	CCMC Corporation		
Connecticut Children's MEDICAL CENTER	☑ **Connecticut Children's Medical Center** ☑**Connecticut Children's Specialty Group, Inc.**	❑**CCMC Affiliates, Inc.** ❑ **Connecticut Children's Medical Center Foundation, Inc.**	
	Provision of Care Treatment & Services	Date Effective:	July 19, 2013
	Policy: Sedation and Analgesia	Date of Origin:	April 01, 1996
	Approved By: Clinical Council, Sedation Committee, Medical Staff Executive Committee	Date Approved:	July 09, 2013

I.Purpose

The purpose of this policy is to describe the actions and responsibilities of health care providers involved in the care of patients receiving sedation and analgesia for diagnostic and therapeutic procedures.

II.Policy

It is the policy of Connecticut Children's Medical Center and Connecticut Children's Specialty Group (Connecticut Children's) that sedation and analgesia (S & A) for diagnostic and therapeutic procedures is administered by a licensed health care provider under the supervision of a credentialed physician of the Connecticut Children's medical staff. The administration of any sedative or analgesic preceding or during a procedure with the intent of producing a relaxed level of consciousness and/or analgesia for that procedure falls within the scope of this policy. Anxiolysis unrelated to diagnostic or therapeutic procedures, analgesics administered to alleviate pain following an invasive procedure or during a pain management program, and medications to promote 'natural' sleep are excluded from the scope of this policy.

III.Criteria

A.Definitions

1.Patient: All outpatients and inpatients within the Connecticut Children's health care facility.

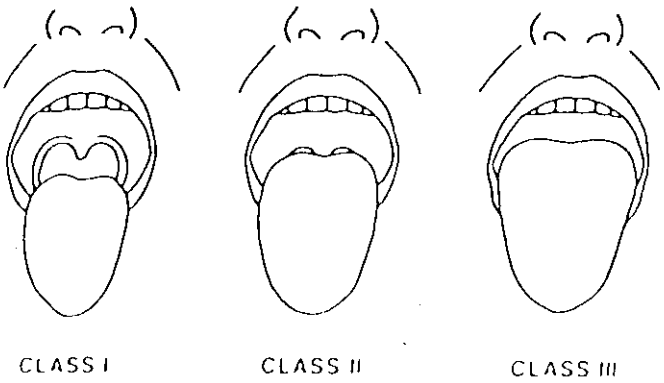
2.Physicians: All medically licensed members of the Medical Staff and House Staff (residents and fellows)

3.Attending Physicians: All medically licensed members of the Medical Staff, including physicians, dentists, and podiatrists.

4.Credentialed Sedation and Analgesia Provider (SAP): Licensed health care provider (LHCP) including physicians, dentists, advance practice registered nurses (APRN), physician assistants (PA), and certified nurse anesthetists (CrNA) who have completed the credentialing requirements as described below for performing (prescribing and supervising) Sedation and Analgesia as outlined in this policy.

5. Sedation Monitor: The sedation monitor is a licensed health care provider and is most commonly a registered nurse (RN). However, the Sedation Monitor may also be a physician, dentist (DMD), advance practice registered nurse (APRN), physician assistant (PA), or certified nurse anesthetists (CrNA). The Sedation Monitor is responsible for the required patient monitoring during the sedation event.and may be responsible for the administration of sedatives and/or analgesics used.

6. Medically Supervised Setting: All areas of the Connecticut Children's health care facility where Sedation and Analgesia is given under the guidance of attending physicians as defined above.
7. Pediatric Code Team: The inpatient Code Team is composed of licensed health care providers from both the Pediatric Intensive Care Unit (PICU) and the inpatient Pediatric house staff. Code Teams in the Emergency Department and Operating Rooms are composed of LHCP's within those areas. An attending anesthesiologist is available via emergency pager if further assistance is needed.
8. Resuscitation Equipment: Equipment required for an acute event including oxygen, manual resuscitator and ventilation mask, oral airway, intubation equipment, suction set-up, and an emergency crash cart.
9. American Society of Anesthesiology (ASA) Risk Classifications (widely used scoring system to assess anesthetic risk):
    (a) Class I - A healthy patient, who requires a procedure for a localized process.
    (b) Class II - A patient with mild to moderate systemic disease.
    (c) Class III - A patient with severe systemic disease.
    (d) Class IV - A patient with severe systemic disease that is life threatening, and not always correctable by the procedure.
    (e) Class V - A moribund patient who has little chance of survival, but is submitted to the procedure in desperation.
10. Mallampati Classifications - A tool that allows the examiner to assess for potential difficulty with the patient's airway. By having the patient's mouth open as wide as possible, the size of the laryngeal inlet relative to the tongue is observed. An airway may be more difficult to manage when fewer pharyngeal structures are visible (e.g., higher Mallampati Class). Infants, who are difficult to assess at any time and those with known craniofacial abnormalities should be considered a Class 3



