

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

| CATEGORY: Provision of Care | EFFECTIVE DATE: 6/08 | | |
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| POLICY CONTACT: David Cho, MD | UPDATE/REVISION DATE: 4/23 | | |
| REVIEWED BY COMMITTEE(S): Procedural Sedation Committee | | | |

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 Medical Center.

DEFINITIONS:

Levels of sedation and anesthesia include:

1. 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.

2. 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.

3. Moderate sedation (formerly "conscious sedation")

A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. This includes when sedatives are given in combination with analgesics to perform a procedure. No interventions are required to maintain

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Chief Nursing Officer



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

a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

4. Deep sedation

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 require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. Ketamine, propofol, etomidate and barbiturates are considered deep sedation agents at any dose or route of administration when used for sedation purposes.

5. 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.

POLICY:

- 1. Harbor-UCLA Medical Center has established a policy to standardize the ordering, administration, monitoring and documentation of procedural sedation to ensure that qualified staff are involved in the procedural sedation process for safe practice.
- 2. 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.
- 3. An interdisciplinary Procedural Sedation Oversight Committee, chaired by a member of the Department of Anesthesiology, shall have the responsibility for oversight of procedural sedation.

THIS POLICY DOES NOT APPLY TO:

- 1. Intubated patients undergoing procedures in an ICU setting or patients undergoing induction for intubations
- 2. Mechanically ventilated patients who are receiving moderate or deep sedating drugs, continuously or intermittently for the purpose of continuous sedation.
- 3. Use of deep sedating agents for pain management.
- 4. Use of minimal sedation (anxiolysis), this includes: Midazolam when used alone at an oral dose ≤ 0.5 mg/kg, rectal dose < 0.4 mg/kg or intranasal dose < 0.3 mg/kg. This policy DOES apply to situations



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

where INTRAVENOUS midazolam is being used alone at any dose or in combination with other medications for procedural sedation.

5. Qualified anesthesia providers, including attending anesthesiologists, 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.

PROCEDURE:

- 1. Authorized Location:
 - a. See **Appendix A** for Authorized Location for Administration of Procedural Sedation Drugs.
- 2. **General Preparation** for Procedural Sedation
 - a. <u>Informed consent:</u> for procedural sedation must be obtained by an individual authorized to order or monitor procedural sedation prior to the administration of sedatives. Informed consent must indicate the risks, benefits of, and alternatives to procedural sedation. Informed consent must be documented in the medical record according to Hospital **Policy 604** (a)(b) and (c). If informed consent for procedural sedation cannot be obtained, the reason shall be documented in the medical record and emergency consent must be attested to by the performing provider according to hospital policy.
 - b. 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, including mallampati score (unless not feasible), is to be performed and documented 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. Overall health status of the patient should be assessed and documented including ASA classification when appropriate. 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.
 - c. Recommended Dietary Precautions (refer to Nutrition guidelines for further definitions):
 - i. <u>Elective Procedures for Adults:</u> 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.
 - ii. 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.
 - iii. <u>Emergent Procedures:</u> 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.
 - d. The ordering provider will enter orders for procedural sedation medications using a Procedural Sedation Order Set.



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

- e. The RN will initiate the Procedural Sedation Order set and verify the provider privileges and all required procedure/sedation consents and H&P.
- f. The RN will communicate effectively with patient or parent and family/significant others to confirm their understanding of the how and why's of the procedure, and confirm the patient has a responsible adult to accompany him/her home as appropriate prior to the procedure.
- g. All patients must have a patent IV established (Exception: IM Ketamine or Nitrous Oxide for sedation).
- h. 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.

3. Procedural Sedation Medication Handling

- a. Refer to Hospital **Policy 399** (Labeling of Medications on and off the Sterile Field in Perioperative and Other Procedural Settings) for labeling procedures.
- b. 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.

