COUNTY OF LOS ANGELES **DEPARTMENT OF HEALTH SERVICES**

HARBOR-UCLA MEDICAL CENTER

SUBJECT: PROCEDURAL SEDATION FOR THE NON-ANESTHESIA PROVIDER **POLICY NO. 355**

PURPOSE:

1. Standardizes the ordering, administration, monitoring and documentation of procedural sedation.
2. Establishes the qualifications of staff involved in the procedural sedation process in order to ensure the safe administration of sedatives and/or narcotics for patients undergoing procedures.
3. Distinguishes between the requirements for providing moderate (analgesia) and deep (anesthesia) sedation.
4. Establishes a structure to oversee procedural sedation at Harbor-UCLA.

DEFINITIONS:
Definitions of the four levels of sedation and anesthesia include:

Minimal sedation (anxiolysis)
A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilator 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. Cardiovascular 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 ventilatory function may be impaired. Patients may be required assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained;

EFFECTIVE DATE: 6/08 **SUPERSEDES:**
REVIEWED: 11/95, 3/96, 5/96, 10/96, 2/99, 1/00, 8/01, 1/02, 6/03, 12/04, 1/05, 5/07, 10/07, 8/09, 4/10, 8/11, 2/12, 7/13, 8/13, 3/14, 10/14, 11/17
REVISED: 11/95, 3/96, 5/96, 10/96, 2/99, 1/00, 8/01, 1/02, 1/05, 5/06, 5/07, 10/07, 8/09, 4/10, 8/11, 2/12, 7/13, 8/13, 3/14, 10/14, 11/17
REVIEWED COMMITTEE: Procedural Sedation Committee – 11/17

APPROVED BY:

Kim McKenzie, RN, MSN, CPHQ
Chief Executive Officer

Anish Mahajan, MD
Chief Medical Officer

Patricia Soltero Sanchez, RN, BSN, MAOM
Chief Nursing Officer

Signature(s) on File.

Anesthesia
Consists of general anesthesia and spinal or major regional anesthesia. It does not include local anesthesia. 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.

Procedural Sedation
Procedural sedation refers to the use of moderate or deep sedation for patients undergoing procedures, including, but not limited to, minor surgical or orthopedic procedures, diagnostic procedures, and/or elective cardioversion, in whom a change in consciousness is anticipated.

THIS POLICY DOES NOT APPLY TO THE USE OF MINIMAL SEDATION. This includes

- choral hydrate (PO or suppository) when used alone, at a dose $\leq$ 75 mg/kg and a total dose $\leq$ 1 gram
- midazolam when used alone at an oral dose $\leq$ 0.5 mg/kg, rectal dose < 0.4 mg/kg or intranasal dose < 0.3 mg/kg. This policy DOES apply to situations where INTRAVENOUS midazolam is being used alone or in combination with other medications for procedural sedation.

POLICY:
Harbor-UCLA Medical Center has establish a policy to standardizes the ordering, administration, monitoring and documentation of procedural sedation to ensure that qualify staff are involved in the procedural sedation process for safe practice.

THIS POLICY DOES NOT APPLY TO INTUBATED PATIENTS UNDERGOING PROCEDURES IN AN ICU SETTING OR PATIENTS UNDERGOING RAPID SEQUENCE INDUCTION (RSI) FOR EMERGENCY INTUBATION.

THIS POLICY DOES NOT APPLY TO QUALIFIED ANESTHESIA PROVIDER (MD/DO) ATTENDING ANESTHESIOLOGIST, RESIDENT IN AN ANESTHESIOLOGY TRAINING PROGRAM OR CERTIFIED REGISTERED NURSE ANESTHETIST (CRNA) WHO MAY PROVIDE SEDATION-LEVEL SERVICES ANYWHERE IN THE FACILITY AS PART OF ANESTHESIA SERVICES. PLEASE REFER TO DEPARTMENT OF ANESTHESIOLOGY POLICY.