(i)Class 1: Uvula, faucial pillars, and soft palate are visible.
(ii)Class 2: Faucial pillars and soft palate are visible
(iii)Class 3: Only the soft palate is visible.

11. Emergency Procedure: Any procedure performed with an associated risk for the loss of life or limb. The nature of the procedure implies possible increased risk with sedation and analgesia.
12. Core Privilege(s): Those clinical activities within a specialty or subspecialty that any appropriately trained practitioner would be competent to perform (based on postgraduate training and field of practice).
13. Non-Core Privilege(s): Those clinical activities that are associated with volume sensitivity and/or special (advanced) training, education and experience.

B.Levels of sedation and analgesia

1.The administration of sedative and analgesic drugs causes a dose dependent continuum of effects, beginning with minimal sedation and ending with general anesthesia. Safe sedation depends on appropriate titration of medications and constant patient monitoring.
2.Four levels of sedation have been defined: Minimal, Moderate, Deep, and General Anesthesia (See Table). Clinically, it is recognized that levels of sedation are a continuum and there are no clear margins between the levels.

Characteristics of Levels of Sedation	AWAKE	MINIMAL[1]	MODERATE	DEEP	GENERAL ANESTHESIA
Loss of Protective Airway Reflexes	NO	NO	NO	YES	YES
Loss of Airway Control	NO	NO	NO	NO[4]	YES
Respiratory Depression	NO [2]	NO [2]	NO [3]	NO [4]	YES
Response to Verbal Stimulus	YES	YES	NO [5]	NO [5]	NO
Response to Tactile Stimulus	YES	YES	NO [5]	NO [5]	NO
Loss of Other Motor Reflexes	NO	NO	NO	NO	YES
Depressed Consciousness	NO	NO	YES	YES	YES

KEY:
1. Minimal sedation occurs in an awake patient with a relaxed consciousness.
2. No change in baseline respiratory rate (RR) or SaO_2.
3. No more than 5% change in SaO2, or 40% change in RR from baseline.
4. Patient may require airway support.
5. Patient responds to persistent verbal/tactile stimulation

IV.Procedure

A.Personnel

1. The administration of medication during a patient's procedure with the intent of producing a particular level of sedation (e.g. minimal, moderate, deep) must be under the supervision of an SAP credentialed to do so.
2. During minimal or moderate sedation events, the SAP may participate as the Sedation Monitor while another LHCP performs the procedure or the SAP can act as the LHCP performing the procedure while another LHCP acts as the Sedation Monitor. The SAP cannot perform all 3 activities simultaneously (provide the sedation, act as Sedation Monitor, or perform the procedure.)
3. A Sedation Monitor, who is someone other than the person performing the procedure, must be responsible for the administration of sedative medications and patient monitoring. This individual must have knowledge of the drug dosing and the effects of the drugs being used. This individual must be knowledgeable about the use of patient monitors and the interpretation of patient data displayed on these monitors. This individual must also have knowledge about airway management and emergency procedures.

4. During minimal and moderate sedation, the role of the Sedation Monitor is patient monitoring. This individual must be present to observe the patient and to record vital signs at the interval defined in this policy (see Minimum Monitoring Requirements). This individual may attend to ancillary tasks, I.e. assist with the procedure, between monitoring intervals, assuming the patient's vital signs and oxygenation are stable, but may not leave the patient.
5. During deep sedation, the Sedation Monitor must observe and monitor the patient at all times and may not attend to ancillary tasks. The SAP must be present during the entire period of deep sedation and may not act as the LHCP performing the procedure.