4. Equipment:

- a. 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 appropriately sized endotracheal tube, stylets, and functioning laryngoscope
 - Pulse oximeter
 - Continuous cardiac monitor
 - Non-invasive blood pressure measurement device (unless arterial line is in place and functioning properly)
 - Crash cart with cardiac monitor and defibrillator
 - Appropriate reversal agents for sedation medications immediately available and/or ordered

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

- a. The patient shall be connected to a:
 - Functioning pulse oximeter
 - Blood pressure cuff or an arterial line pressure monitor
 - Functioning cardiac monitor
 - End-tidal CO2 monitoring should be used when possible
- b. Baseline vital signs including heart rate, respiratory rate, blood pressure, and pulse oximeter, and level of consciousness will be obtained prior to procedural sedation.
- c. 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.
- d. The patient's head, neck, and chest must be visible to the monitor at all times throughout the procedure.



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

- e. 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

6. Reversal Agents (See Appendix B)

7. Recovery

- a. 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.
- b. After the procedure, a safe and controlled environment (e.g., side rails upright and locked, gurney locked) shall be provided until the patient recovery criteria are met.
- c. 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).
- d. 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.

8. Discharge

- a. 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) (**Appendix C**).
 - Patients who have received procedural sedation as outpatients (including patients in the emergency room) are to be discharged in the company of an adult 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 been fully assessed by the provider and 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.
- b. The individual in charge of the procedure is responsible for discharging the patient after completion of the procedure and shall remain 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:



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

- 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.
- o Document the response of the patient, or parent and family/significant other to that education.
- c. 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.

ORDERING, MONITORING, AND ADMINISTRATION REQUIREMENTS

MODERATE SEDATION:

Moderate procedural sedation requires at least two staff to be present and dedicated throughout the procedure:

- an authorized *operator* who performs the procedure (may also order moderate sedation medications if qualified to do so, but they cannot monitor the patient if they are performing the procedure)
- a monitor who is responsible for monitoring the appropriate physiologic parameters and for assisting in
 any supportive or resuscitative measures that may be required. The monitor can be the ordering
 provider, so long as they are not performing the procedure, or a separate individual authorized to
 monitor moderate sedation.
- 1. Individuals Authorized to **ORDER MODERATE** Procedural Sedation:
 - a. Fellow/Chief Resident, Attending Physician, or Dentist who is privileged for MODERATE sedation.
 - Nurse Practitioner (NP) or Physician Assistant (PA) who has competency in procedural sedation as demonstrated by compliance with the qualifications noted, as determined by the individual's Department, and subsequently approved by the Interdisciplinary Practice Committee.
 - c. Either the operator or monitor may **order** the procedural sedation drugs provided that they are authorized to do so.
 - d. The sedation medications may be ordered by another provider who is under the direct supervision of an authorized individual.
- 2. Any individual authorized to **ORDER** moderate sedation must:
 - a. Be aware of the differences between moderate and deep sedation and their potential complications.
 - b. Be knowledgeable about the pharmacology of the approved procedural sedation drugs.
 - c. Be trained in proper use of the approved procedural sedation drugs.
 - d. Be proficient in providing age-appropriate monitoring and age-appropriate bag-valve-mask ventilation.
 - e. Be 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). This includes competency in advanced life support.
 - f. Have current advanced cardiac life support certification (ACLS) or equivalent (e.g., pediatrics advanced life support (PALS) and/or has Board Certification/eligibility in adult/pediatric Emergency Medicine and/or adult/pediatric Critical Care Medicine. This certification will be needed at the time of initial credentialing and/or at subsequent renewal of privileges.
 - g. Have reviewed the LACDHS Moderate Sedation Module and successfully completed the moderate sedation post-test (with a 100% score). This will be completed to each subsequent renewal of



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

privileges.