1. Procedural sedation may only be ordered and administered by appropriately qualified staff, and only in authorized locations. Patients receiving procedural sedation may only be monitored by appropriately qualified staff. The practitioner who monitors patients receiving procedural sedation must be different from the individual who performs the diagnostic or therapeutic procedure.
    a. ***MODERATE*** procedural sedation requires at least two staff: 1) an authorized ***operator*** who performs the procedure, and 2) a ***monitor*** (an authorized Physician, Dentist, Nurse Practitioner, Physician Assistant, or Registered Nurse) who is responsible for monitoring the appropriate

physiologic parameters and for assisting in any supportive or resuscitative measures that may be required. The monitor, who may also administer the sedation, shall be trained in the pharmacology of procedural sedation medications and shall have no other responsibilities that would interfere with drug administration and/or the monitoring of the patient while the patient's consciousness is diminished. This individual must be present at the patient's bedside at all times once the procedural sedation is initiated and must remain available until the procedure is completed (or no further sedative medications are given). The patient must be monitored by an RN until his/her status has returned to baseline. Either the operator or monitor may order the procedural sedation drugs provided that he/she is authorized to do so (see below).

b. ***DEEP*** procedural sedation also requires at least two staff: an operator and a monitor (who may also administer the sedation). Any professional who orders and monitors DEEP sedation must be dedicated to that task. Therefore, the non-anesthesiologist sedation practitioner who orders and monitors **DEEP** sedation must be different from the individual who performs the diagnostic or therapeutic procedure.

   When **DEEP** sedation is intended, there is a significant risk that patients may slip into a state of general anesthesia from which they cannot be aroused by painful or repeated stimulation. Therefore, individuals with privileges or authorization to order **DEEP** sedation must demonstrate their ability to (1) recognize that a patient has entered a state of general anesthesia and (2) maintain a patient's vital functions until the patient has been returned to an appropriate level of sedation. Only physicians and other practitioners specifically privileged by the Medical Staff and/or qualified by education, training, licensure and demonstrated competence to do so may order and/or directly supervise the administration of **DEEP** sedation (please see authorization criteria below, section I, C). Only physicians and other practitioners specifically privileged by the Medical Staff and/or qualified by education, training, licensure and demonstrated competence to order **DEEP** sedation may monitor patients receiving **DEEP** sedation. RNs, NPs and PAs are not authorized to monitor patients receiving **DEEP** sedation.

c. Documentation of informed consent for the procedure and the sedation, the appropriate pre-sedation assessment, the administration of the sedation and the monitoring of the patient must be documented in the electronic medical record.

2. An interdisciplinary Procedural Sedation Oversight Committee, chaired by a member of the Department of Anesthesiology, shall have the responsibility for oversight of procedural sedation.

PROCEDURE:

1. Authorization

a. Authorized Location for Administration of Procedural Sedation Drugs (See Appendix A)

b. Moderate Sedation

i. Physicians (Attending or licensed and **PRIVILEGED** Fellow/Chief Resident) or Dentists, Nurse Practitioners, or Physician Assistants who are:

- Aware of the differences between moderate and deep sedation and their potential

complications.

- Knowledgeable about the pharmacology of the approved procedural sedation drugs.
- Trained in proper use of the approved procedural sedation drugs.
- Proficient in providing age-appropriate monitoring and age appropriate bag-valve-mask ventilation.
- Able to manage complications of sedation as well as able to rescue patients at whatever level of sedation or anesthesia is achieved either intentionally or unintentionally, e.g. when the patient slips from moderate to deep sedation.

ii. The Physician or Dentist who orders **MODERATE** sedation may be either a **PRIVILEGED** Fellow/Chief Resident physician, Attending Physician, or Dentist.

- The Fellow/Chief Resident, Attending Physician, or Dentist must be privileged for MODERATE sedation.
- Has competency in rescuing patients who fall into deeper levels of sedation than is planned, including competency in advanced life support.

iii. The Nurse Practitioner or Physician Assistant

- Has competency in procedural sedation as demonstrated by compliance with the qualifications noted above, as determined by the individual's Department, and subsequently approved by the Interdisciplinary Practice Committee.
- Has competency in rescuing patients who fall into deeper levels of sedation than is planned, including competency in advanced life support. Individuals Authorized to Monitor Patients under **MODERATE** Procedural Sedation.

iv. Physicians, Dentists, Nurse Practitioners, Physician Assistants, or Registered Nurses who are:

- Capable of providing advanced life support.
- Familiar with the pharmacology of the medications being used and reversal agents, including appropriate routes of administration and possible untoward effects.
- Able to recognize complications associated with administration of procedural sedation medications and to initiate age-appropriate interventions.
- Familiar with the basic principles of oxygenation and use of oxygen delivery devices.
- Able to establish a patent airway and apply age-appropriate bag-valve mask ventilation.

v. The Physician or Dentist may be either an Attending or a Resident as follows:

- An Attending Physician or Dentist privileged for **MODERATE** procedural sedation as described above in Procedures I, B, 1, b.
- A Resident Physician or Dentist (first year or greater) with current advanced life support certification who has successfully completed training and has demonstrated clinical competency in age appropriate **MODERATE** procedural sedation.

vi. A Nurse Practitioner, or Physician Assistant with competency in **MODERATE** procedural sedation as described above in I.B.1.c. Alternatively, a Nurse Practitioner or Physician Assistant may serve as a monitor if there is current advanced cardiac life support certification (ACLS) or equivalent (i.e. pediatric advanced life support (PALS))

and an age appropriate clinical competency on **MODERATE** procedural sedation has been successfully completed.

vii. A Licensed Registered Nurse (RN) who has a current advanced cardiac life support certification (ACLS) or equivalent (i.e. pediatric advanced life support (PALS)) and has successfully completed an age appropriate clinical competency on **MODERATE** procedural sedation.

c. **Deep Sedation**

i. **Individuals Authorized to Order DEEP Procedural Sedation Drugs**

- Non-Anesthesiologist Physicians (Attendings, or licensed and PRIVILEGED Fellows/Chief Residents), Dentists or Oral Surgeons who will have completed a Procedural Sedation Oversight Committee approved structured training program in:
- The safe administration of sedative and analgesic drugs used to establish a level of **DEEP** sedation, and rescue of patients who exhibit adverse physiologic consequences of a deeper-than-intended level of sedation.
- A knowledge-based test to objectively demonstrate the knowledge of concepts required to obtain privileges.
- Has received advanced training consistent with Advanced Cardiac Life Support Certification or equivalent (i.e. Pediatric Advanced Life Support (PALS)) and/or has Board Certification/eligibility in adult/pediatric Emergency Medicine and/or adult/pediatric Critical Care Medicine.

ii. The Physician or Dentist who orders **DEEP** sedation may be either an Attending or licensed and **PRIVILEGED** Fellow/Chief Resident physician as follows:

- Attending or Fellow/Chief Resident Physician or Dentist. The Attending or Fellow/Chief Resident Physician or Dentist must meet the criteria indicated in section I, C, 1, a above and have been credentialed and privileged by their respective departments for both moderate and deep sedation.
- Has competency in rescuing patients who fall into deeper levels of sedation than is planned, including competency in endotracheal intubation and advanced life support.

iii. **Individuals Authorized to Monitor Patients Under DEEP Procedural Sedation**

- Only the individuals (as defined above in I, C, 1, b) who are privileged and/or authorized to order **DEEP** sedation can also monitor patients receiving **DEEP** sedation. These are:
- Non-anesthesiologist physician M.D.'s. or D.O.'s (Attendings, or licensed and **PRIVILEGED** Fellows/Chief Residents)
  - Dentists
  - Oral surgeons
  - Any professional who orders and monitors **DEEP** sedation must be dedicated to that task. Therefore, the non-anesthesiologist sedation practitioner who orders and monitors **DEEP** sedation must be different from the individual performing the diagnostic or therapeutic procedure.

iv. **Individuals Authorized to Administer Procedural Sedation Medications**

The following individuals may administer procedural sedation medications upon order by an authorized individual, provided this is in accordance with Hospital and his/her Departmental policies and the patient is being monitored by an authorized individual.