B. Pre-sedation assessment

1. The credentialed SAP who is ordering the sedation must perform a review and update of the complete history and physical performed by a credentialed practitioner or perform a thorough health evaluation that includes:
   a) Past health history
   b) Medications
   c) Allergies
   d) Review of systems
   e) Weight
   f) ASA risk classification
   g) Mallampati airway classification
2. The level of sedation that is expected or intended for the procedure must be determined at the time of the health evaluation.
3. This pre-sedation assessment must take place immediately prior to the scheduled procedure.
4. On the day of the procedure, the Sedation Monitor or Sedation Provider must record baseline vital signs, weight, dietary status, pre-sedation score, and any other pertinent information on the patient's Sedation and Analgesia flowsheet.
5. If there is a change in the patient's medical history at the time the procedure is to be performed, the SAP must re-evaluate the patient and document the re-evaluation on the Sedation and Analgesia flowsheet.
6. Personnel involved with cases involving sedation must perform a final verification procedure ("time out") before the administration of the sedation. The final verification procedure includes:
   a) review of 2 unique patient identifiers for all procedures,
   b) a site review for procedures with laterality,
   c) verification of the operator's privileges.
   d) The final verification procedure must be documented in the patient's medical record.

C.Candidates

1. Patients in the ASA risk classification I, II, III may receive sedation and analgesia at the level for which the SAP is credentialed.
2. Credentialed physicians from Critical Care Medicine, Neonatology, or the Cardiac Catheterization Lab may also sedate patients with ASA classification IV without consultation from the Department of Anesthesia.
3. Patients with an unsecured Mallampati Class 3 airway, who require more than moderate level sedation, must have a consultation from the Department of Anesthesia prior to Sedation and Analgesia.
4. This policy does not apply to patients with artificial airways in place (tracheostomy or endotracheal tube) and on mechanical ventilation. These patients are at a lower risk of airway and ventilatory problems related to sedative administration, but this risk may be offset by their higher ASA risk classification. Sedation and Analgesia for these patients should be performed only by SAP's familiar with the management of artificial airways and chronic respiratory failure.
5. Emergency procedures performed with sedation are bound by this policy. Any patient who undergoes a procedure in an emergency situation is considered to be in a higher risk category. In the event a deviation from the policy is necessary because of possible loss of limb or life, the SAP must document the reason for the policy deviation in the patient's medical record.
6. Patients who have received sedative agents prior to presentation to Connecticut Children's for a scheduled sedation event, will have additional agents for S&A prescribed only at the discretion of the SAP. Co-administration of multiple sedative/analgesic agents may add to the risk associated with the event. Factors to be considered include the underlying health status of the patient undergoing sedation, the agent prescribed, the nature of the procedure, and the desired level of sedation. For truly elective procedures, the added risk of multiple agents may prompt the procedure to be delayed or rescheduled. The patient must be cleared for discharge by their department sedation staff, sedation service staff, PACU staff, or Anesthesia department staff.
7. Patients who have received sedative agents prior to presentation to Connecticut Children's for a procedure not scheduled for sedation will require sedation monitoring that is appropriate to the intended level of sedation. If the provider prescribing the sedative is not credentialed for Sedation and Analgesia by Connecticut Children's, a sedation service or Anesthesia consultation will be necessary. The sedation provider has the discretion to delay or reschedule the procedure. If a sedation monitor or credentialed sedation provider is not available in

the patient's location (department) at the time of the procedure, the procedure will be cancelled. The patient must be assessed and cleared for discharge home by a credentialed sedation monitor (department RN [i.e., Radiology, Urology, Hematology], sedation service RN or Bed Manager) or SAP (department [i.e., Radiology, Urology, Hematology], sedation service, anesthesia or Emergency Department staff). If the patient is not back to baseline mental status, he/she will be monitored until cleared in either their department recovery area or the Emergency Department (if no department sedation monitor is available). The provider(s) who ordered the procedure and prescribed the sedative will be contacted about the status of the procedure, either by the sedation monitor and/or sedation provider.

8. Patients in need of multiple procedures within a short period of time require a coordinated approach, clear communication between providers, and possibly the involvement of additional personnel. Multiple procedures should be performed with as few sedation events as possible. In addition, care should be taken to minimize the need for transferring sedated patients. The best recommended approach to these cases would be to involve Anesthesiology or S&A staff early in the process to coordinate the multiple procedures.