- Record of successful completion of the module and test will be kept by the authorizing department/division and be available for review by the credentialing advisory subcommittee (CAS) and/or Professional Staff Association (PSA) governing body.
- 3. Individuals Authorized to MONITOR MODERATE Procedural Sedation:
 - a. A Fellow/Chief Resident, Attending Physician, or Dentist who is privileged to **ORDER MODERATE** sedation (including necessary training and life support certification -2f).
 - 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 ageappropriate MODERATE procedural sedation.
 - c. A Nurse Practitioner (NP) or Physician Assistant (PA) who is privileged to **ORDER MODERATE** procedural sedation. Alternatively, a Nurse Practitioner or Physician Assistant may serve as a monitor if there is current advanced cardiac life support certification (ACLS) or equivalent (e.g., pediatric advanced life support (PALS)) and an age-appropriate clinical competency on **MODERATE** procedural sedation has been successfully completed.
 - d. An RN who meets all the following criteria:
 - Works in areas authorized to give moderate procedural sedation drugs (see Appendix A)
 - Meets the following training/educational requirements <u>prior</u> to being allowed to perform the role
 of a monitor:
 - Initial education: Successfully complete the Moderate Sedation Module and the moderate sedation post-test (with a 100% score).
 - o Initial competency evaluation: Addressed during unit orientation
 - Continuing competency evaluation: Annually by completing a moderate sedation competency course and moderate procedural sedation posttest (with a 100% score) or other competency methodologies administered by the nursing department or unit.
 - Current ACLS and/or PALS certification
 - Record of successful completion of the above requirements will be kept in the employee record
 - Meets the following practice requirement:
 - Administers moderate procedural sedation drugs only when ordered
 - Notify the physician immediately to communicate concerning patient's condition
 - An RN does not need direct supervision while performing the monitor role, but must have an immediate access to
 - o Physicians in the event of significant change in patient condition
 - Advanced life support equipment
 - e. If the monitor is not an authorized ordering provider, the authorized ordering provider must be present at the patient's bedside while procedural sedation is initiated and must remain immediately available to the monitor until the procedure is completed (or no further sedative medications are given).
- 4. Any individual authorized to **MONITOR** moderate sedation must:
 - a. Be capable of providing advanced life support.
 - b. Be familiar with the pharmacology of the medications being used and reversal agents, including appropriate routes of administration and possible untoward effects.



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

- c. Be able to recognize complications associated with administration of procedural sedation medications and to initiate age-appropriate interventions.
- d. Be familiar with the basic principles of oxygenation and use of oxygen delivery devices.
- e. Be able to establish a patent airway and apply age-appropriate bag-valve mask ventilation.
- 5. Individuals Authorized to **ADMINISTER MODERATE** Procedural Sedation drug(s):
 - a. Any individual who has been authorized to order or monitor moderate sedation.
 - b. An appropriately trained physician or dentist under the direct supervision of the moderate sedation monitor.

DEEP SEDATION:

Any individual who orders and monitors **DEEP** sedation must be dedicated to that task. Therefore, the sedation provider who orders and/or 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 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. 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.

- 1. Individuals Authorized to **ORDER DEEP** Procedural Sedation:
 - a. Attending physician or licensed and privileged Fellow/Chief/Senior Resident physician, Dentist or Oral Surgeon as follows:
 - Has 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.
- 2. Any individual authorized to **ORDER DEEP** sedation must:
 - a. 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. This will be completed at the time of initial privileging and at each subsequent renewal.
 - b. Have passed a knowledge-based test to objectively demonstrate the knowledge of concepts required to obtain privileges, such as the DHS Deep Sedation Module (with a 100% score).
 - Record of successful completion of such a module and testing will be kept by the authorizing department/division and be available for review by the credentialing advisory subcommittee (CAS) and/or Professional Staff Association (PSA) governing body.
 - c. Has received advanced training consistent with Advanced Cardiac Life Support Certification or



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

equivalent (e.g., Pediatric Advanced Life Support (PALS)) and/or has Board Certification/eligibility in adult/pediatric Emergency Medicine and/or adult/pediatric Critical Care Medicine.