- Any individual authorized to ***order*** procedural sedation medications;
- Any individual authorized to ***monitor*** patients under procedural sedation;
- Any RN, even if he/she is not serving as the monitor;
- Any physician, dentist or physician assistant, even if he/she is not serving as the monitor;

d. **Administration of Procedural Sedation Drug(s)**

i. **Pre-requisites**

- Confirm that informed consent for procedural sedation has been obtained prior to the administration of sedatives. The signed consent form must indicate the risks, benefits of and alternatives to the sedation. If informed consent for procedural sedation cannot be obtained, the reason shall be noted on the same form.
- ***Pre-sedation assessment*:** A history and physical examination (H&P) pertinent to both the procedure being performed and the sedation being administered must be performed within 30 days prior to the procedure and documented in the patient's medical record. If applicable, there should be documentation that the patient was re-examined and reassessed within 24 hours of the procedure with any interim changes noted in the medical record. An airway assessment is to be performed as part of the assessment, prior to the procedure. Evaluation of the heart, lungs and other pertinent components of the physical exam should also be performed and documented prior to the procedure. For patients in whom ventilation is anticipated to be difficult, consideration shall be given to consultation with an anesthesiology provider. A "Time Out" will be performed immediately prior to the procedure to verify the correct patient, procedure, and site.
- Immediately prior to the initiation of sedation, the patient's baseline values of blood pressure, oxygen saturation, respiration rate, and level of consciousness will be assessed.
- Communicate effectively with patient or parent and family/significant others concerning the how and why's of the procedure and confirm the patient has a responsible adult to accompany him/her home as appropriate.
- All medications, medication containers (e.g. syringes, medicine cups, basins) or other solutions on and off the sterile field in perioperative and other procedural settings must be labeled. Note 1: Pre-labeling medication and solution containers is prohibited. Labeling is part of the medication management preparation process and is done at the same time the medication or solution is prepared. Note 2: Medications that are transferred from one container to another and used immediately do not need to be labeled, e.g., transfer of medication from a vial to a syringe for immediate administration.
    - Medications and solutions both on and off the sterile field must be labeled even if there is only one medication being used.

- Labeling occurs when any medication or solution is transferred from the original packaging to another container.
- Labels must include the name, strength, and amount (if not apparent from the container) of the medication or solution, the expiration date when not used within 24 hours and expiration time when expiration occurs in less than 24 hours of the person preparing the label.
- All labels must be verified both verbally and visually by two qualified individuals when the person preparing the medication is not the person administering the medication. **No more than one medication or solution is labeled at a time, e.g., if two drugs are being prepared for a procedure the first drug must be transferred and labeled before proceeding with the transfer and labeling of the second drug.**
- Any medication or solution found unlabeled must be immediately discarded.
- All original containers from medications or solutions must remain available for reference in the perioperative or other procedural area until the conclusion of the procedure. All labeled containers on the sterile field must be discarded at the conclusion of the procedure.
- At shift change or break relief all medications and solutions both on and off the sterile field and their labels must be reviewed by entering and exiting personnel.

- Recommended dietary precautions:
  - Elective Procedures for Adults: The patient should be NPO for 8 hours before administration of procedural sedation. However, clear liquids may be taken up to 2 hours prior to administration of procedural sedation, if necessary.
  - Elective Procedures for Pediatrics: NPO guidelines include no clear liquids in the 2 hours prior to procedure. Patients younger than 6 months should not have taken formula nor breast milk in the 4 hours prior to procedure. Patients aged 6 months to 36 months should not have taken breast milk in the 4 hours prior to procedure nor formula in the 6 hours prior to procedure.
  - Emergent Procedures: If proper fasting has not been assured, the increased risks of sedation must be carefully weighed against its benefits. The lightest effective sedation should be used, and the necessary precautions taken.
- All equipment shall be checked for proper functioning prior to the procedure. Equipment must be suitable for the age and size of the patient being treated. The following age appropriate equipment must be readily available throughout the procedure:
  - Oxygen supply.
  - Resuscitation bag and mask.
  - Suction apparatus with appropriate suction catheters.
  - Intubation tray with appropriate sized endotracheal tube, stylets, and

functioning laryngoscope.
- Pulse oximeter.
- Non-invasive blood pressure measurement device (unless arterial line is in place and functioning properly).
- Crash cart with cardiac monitor and defibrillator.
- Appropriate reversal agent (See Appendix C).