D. Dietary status

1. NPO guidelines for elective procedures follow those used by the Department of Anesthesia:

	Solids[1]	General Liquids[2]	Clear Liquids[3]	Human Milk
Newborns	*	6 hours	2 hours	4 hours
Infants	6-8 hours	6 hours	2 hours	4 hours
Children	6-8 hours	6 hours	2 hours	6 hours

a) Each box contains the recommend time interval between the last PO intake and the time of sedation.
b) Solids include cereal, meat, fruits and vegetables, candy, and tube feedings.
c) General liquids include milk, formula, and orange juice.
d) Clear liquids include apple juice, grape juice, Pedialyte, tea (no cream), water, and non-barium enteral radiologic contrast fluids.

2. For urgent (non-elective, non-emergent procedures), NPO criteria may be reduced at the discretion of the SAP. The following factors must be considered prior to administering S&A to patients for urgent procedures before the appropriate NPO interval:
a) Urgency of the procedure
b) Time since last meal
c) Volume and consistency of last meal
d) Intended level of sedation

e)Patient risk factors or co-morbidities (age, obesity, delayed gastric emptying, GI dysmotility, presence of GERD,…)

3. The determination that a procedure is urgent must be made based on patient and procedure considerations, not on time constraints or scheduling conflicts of the SAP or the provider performing the procedure. Direct verbal communication between the SAP and the attending of record is recommended if concerns about the NPO interval are raised. The nature of the procedure (elective, urgent, or emergent) must be documented on the Patient History Form or in the sedation record.
4. When a patient has additional risk factors as described above or has had a recent large volume meal, NPO guidelines for elective procedures must be followed. The reduced NPO interval is left to the discretion of the SAP but as a rule, general liquid intervals of 2 hours and a solid food interval of 4 hours are acceptable for most urgent procedures.
5. When nitrous oxide is used as the sole agent for sedation and analgesia, NPO fasting guidelines may be reduced to 2 hours for solids and liquids at the discretion of the SAP.
6. NPO guidelines still apply to patients who are receiving serial sedations for multiple procedures within the same day. Additional care must be taken to schedule these procedures with attention to NPO criteria.
7. Consultation with Anesthesiology should be considered for S&A for any emergent procedure not adhering to NPO guidelines and for urgent procedures in patients with significant co-morbidities not meeting NPO guidelines.

E. Informed consent

1. The credentialed SAP is responsible for explaining and obtaining informed consent from the parent or legal guardian. This includes the benefits any associated risks of sedation and analgesia, and any alternatives to sedation and analgesia.
2. A single completed consent form may suffice for serial procedures as long as the form clearly documents the multiple similar procedures. Any change in the patient's medical status requires completion of a new consent form.
3. Informed consent is documented on the Connecticut Children's Informed Consent form prior to the administration of sedation and analgesia. Documentation should also be included on the Progress Notes in the patient's medical record.

F. Responsibility

1. A SAP order is required for all medications administered for sedation and analgesia. Exceptions include a certified nurse anesthetist in either the OR or PACU, who may order and administer sedation and analgesia under the direction of an attending anesthesiologist.
2. The SAP ordering the sedation and analgesia retains responsibility for the patient's care until either:

a)Another SAP assumes the patient's care, or

b)The patient recovers to the level of an awake state.

3.The responsible SAP is expected to adhere to this policy and to insure that the level of sedation does not exceed expectations. If sedation advances beyond the scope of the provider, the appropriate resource (e.g., Pediatric Code Team, an anesthesiologist, or an attending physician credentialed to administer deep sedation) should be notified immediately.

G.Minimum Monitoring Requirements:

1.Patient monitoring during sedation is consistent with the patient's medical needs and condition. The stable, awake patient does not require special monitoring or equipment.

2.Monitoring is performed by the Sedation Monitor according to the standards defined under "Personnel."