- 3. Individuals authorized to **MONITOR DEEP** Procedural Sedation:
 - a. Only an individual who is authorized to **ORDER** deep procedural sedation can be the monitor during deep procedural sedation.
 - b. The individual monitoring deep sedation will **NOT** be the individual who is performing or supervising the diagnostic or therapeutic procedure.
- 4. Individuals authorized to **ADMINISTER DEEP** Procedural Sedation drug(s):
 - a. The following individuals may administer procedural sedation medications upon order by an authorized individual, provided this is in accordance with Hospital and their Departmental policies and the patient is being monitored by an authorized individual.
 - b. An individual authorized to **order and monitor** patients under deep procedural sedation.
 - c. An appropriately trained physician or dentist under the **direct supervision** of the deep sedation monitor.

DOCUMENTATION:

- 1. **Complete** documentation of vital signs, medications administered, level of consciousness, adverse events and provider interventions will be documented in the procedural sedation section of the electronic medical record.
- The individual documenting can be a different individual than the person monitoring the patient even if they are not authorized be a monitor during sedation. In the case of deep sedation, an RN, NP, or PA must be present to document throughout the procedure while the authorized monitor solely monitors the patient.
 - a. <u>Procedure Phase</u>: Vital Signs, including level of consciousness (LOC) and oxygen saturation, will be monitored, and recorded immediately prior to initiation of procedural sedation, every 5 minutes after procedural sedation has begun through completion of the procedure and no more meds are to be given.
 - b. <u>Recovery Phase</u>: 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.
- 3. Downtime Documentation for use of the Procedural Sedation Documentation Record
 - a. See Form HH751 (Appendix C)
 - 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(es). The Physician/ Dentist/Nurse Practitioner/Physician Assistant shall sign, complete Identification Number, date, and time, where indicated.
 - o Indicate patient's ASA classification
 - Complete patient assessment
 - Pre-Procedure preparation: Check the appropriate box(es).
 - o Procedure Information: Fill in the blanks with the appropriate information requested.
 - o If an identified complication occurs during the procedure, indicate this with a check mark and create a Safety Intelligence (SI) event.



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

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".
- Recovery:
 - Recovery criteria shall be documented on all patients receiving procedural sedation of any type.
 - 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.
 - A post-DEEP SEDATION note must be filled out within 48 hours of the procedure for all planned deep sedations.
- o Discharge Checklist:
 - 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.
- Patient identification: Affix a patient identification label to each page of the Procedural Sedation Record.
- 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.

OVERSIGHT:

- 1. 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:



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

- 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 via regularly generated electronic reports, 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
 - o 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

Meetings

- The Procedural Sedation Oversight Committee shall meet at least once quarterly and maintain a permanent record of its proceedings and actions and shall submit meeting minutes to the Medical Center's Chief Medical Officer, 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.



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

Reviewed and approved by:

Medical Executive Committee 04/2023

Beverley a. Felice

Beverley A. Petrie, M.D.

President, Professional Staff Association



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

APPENDIX A

Appendix A: Authorized Locations for The Administration of Procedural Sedation Drugs

- Adult ICUs, PCU's, Step Down Units
- Cath Lab
- Heart Station* (not authorized for ketamine)
- Emergency Department and Pediatric Emergency Department
- Endoscopy Suite
- Pediatric/Neonatal ICUs
- Pediatric Ward Treatment Room
- Radiology (including Imaging Center)
- Oral and Maxillofacial Surgery/Dental Clinics
- Endovascular Room (PCDC)
- PACU

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

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



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

APPENDIX B

Appendix B: Reversal Agents

A. Naloxone (Narcan)

- 1. <u>Indications/Actions</u>: Indicated for the complete or partial reversal of opioid effect, including respiratory depression.
- 2. Dose and Administration:
 - Adult: 0.4-2mg IV, IM, IO, SC, ETT, may repeat doses every 2-3 minutes as needed up to 10mg.
 - Children: 0.1 mg/kg up to 2mg/dose IV, IM, IO, SC, ETT, may repeat doses every 2 minutes as needed.
- 3. <u>Precautions:</u> Naloxone has a shorter half-life than most narcotics used in procedural sedation, its use as a reversal does not shorten the post-procedure monitoring period. When naloxone is used, the patient must be monitored for re-sedation (up to 2 hours).