- The patient shall be connected to a:
  - Functioning pulse oximeter.
  - Blood pressure cuff, or have an arterial line.
  - Functioning cardiac monitor.

ii. **General Procedures for Administration of Procedural Sedation Drugs(s)**

- All patients must have a patent IV established (Exception: IM Ketamine or Nitrous Oxide for sedation)
- Patient's head, neck, and chest must be visible at all times.
- The provider will enter the Procedural Sedation Order Set.
- The RN will initiate the Procedural Sedation Order set and verify the provider privileges and all required procedure/sedation consents and H&P. After the procedure, a safe and controlled environment (i.e. side rails upright and locked, gurney locked) shall be provided until the patient is conscious and alert.

e. Monitoring of Patients during Administration of the Procedural Sedation Drug(s)

i. **General Monitoring Procedures**

- Vital signs including heart rate, respiratory rate, blood pressure, and pulse oximeter, and level of consciousness will be obtained prior to procedural sedation.
- Oxygen saturation, vital signs including heart rate, blood pressure, and respiratory rate, as well as level of consciousness, will be continuously monitored and documented in the electronic medical record every 5 minutes once procedural sedation has begun, every 5 minutes during the procedure and then every 15 minutes after completion of the procedure until recovery criteria are met.
- The authorized individual assigned to monitor the patient shall notify the individual ordering the procedural medication in the event the patient experiences any of the following:
  - Obstructed airway
  - Hypoventilation
  - Decreased oxygen saturation
  - Decreased blood pressure
  - Bradycardia
  - Tachycardia

f. Reversal Agents (See Appendix B)

g. Recovery and Discharge

i. **Recovery**

- Oxygen saturation, vital signs including heart rate, blood pressure, and respiratory rate, as well as level of consciousness, will be continuously monitored and

documented in the electronic medical record every 15 minutes after the procedure is concluded until recovery criteria are met.

- Recovery criteria:
  - Blood pressure, heart rate, airway patency, and respiratory rate are stable and have returned to baseline.
  - The patient is easily aroused (see re-sedation effect).
  - The patient can talk coherently (if age-appropriate).

- Vital signs including heart rate, respiratory rate, blood pressure, and pulse oximeter, as well as neurological status will be obtained after recovery criteria are met.

ii. **Discharge**

Patients receiving procedural sedation in a clinic or diagnostic area will not be released from those areas until the patient meets the recovery and/or discharge criteria as specified on the Aldrete #1 Assessment section of the electronic medical record procedural sedation form (discharge check lists for the downtime Procedural sedation Record, Form HH751)

- Patients who have received procedural sedation as outpatients (including patients in the emergency room) are discharged in the company of an individual who accepts responsibility for the patient.
- In case of an emergency procedure that cannot be delayed, in the unusual situation that a responsible adult cannot be located to accompany the patient (e.g. homeless patient), attempts to locate a responsible adult will be made after the procedure is complete. If no responsible adult can be found, the patient will only be discharged after they have met post procedural sedation discharge criteria and have returned to their baseline activities of daily living. If the recovery period is prolonged, the patient will continue to be observed until they have returned to their baseline activities of daily living.
- The individual in charge of the procedure is responsible for discharging the patient after completion of the procedure, and shall be available until this is achieved.
- If the patient is to be immediately discharged, the individual in charge of the procedure or the individual monitoring the patient during the procedure shall:
  - Review printed Patient Discharge/After Care Instructions with patient, or parent and family/significant other. These instructions should include but are not limited to the importance of not driving for 24 hours after procedural sedation.
  - Document the response of the patient, or parent and family/significant other to that education.
- ALL patients undergoing deep sedation must have a post sedation evaluation performed within 48 hours of their procedure. This evaluation must include respiratory function, cardiovascular function, mental status, temperature, pain, nausea/vomiting, and postoperative hydration.

h. Documentation

i. **Informed consent**

Informed consent for procedural sedation shall be obtained by an authorized individual prior to administration of procedural sedation medication(s). Documentation that the patient has agreed to procedural sedation is on the consent form for the procedure being performed, while the information given to the patient is documented in the electronic medical record. If informed consent cannot be obtained, the reason shall be documented on the consent form for the procedure. Ongoing documentation of the procedure, patient responses, and care provider interventions will be documented in the electronic medical record.

