

C. Equipment availability and maintenance during the administration of such sedation.

D. Monitoring of patients during such sedation.

E. Availability, numbers, background, and training of professional personnel during the administration of such sedation.
F. Intra-procedure monitoring including time based recording of physiologic data.

G. The concurrent recording of the patient’s response to the medications given, documentation of the pre-procedure status of the patient, and fitness for release from medical supervision.

VI. PERSONNEL AND TRAINING:

The practitioner responsible for the care of the patient shall be appropriately trained.

A. The minimum number of available personnel shall be two: the operator (who performs the surgical or diagnostic procedure), and the monitor (an assistant trained to monitor appropriate physiologic variables and to assist in any support or resuscitation measures required), each assigned to their specific roles in patient care for the purpose of the planned procedures. Such personnel will be available to the patient from the time of administration of these sedative medications until recovery is judged adequate or recovery care is transferred to other trained personnel.

B. The director of the care unit or service performing the procedure shall ensure that all clinicians utilizing sedative medication are trained in airway management and trained in the safe use of these drugs.

1. “Trained in advanced airway management” means training is consistent with airway management goals and procedures used for Advanced Cardiac Life Support, including establishment of definitive airway and the application of positive-pressure ventilation. Practitioners are certified in BCLS and ACLS, or PALS.

2. “Trained in the safe use of these drugs” will be achieved through suitable educational programs. The education should address at a minimum the pharmacology of the agents that are administered as listed below:

   (1) potentiation of sedative induced respiratory depression by concomitantly administered opioids,

   (2) adequate time intervals between doses of sedative or analgesic agents avoiding cumulative overdose and

   (3) familiarity with the role of pharmacological antagonists for sedative and analgesic agents.

VII. MEDICATION ADMINISTRATION:

Sedative medication must be ordered by a credentialed practitioner and its administration, including additional doses must be supervised by that practitioner. Careful titration of drugs is mandatory. The practitioner may be directly involved in the procedure, or may delegate aspects of the procedure to other practitioners, i.e. specifically trained healthcare professionals.
VIII. PATIENT EVALUATION:

Clinicians utilizing sedation/analgesia must be familiar with sedation-oriented aspects of the patient’s medical history and how these might alter the patient’s response to sedation/analgesia. These include:

1. Abnormalities of the major organ systems;
2. previous adverse experience with sedation/analgesia as well as regional and general anesthesia;
3. drug allergies, current medications, and potential drug interactions;
4. time and nature of last oral intake; and
5. history of tobacco, alcohol, or substance use or abuse.

Patients presenting for sedation/analgesia must undergo a focused physical examination, including vital signs, auscultation of the heart and lungs, and evaluation of the airway. Pre-procedure laboratory testing should be guided by the patient’s underlying medical condition and the likelihood that the results will affect the management or sedation/analgesia. These evaluations must be confirmed immediately before sedation is initiated.

IX. CONSENT:

The patient or guardian must be informed about the risks of and alternatives to sedation as a component of the planned procedure. Documentation of consent should be placed in the medical record prior to the procedure.

X. EQUIPMENT AND MAINTENANCE:

A. A self-inflating positive-pressure oxygen (O₂) delivery system with various bag and mask sizes available.

B. Supplemental O₂ delivery via nasal prongs, non-rebreathing or rebreathing O₂ masks.

C. A source of suction (portable or wall).

D. An emergency cart or kit, and defibrillator must be readily available and should include the necessary drug (including opioid and diazepam specific antagonists) and equipment.

E. Equipment appropriate to the technique being used must be available in good working order immediately before, during, and after the procedure.

F. When inhalation sedation is provided with nitrous oxide (N₂O), it must be delivered with equipment that.

    1. Cannot provide a concentration of N₂O in excess of 50% inspired.
2. Will provide a maximum of 100% O\textsubscript{2} and never less than 21% O\textsubscript{2} concentrations.

3. Is outfitted with an O\textsubscript{2} analyzer to monitor the accuracy of delivered gases.

4. Is checked and calibrated annually, or according to a maintenance schedule established in conjunction with the hospital’s contracted biomedical engineering service.

G. All equipment shall be inventoried and maintained on a regularly scheduled basis, in conjunction with policies established by the hospital’s engineering department.

XI. MONITORING:

Whenever drugs for sedation/analgesia are administered, a trained individual will frequently monitor the patient.

A. Patients ventilatory and oxygen status and hemodynamic variables should be recorded at a frequency to be determined by the type and amount of medication administered as well as the length of the procedure and general condition of the patient.

At a minimum this should be:

1. Before the beginning of the procedure.

2. Following administration of sedative/analgesic agents.

3. At regular intervals during the procedure unless such monitoring interferes with procedure.

4. Upon completion of the procedure.

5. During initial recovery.

6. At time of discharge.

B. Patient response to verbal command must be monitored except in patients who are unable to respond appropriately (i.e. young children, verbally impaired). During procedures where a verbal response is not possible (i.e. upper endoscopy, oral surgery) other indication of consciousness should be monitored (i.e. “thumbs up”.)

C. Ventilation function must be continually monitored by observation and or auscultation. Monitoring of exhaled carbon dioxide should be considered for all patients receiving deep sedation and for patients whose ventilation cannot be directly observed during moderate sedation.

D. Oxygen saturation shall be monitored noninvasively on a continuous basis by pulse oximetry with appropriate alarms.

E. EKG should be used in all patients undergoing deep sedation and all patients undergoing moderate sedation with significant cardiovascular disease or where dysrhythmias are anticipated. Heart, respiratory rates and non-invasive blood pressure should be recorded and measured, at 5-minute intervals, during the procedure.
XII. RECOVERY AND DISCHARGE:

A. Principles for recovery:

1. All patients receiving sedation/analgesia should be monitored until appropriate recovery criteria are satisfied. The duration 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.

2. The recovery area should be equipped with appropriate monitoring and resuscitation equipment.

3. A trained individual should be in attendance until recovery/discharge criteria are fulfilled. An individual capable of establishing a patent airway and providing positive pressure ventilation should be immediately available.

4. Level of consciousness and vital signs (including frequency and depth of respiration in the absence of stimulation) should be monitored and recorded at regular intervals during recovery.

B. Guidelines for Discharge:

1. Patients should be alert and oriented; infants and patients whose mental status was initially abnormal should have returned to their baseline.

2. Vital signs should be stable and within acceptable limits.

3. Sufficient time (up to 2 hours) should have elapsed following the last administration of reversal agents (naloxone, flumazenil) to ensure that patients do not become resedated after reversal effects have worn off.

4. Outpatients should be discharged in the presence of a responsible adult who will accompany them home.

5. Outpatients should be provided with written instructions regarding post-procedure diet, medications, activities, and a phone number to be called in case of emergency.

6. In the absence of a Licensed Independent Practitioner (LIP), a patient may be discharged based on discharge criteria established by the Medical Staff as noted above.
XIII. PERFORMANCE IMPROVEMENT:

Each division and/or department providing sedation/analgesia will collect data on the performance of individual practitioner providing the service. The elements to be monitored include:

1) Death, cardiac or respiratory arrest
2) Intubation or emergency airway intervention requiring code team
3) Myocardial infarction periprocedure
4) Pulmonary edema periprocedure
5) Aspiration
6) Anaphylaxis or adverse drug reactions
7) Unplanned admission related to sedation
8) Drug errors

The data from each division and/or department will be presented to the Sedation/Analgesia PI Committee, at minimum quarterly.