B. Flumazenil (Romazicon)

- 1. <u>Indications/Actions:</u> 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 and Administration:
 - Adult: Initial: 0.2 mg IV over 2 minutes; if the desired level of consciousness is not obtained after 1 minute, 0.2 mg may be repeated at 1-minute intervals up to 4 times; usual cumulative dosage range: 0.6 to 1 mg; maximum cumulative dose: 1 mg
 - Pediatric: Initial dose: 0.01 mg/kg IV; maximum dose: 0.2 mg/dose; given over 15 seconds; if needed, may repeat same dose after 45 seconds, and then every minute to a maximum cumulative dose of 0.05 mg/kg or 1 mg total, whichever is lower; usual total dose: 0.08 to 1 mg
 - Appropriate measures to secure the airway shall be taken while flumazenil is being administered.
- 3. <u>Precautions</u>: Flumazenil may be expected to improve the alertness of patients recovering from a procedure involving sedation with benzodiazepines, but its use as a reversal does not shorten the post-procedure monitoring period. The availability of flumazenil does not reduce the risks associated with the use of large doses of benzodiazepine for sedation. When flumazenil is used, the patient must be monitored for re-sedation (up to 2 hours).



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

APPENDIX C

Appendix C: Downtime Procedural Sedation Record (FORM HH751)