3.Minimum Monitoring Requirements, according to level of sedation, are as follows:

	Minimal	Moderate	Deep	General Anesthesia [1]
Medically supervised setting	YES	YES	YES	YES [1]
Resuscitation equipment [2] immediately available	YES	YES	YES	YES
Pulse oximetry	YES [3]	YES	YES	YES
Cardiac Monitoring	NO	NO	YES	YES
End-tidal CO_2 monitoring	NO	NO	Recommended	Recommended
Vital Signs (include level of sedation)	YES	YES [4]	YES	YES
Maximum interval for recorded Vital signs	20 min	10 min	5 min	5 min
Intravenous Access	NO	YES [5]	YES	YES
Staff required in room	Sedation Monitor with SAP or Sedation Monitor and individual performing procedure with SAP aware and on CT Children's grounds		Sedation Monitor and SAP not performing procedure	Sedation Monitor and Anesthesiology LIP

KEY:
1. Patient must be under the supervision of an attending Anesthesiologist.
2. See Definitions.
3. Pulse oximetry will be continuous and recorded q5 minutes in the event other tactile monitoring (BP cuff) cannot be used within the maximum interval. Oximetry can be monitored by health care personnel in a medically supervised setting, assuming a LHCP monitors the patient q20 min and is immediately available.
4. In locations where respiratory rate is difficult to assess within required intervals, a continuous

	Minimal	Moderate	Deep	General Anesthesia [1]

monitor (Apnea or end-tidal CO_2 monitors) should be used.

5. When moderate sedation is achieved via a non-intravenous route, the SAP may choose not to establish intravenous access. However, in each case, a licensed health care provider with the ability to establish IV access must be immediately available during the period of moderate sedation.

H. Post-sedation recovery

1. Patients must be observed according to the minimum monitoring requirements until they reach an awake state (see levels of sedation and analgesia above).
2. Term infants (>37 weeks post-conceptual age) under the age of 44 weeks post-conceptual age and premature infants (<37 weeks post-conceptual age) under the age of 60 weeks post-conceptual age are at greater risk of prolonged sedative effects. Following sedation and analgesia, they must be observed for a minimum of 12 hours post-sedation.
3. Discharge from Connecticut Children's is permissible when:
   a) Criteria for discharge are met.
   b) The SAP who ordered the sedation approves the discharge and documents that the discharge criteria have been met, and
   c) The patient's parents or legal guardians are present to accompany the patient.
4. The SAP or sedation monitor discharging the patient is responsible for:
   a) Providing appropriate discharge instructions for the type of drugs that were administered.
   b) Providing the patient's parent or guardian with a phone number to call if problems occur.
   c) Providing appropriate follow-up provider names and phone numbers, and
   d) Providing medication instructions and a plan for pain management.

I. Patient transfer

1. Following a sedation event, a patient may be transferred from the area where sedation occurred to another area when the following criteria are met:
   a) The patient meets the discharge criteria or the area accepts responsibility for on-going monitoring.
   b) The primary service, if different from the service that administered the sedation, accepts responsibility for the patient.
2. The transport of a patient in a state of moderate or deep sedation between areas of the hospital requires:
   a) The appropriate monitors available for the patient's level of sedation.
   b) A minimum of two licensed health care providers escort the patient. One of the LHCP's must function as the Sedation Monitor and be solely responsible for monitoring the patient during the transfer.

c)A supplemental oxygen source, positive pressure bag and mask are available.

d)The SAP or an attending anesthesiologist must accompany patients with deep sedation.

e) Emergency resuscitation equipment is available.

J.Credentialing

1. Credentialing criteria are developed under the auspices of the Director of Anesthesiology and the Sedation & Analgesia Committee.
2. The requirements for SAP credentialing for mild and moderate sedation consist of:
    a. A working knowledge of the principles contained in this document;
    b. Review of the SAP Educational Module approved by the Sedation and Analgesia Committee;
    c. Successful completion of the Sedation and Analgesia Qualifying Examination; and
    d. Documentation of adequate bag/mask airway management skills by completing an airway skills practicum or by providing documentation of successful completion (current) of an appropriate life support skills course (i.e. PALS, ACLS, NRP or ATLS).
3. Sedation and Analgesia privileges may be renewed if all requirements a., b. and c. of the credentialing requirements above continue to be met and the provider has documentation of having performed ten (10) or more cases in the preceding 24 months. If fewer than ten (10) cases are documented in the preceding 24 months, the requirements above (a. through d.) must be met.
4. Credentialing for the use of nitrous oxide as an agent for sedation requires current privileges to perform minimal and moderate sedation as outlined in this document. Additional credentialing requirements may include successful completion of accredited nitrous oxide administration course and/or successful completion of a number of proctored sedations using nitrous oxide.
5. Credentialing to perform deep sedation requires evidence of significant sedation and analgesia experience from a training program or evidence of extensive clinical sedation experience. This includes residency or fellowship training in Emergency Medicine, Critical Care Medicine, and/or Anesthesiology. Exceptions to this training and/or clinical experience may be considered after successful demonstration of the core competencies outlined by the Sedation and Analgesia Committee and must be approved by the Director of Anesthesiology, the Sedation & Analgesia Committee, and the Medical Staff Executive Committee.
6. Processing of sedation and analgesia privileges is done in accordance with Medical Staff policy. Upon successful achievement of credentialing criteria, the Director of Anesthesiology and Department/Division shall recommend action on the privilege request. All privilege requests for deep sedation must be favorably recommended by the Director of Anesthesiology.