ii. **General Documentation Procedures**

- The individual documenting vital signs and level of consciousness on the Procedural Sedation Record can be a different individual than the person monitoring the patient. In the case of deep sedation, an RN, NP or PA may document the vital signs but monitoring of the patient must be performed by an authorized individual as delineated in Procedures C.2.
- Vital Signs, including level of consciousness (LOC) and oxygen saturation, will be monitored and recorded every 5 minutes after procedural sedation has begun and during the procedure, then every 15 minutes after the procedure until recovery criteria are met.
- Recovery Phase: The patient's vital signs, and LOC will be reassessed and documented after the procedure every 15 minutes until the patient meets the recovery criteria.
- Procedural Sedation Reports will be generated electronically and will be reviewed by the Procedural Sedation Oversight Committee on a regular basis.

iii. Downtime **Instructions for use of the Procedural Sedation Documentation Record** (Form HH751)

- Front Page:
  - Patient Information: Fill in blanks with appropriate information requested. Indicate appropriate level of sedation **PLANNED** (moderate vs. deep)
  - Practitioner Documentation: Check appropriate box(s). The Physician/ Dentist/Nurse Practitioner/Physician Assistant shall sign, complete Identification Number, date and time , where indicated.
  - Indicate patient's ASA classification
  - Complete patient assessment
  - Pre-Procedure preparation: Check the appropriate box(es).
  - Procedure Information: Fill in the blanks with the appropriate information requested.
  - Patient identification: Affix a patient identification label to the right lower portion of the Procedural Sedation Record.
  - If an identified complication occurs during the procedure, indicate this with a check mark and create a Safety Intelligence (SI) event.

- Second Page:
  - Vital Signs: Fill in the blanks with the time and corresponding oxygen saturation, level of consciousness (utilizing the LOC legend located on the Procedural Sedation Documentation Record), heart rate, blood pressure, respiratory rate every 5 minutes after procedural sedation has begun and during the procedure, then every 15 minutes after the procedure until recovery criteria are met**.** Baseline of vital signs will be taken immediately prior to the initiation of procedural sedation.
  - Medication Administration: Complete the name of the individual who administers the medication. Fill in the time and name of medication, dose, route and fluids administered in appropriate box.
  - Signature Box:
  - Physician/Dentist or other authorized individual performing the procedure that requires procedural sedation will sign as "Physician/Dentist in Charge"
  - Authorized Physician, Dentist, Nurse Practitioner, Physician Assistant, or Registered Nurse monitoring the patient will sign as "Person Monitoring".
  - A post-**DEEP SEDATION** note must be filled out within 48 hours of the procedure.
  - Recovery criteria shall be documented on all patients requiring procedural sedation.
  - Check the appropriate boxes and fill in the time recovery criteria met.
  - The person validating that recovery criteria was met shall sign in the space provided.
  - Discharge checklist shall be documented only on outpatients.
  - Fill in the appropriate blanks and check the appropriate boxes and fill in the time recovery criteria met.
  - Mode of Discharge: Indicate mode of transportation. Fill in the signature of the nurse discharging the patient.
  - Ensure that name of responsible adult accompanying patient home is entered when applicable.
  - Discharge Checklist:
  - Patient Identification: Stamp with the patient's address-o-graph card.
- After the Procedural Sedation Record (Form HH751) is completed, the original documentation should be placed into the patient's medical record, the copy should be sent to the Procedural Sedation Oversight Committee (Department of Anesthesiology - Box 10). These documents may be sent to an individual department's representative on the Procedural Sedation Oversight Committee for review first. This representative will then report to the Procedural Sedation Oversight Committee Chair.