| | Pi | ROCEDURAL S | IFORMATION | CHD | | | |
|--|--|---|--------------------|-------------|-----------------|------------------|---|
| Age Sex ☐ M ☐ | E Weight | PAHENTIN | FORMATION | | | SEDATI | ON PLAN: |
| Time since last clear liquid: | | nce last solid: | | | | Moderate Se | |
| Diagnosis: | Title of | nce last solid. | | | | | |
| Allergies: | | | | | | | ropofol, ketamine |
| ☐ Inpatient ☐ Outpatient DOCUMENTATION BY | DDACTITIONE | D ALITHODIZE | TO OPPER | DOCED | IDAL CED | | |
| I have spoken with | PRACTITIONE | RAUTHURIZE | | | | | nd its alternatives |
| which include general anesthesia | and no sedation. | Procedural sedat | | | | | |
| Allergic reaction | | eed for endotrach | | | | | |
| Vivid dreams (ketamine) | | dmission to Hosp | ital | | | | |
| Hypotension | | ardiac arrest eath | | | | | |
| Hypoxia Respiratory arrest | | eath ther | | | | | |
| He/she (or guardian) has underst | | | sedation and agr | eed by aiv | ina his/her i | nformed conse | ent. |
| *ASA CLASSIFICATION - Circle | | , | | | | | |
| A normal healthy patient | | | ribund patient w | | | | |
| II. A patient with mild systemic | | | clared brain-dead | d patient w | hose organs | s are being ren | noved for donor |
| A patient with severe system A patient with severe system | | E. Emer | | | | | |
| Patient Assessment | iic disease that is | a constant threat | to life | | | | |
| History & Physical within 30 days | on chart | ☐ Yes | □No | | | | |
| History & Physical Updated within | n 24 hours | ☐ No change | ☐ Changes no | ted in med | lical record | □ N/A | |
| ☐ Normal Airway Assessment | | ☐ Current Medica | | | | | |
| □ Patient is appropriate candidate □ For DEEP sedation-pre-sedation | te for the planned | procedural sedat | ion | | | | |
| ☐ For DEEP sedation-pre-sedation | | RE-PROCEDU | | ION | | | |
| PATIENT CH | | NE-PROCEDO | | | TE EOLIID | MENT FUNC | CTIONING |
| /aluables removed/secured: | | No □N/A □ | 102 | | | ation Bag and | |
| Contact lenses/dentures removed: | | | Suction | | | uring Device | THIS OF THE PARTY |
| | | | Pulse Oximeter | | □ Reversal | Agent | |
| Procedure consent signed?: | Yes No C | | Crash Cart, Mo | | orillator, Lary | ngoscope, Bla | ade, Light |
| | | PROCEDURE | INFORMATIO | N | | | |
| Location: | | | Procedure: | | | | |
| Operator (Physician,Technician or I | RN Performing Pro | ocedure): | | | | | |
| Date: | | | Procedure Star | rt Time: | | End Time: | |
| "Time out" performed: 5 W's (Who - Patient ID/Team Member How - Equipment/Concerns) | rs, What - Proced | ure/Consent, Whe | en - Antibiotics/S | tudies/Lab | os, Where - I | Procedure Site | |
| Individual Ordering Sedation Signature | Individual Ordering | Sociation (printed) | Sedation Monitor | Clanatura | - | Sedation Monitor | (printed) |
| municular ordering Secalion Signature | ilidividual Ordering | Sedation (printed) | Sedaboli Mollitor | Signature | Ι, | Sedation Monitor | (printed) |
| | | | | | | | |
| Practitioner ID#: | Date | Time | Practitioner ID#: | | | Date | Time |
| | | | | | | | |
| | | | | | | | |
| 20MDLICATIONIC | ered during the proces | dure- | | _ | | | |
| | | | | | | | |
| Nere any of the following events encounte | tation | deltas. | | | | | |
| Nere any of the following events encounte | on any eleven medele | uramon: | acheal Intubation | | | | |
| Were any of the following events encounts NONE Code blue or code white relating to sec Unanticipated over sedation that requir | es any airway manipi • Ban mask ventilat | ion • ⊨noom | donous mitabation | | | | |
| Were any of the following events encounts NONE Code blue or code white relating to sec Unanticipated over sedation that requir Nasal/oral airway | Bag mask ventilat | ion • Endotr | | | | | |
| Were any of the following events encounts NONE Code blue or code white relating to sec Unanticipated over sedation that requir Nasal/oral airway Unanticipated use of any reversal agen Naloxone | Bag mask ventilat ts Flumazenil | Reason: | or humauspitteiten | | | | |
| Were any of the following events encounts NONE NONE Code blue or code white relating to sec Unanticipated over sedation that requir Unanticipated use of any reversal agen Significant hemodynamic instability in | Bag mask ventilat ts Flumazenii the patient that is a re | Reason: | or hypoventilation | - | | | |
| Were any of the following events encounts NONE Code blue or code white relating to see Unanticipated over sedation that requir Nasal/oral airway Unanticipated use of any reversal agen Naloxone Significant hemodynamic instability in a significant decrease in oxygen saturati | Bag mask ventilat ts Flumazenil the patient that is a re on | Reason: esuit of over sedation | or hypoventilation | | | | |
| Were any of the following events encounts: NONE Code blue or code white relating to see Unanticipated over sedation that requir Nasal/oral airway Unanticipated use of any reversal agen Significant hemodynamic instability in a significant decrease in oxygen saturation of the same of the s | Bag mask ventilat ts Flumazenii Flumazenii the patient that is a re on nability to respond to v | Reason: esuit of over sedation | or hypoventilation | | | | |
| 🗆 Unanticipated use of any réversal agen | Bag mask ventilat ts Flumazenii Flumazenii the patient that is a re on nability to respond to v | Reason: esuit of over sedation | or hypoventilation | | | | |

CANARY - ANESTHESIOLOGY

PAGE 1 OF 2 HH751 (3-4-13)