7. Housestaff physician (resident or fellow) credentialing occurs under the auspices of the Medical Education Department and is reviewed on a biennial basis. Housestaff physician credentialing includes the above requirements for other SAP's but also includes documentation of a minimum of 6 observed successful sedations. These qualifying sedations must be directly observed by another credentialed SAP and recorded.
8. Nursing validation is under the auspices of the Education and Development Department and the specific unit managers. Validations are reviewed on an annual basis.
9. Failure to comply with this policy shall result in corrective action in accordance with the Medical Staff Bylaws or disciplinary action in accordance with Human Resources policy.
   (1) The performance of > six (6) cases in past twelve (12) months.

K. Performance Improvement Monitoring

1. S & A events at Connecticut Children's will include documentation on a Sedation and Analgesia Patient History form to be included in the medical record. Copies of these forms will also be forwarded to S & A Committee leadership for monitoring and reviewing S & A performance. S & A events in the Emergency Department are recorded in the medical record and copies of the sedation event notes are forwarded to S & A Committee leadership for review.
2. Deviations from this policy authorized by a credentialed SAP must be documented in the patient's medical record and on Sedation and Analgesia Patient History form and are subject to review.
3. Adverse events are also to be reported on the Sedation and Analgesia Patient History form or on the appropriate history incident report forms. Adverse events are to be regularly reviewed by the Sedation and Analgesia Committee. Adverse events include, but are not limited to:
   a) Hypoxemia
   b) Hypoventilation
   c) Hypotension
   d) Other cardiovascular events
   e) Vomiting/aspiration
   f) Inadequate sedation – defined as an unsuccessful test or procedure due to a lack of adequate sedation.
   g) Progression beyond intended level of sedation.
4. In the event of a critical incident or adverse outcome, Risk Management should be notified and a hospital incident report form completed in a timely fashion. Adverse outcomes include, but are not limited to, unplanned admission to the hospital, transfer to a higher level of care, cardiopulmonary arrest, pulmonary aspiration, neurological injury, and death.

L.Documentation

1. Informed consent for the sedation and analgesia must be obtained according to Connecticut Children's policy and documented in the medical record.
2. The final verification procedure must be documented in the patient's medical record on a "Time Out" form.
3. All medications/fluids administered before and during the Sedation and Analgesia event must have a SAP order documented according to Connecticut Children's policy.
4. All medications/fluids administered before and during the procedure or recovery period must be documented on the Sedation and Analgesia flowsheet.
5. The patient's vital signs during the procedure and recovery period will be recorded as outlined by the minimal monitoring requirements for the level of sedation.
6. The patient's sedation assessment scores pre-procedure and upon release are to be documented on the Sedation and Analgesia flowsheet.
7. Patient/family education regarding sedation and analgesia is to be documented in the medical record.
8. For serial sedations, the Sedation and Analgesia Patient History Form and Flowsheet must be completed for each sedation event (a photocopy of an original history form may be used with new dates and post-procedure documentation.)

V.References

Advisory on Granting Privilieges for Deep Sedation to Non-Anesthesiologist Sedation Practitioners. Ad Hoc Committee on Non-Anesthesiologist Privileging, ASA. 2010. Available at www.ASAHQ.org.
(Approved by the ASA House of Delegates on October 20, 2010)

Society for Pediatric Sedation Consensus Statement: Core Competencies for Pediatric Providers Who Deliver Deep Sedation. Available at www.pedsedation.org/documents/SPS_Core_Competencies.pdf

VI.Related Documents

Informed Consent
Site Identification for Invasive Procedures
Time Out for Sedation and Analgesia and Procedures Outside of the OR
Propofol Infusion Policy