i. Oversight

i. **A multi-disciplinary Procedural Sedation Oversight Committee**

- This committee will be composed of members of various departments within Harbor-UCLA and led by a member of the Department of Anesthesia. The Committee is responsible for the oversight of procedural sedation (Moderate and Deep) throughout the Medical Center and will perform the following duties:
    - Propose, develop, and oversee hospital wide procedures and policies as they relate to procedural sedation.
    - Oversee and review actions related to procedural sedation proposed by other committees, both those within the Institution and within DHS, analyze how these will impact patient care, and make appropriate recommendations.
    - Review and approve resident and faculty training for procedural sedation.
    - Review and approve the criteria for privileging procedural sedation.
    - Monitor procedural sedation in the Medical Center, including any complications related to procedural sedation, and make recommendations as appropriate.
    - Provide on-going, regular feedback to those services performing procedural sedation.
    - Analyze specific procedural sedation patient safety issues brought to the Committee's attention via Safety Intelligence Reports, and other reporting methodologies, and share findings with other Medical Staff Committees, including the Department of Anesthesiology Quality Improvement Committee.
- Specific events that will be reviewed will include but will not be limited to:
    - Code blue or code white cases relating to sedation.
    - Unintentional/Unanticipated over sedation that requires any airway manipulation:
        - Nasal/oral airway
        - Bag mask ventilation
    - Unintentional/Unanticipated use of any reversal agents:
        - Naloxone
        - Flumazenil
    - Significant hemodynamic instability in the patient that is a result of over sedation or hypoventilation.
    - Significant decrease in oxygen saturation.
    - Unintentional/Unanticipated loss of consciousness (inability to respond to verbal commands).
    - Aspiration as a result of over sedation.
    - Allergic reaction to administered medications.

ii. **Meetings**

- The Procedural Sedation Oversight Committee shall meet at least once quarterly, shall maintain a permanent record of its proceedings and actions, and shall submit meeting minutes to the Medical Center CMO, and periodic reports (at least annually) to the Clinical Data Monitoring Panel on its activities.

- The Committee will also provide reports regarding the complications of procedural sedation to the Department of Anesthesiology Quality Improvement Committee no less than bi-monthly**.**

Appendix A: Authorized Locations for the Administration of Procedural Sedation Drugs*

- Adult ICUs, PCU's, Step Down Units
- Cath Lab
- CORE Unit
- Heart Station* (not authorized for ketamine)
- Emergency Department and Pediatric Emergency Department
- Endoscopy Suite
- Endovascular Room (PCDC)
- General Clinical Research Center (GCRC)
- OB/GYN Urgent Care* (not authorized for ketamine)
- OB/Labor & Delivery
- Operating Room
- Oral and Maxillofacial Surgery/Dental Clinics
- Pediatrics Clinic
- Pediatric/Neonatal ICUs
- Pediatric Ward Treatment Room
- Radiology (including Imaging Center)

Note: Nursing wards are not authorized locations for performance of procedural sedation.

Note: In the case of a life-threatening emergency, procedural sedation may be used in other areas not specifically listed.

Appendix B: Reversal Agents

A. Naloxone (Narcan)

1. Indications/Actions: Indicated for the complete or partial reversal of opioid effect, including respiratory depression.
2. Dose and Administration:
   - Adult: 0.4-2mg IV, IM, SC, ETT, may repeat up to 10 mg as needed.
   - Children: 0.1 mg/kg up to the adult dose IV, IM, SC, ETT
3. Precautions: Because naloxone has a shorter half-life than most narcotics used in procedural sedation, the patient must be monitored for re-sedation (up to 2 hours).

B. Flumazenil (Romazicon)

1. Indications/Actions: Flumazenil is indicated for the complete or partial reversal of the actions of benzodiazepines. If the oxygen saturation declines, the practitioner should

consider use of flumazenil. The first priority, however, is to reposition the airway and administer oxygen.

2. Dose & Administration:
   - Titrate to effect 0.2mg (2ml) IV over 15 seconds. If the desired level of consciousness is not obtained in 45 seconds, a further titrated dose of 0.2mg may be repeated (up to 4 times, to a maximum dose of 1mg).
   - Appropriate measures to secure the airway shall be taken while flumazenil is being administered.

   Note: A lower dose may be used in children. Start with 0.1mg (1ml) depending on the age and weight.

3. Precautions:
   Flumazenil may be expected to improve the alertness of patients recovering from a procedure involving sedation with benzodiazepines, but should not be substituted for an adequate period of post-procedure monitoring. The availability of flumazenil does not reduce the risks associated with the use of large doses of benzodiazepine for sedation. Monitor the patient for re-sedation (up to 2 hours).

Appendix C: **Downtime** Procedural Sedation Record (Form HH751) (***SEE APPENDIX C***)

Reviewed and Approved by:
Medical Executive Committee on 11/2017

_____

Brant Putnam, M.D.
Professional Staff Association, President

Signature(s) on File.