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

| BP | | | | | | | |
|--|--|--|--|--|--|--|--|
| Record vitals q 5 min once procedural sedation has begun until procedure is completed; then q 15 min until recovery criteria are met too tagend. A-MWASE - Alant LeternWate (priper upon to vote stimul). Estativ=00016 (priper upon until recovery criteria are met too tagendary). Basaline Dog SAT LOC | | | | | | | |
| then q 15 min until recovery criteria are met TIME → Bassitre Q, SAT LOC HR RR BP MEDICATION ADMINISTRATION Administered by: Plain Score Fluids & TIME - DOSE Medication (POUTB) MEDICATION NOTE POST DEEP-SEDATION NOTE Recovery Satisfaction: Yes No Vital Signs Stable: Yes No No Mental Status NV Hydration Mental Status NV Hydration Provider Signature Provider Signature Provider Signature Provider Signature Provider Or development/age Ambulates without assistance Vaginal bleeding/discharge Rection yes no Name Statiscoral Plain Score Signature Statiscoral Signature Provider Signature Provid | | | | | | | |
| TIME Statistic Statistic | | | | | | | |
| O3 SAT | | | | | | | |
| MEDICATION ADMINISTRATION Administered by: Paids 8 | | | | | | | |
| HR RR RR BP | | | | | | | |
| MEDICATION ADMINISTRATION Administered by: Date: Time: | | | | | | | |
| MEDICATION ADMINISTRATION | - | | | | | | |
| Administered by: Date: Time: | | | | | | | |
| Administered by: Date: Time: | | | | | | | |
| POST DEEP-SEDATION NOTE Recovery Satisfaction: Yes No Vital Signs Stable: Yes No Pain Score Mental Status No Medicalion for development/age No No No No No No No N | | | | | | | |
| Initials Oz (only if needed) POST DEEP-SEDATION NOTE Recovery Satisfaction: Yes No Vital Signs Stable: Yes No Provider Provider No Provider Provi | \neg | | | | | | |
| POST DEEP-SEDATION NOTE | | | | | | | |
| POST DEEP-SEDATION NOTE | | | | | | | |
| Post Deep-sedition Yes No Vital Signs Stable: Yes No Pain Score No Provider ID# Date Time Signature of Person Validating Recovery Date Time Time Time Time Signature of Person Validating Recovery Date Time | \rightarrow | | | | | | |
| POST DEEP-SEDATION NOTE | - | | | | | | |
| Recovery Satisfaction: Yes No Vital Signs Stable: Yes No PR PR T SPO2 Seation Complications: Yes No W/S Stable, satisfactory Easily arousable Talks coherently Pain Score Time T | | | | | | | |
| Recovery Satisfaction: Yes No Vital Signs Stable: Yes No PR T SPO2 Seasily arousable Talks coherently Signature Provider ID# Date Time Time Time Signature of Person Validating Recovery Date Time Time | | | | | | | |
| BP | | | | | | | |
| Provider Signature Provider ID# Date Time Pain Score Provider ID# Pain Score Provider ID# Pain Score Time recovery criteria met: Signature of Person Validating Recovery Date Time Pain Score Time recovery criteria met: Signature of Person Validating Recovery Date Time Pain Score Pain S | ☐ Easily arousable ☐ Talks coherently ☐ Pain Score ☐ | | | | | | |
| Provider Signature Provider ID# Provider Signature of Person Validating Recovery Date Time Signature of Person Validating Recovery Date Time | | | | | | | |
| Provider Signature Provider ID# Date Time Signature of Person Validating Recovery Date Time | | | | | | | |
| Signature of Person Validating Recovery Date Tri | | | | | | | |
| DISCHARGE CHECKLIST Complete on ALL Outpatients Only Vital Signs: B/P P RR Pain Score (0-10) Time: YES NO N/A COMMENTS Appropriate orientation for development/age | Time | | | | | | |
| Vital Signs: B/P P RR Pain Score (0-10) Time: YES NO N/A COMMENTS Appropriate orientation for development/age | inic | | | | | | |
| Vital Signs: B/P P RR Pain Score (0-10) Time: YES NO N/A COMMENTS Appropriate orientation for development/age | | | | | | | |
| Appropriate orientation for development/age | | | | | | | |
| Ambulates without assistance | | | | | | | |
| Voided since procedure Retains oral fluid Dressing dry and intact Vaginal bleeding/discharge Minimal pain controlled by analgesics Verbalizes understanding of discharge instructions Accompanied by responsible adult | | | | | | | |
| Retains oral fluid | | | | | | | |
| Dressing dry and intact Vaginal bleeding/discharge Minimal pain controlled by analgesics Verbalizes understanding of discharge instructions Accompanied by responsible adult Name | | | | | | | |
| Minimal pain controlled by analgesics | | | | | | | |
| Verbalizes understanding of discharge instructions | | | | | | | |
| Accompanied by responsible adult | | | | | | | |
| | | | | | | | |
| MODE OF DISCHARGE | | | | | | | |
| | | | | | | | |
| Ambulatory Carried/assisted by parents Stretcher Wheelchair | | | | | | | |
| ☐ To home ☐ To other | | | | | | | |
| Signature of Person Discharging Patient Print Name of Person Discharging Patient | | | | | | | |
| | | | | | | | |
| Date Time | | | | | | | |
| | | | | | | | |
| I | | | | | | | |



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

APPENDIX D

Appendix D: Adverse Drug Reactions

| <u>Drug</u> | Route | Onset (minutes) | <u>Peak</u> Effect | <u>Duration</u> (hours) | Adverse Drug Reactions |
|--|----------------|--------------------|-----------------------|--|--|
| | | (minutes) | (minutes) | (Hours) | |
| Morphine | IV | 5 | 15-20 | 4-6 | Respiratory and circulatory depression, orthostatic hypotension, euphoria, dysphoria, nausea, vomiting, ileus, biliary colic, urinary retention, pruritus. |
| Meperidine (Demerol) Restricted to Pain Service, Hematology/Oncology | IV | 3-5 | 15-30 | 2-4 | ADRs similar to morphine. Vagolytic, sinus tachycardia. Prolonged high dose therapy may cause CNS stimulation. |
| Fentanyl (Sublimaze) | IV | <0.5 | 3-5 | 1 | ADRs similar to morphine. Bradycardia, skeletal and thoracic muscle rigidity with rapid IV injection. |
| Ketamine Restricted to Anesthesiology, Labor and Delivery, Neonatal, Emergency Medicine, Palliative Care, Critical Care, Addiction Medicine, and Pain Medicine | IV IM | 0.5 5-8 | | 0.1-0.2 0.25-0.5 | Hypertension, tachycardia, increase intracranial pressure, vivid dream, tremor, tonic-clonic movements |
| Etomidate (Amidate) Restricted to Anesthesiology, Emergency Medicine, and ICU | IV | 30-60 seconds | 1 minute | 3-5 minutes terminated by redistribution | >10% gastrointestinal: Nausea, vomiting on emergence from anesthesia. Local: Pain at injection site (30-80%). Neuromuscular and skeletal: Myoclonus (33%) transient skeletal movements, uncontrolled eye movements. |
| Diazepam (Valium) | IV | 3-5 | 30 | 3-4 | CNS effects: drowsiness, vertigo, ataxia, anterograde amnesia, hallucination, behavior change, abnormal mentation. Respiratory and cardiovascular depression. Pain on injection and risk of congenital malformation during early pregnancy. Use with caution in ongoing pregnancy. |
| Lorazepam (Ativan) | IV | 1-5 | 10-15 | 0.5-8 | ADRs similar to diazepam. Use with caution in ongoing pregnancy. |
| Midazolam | IV | 1-2 | 10 | 1 | ADRs similar to diazepam. Pain on |
| (Versed) | PO | 10-20 | 20-30 | 1-1.5 | injection but less common than with |
| Restricted to Anesthesiology, | PR | 10-20 | 20-30 | 1-1.5 | diazepam. Potent respiratory depressor |
| Emergency Department, and specialties/areas approved per facility moderate sedation policies | Intran asal | 5-10 | 10-20 | 1 | especially in elderly and COPD patients. Use with caution in ongoing pregnancy. |