SAFETY AND QUALITY PROTOCOL

Purpose: Patient safety is our #1 priority. This protocol describes detailed requirements that must be met by healthcare organizations performing cleft surgeries funded by Smile Train. The following requirements outline important policies and procedures to ensure safe surgery and anesthesia care for all Smile Train patients.

PART 1: PATIENT MEDICAL RECORDS

Requirement 1.1: Documentation Standards:

- Use the Smile Train Patient Medical Record and Smile Train Express (www.smiletrainexpress.org) for all patients undergoing Smile Train-sponsored cleft surgeries.
- Patient medical records must include details of the preoperative surgical assessment, anesthetic preoperative evaluation, intra and postoperative medical records including the anesthesia intraoperative record, anesthesia notes, surgeon operative record, surgeon notes, post-anesthesia care unit nursing notes, and ward notes. Documentation must be clear, legible, and contemporaneous.

Requirement 1.2: Evaluation of Surgical Outcomes:

- Have regularly scheduled meetings where members of the cleft team (surgeons, anesthesiologists or participating anesthesia providers, pediatricians, speech services providers, orthodontists and other comprehensive care specialists) review all patient records, develop treatment plans for patients, discuss surgical outcomes and treatment results no less than every 3 months.

PART 2: PREOPERATIVE ASSESSMENT

Requirement 2.1: Patient Selection:

- All patients undergoing Smile Train-funded surgeries must be American Society of Anesthesiology (ASA) physical status class 1 or class 2.
    - ASA 1 patients have no organic, physiologic, biochemical, or psychiatric disturbance and the disease for which the operation is to be performed is localized and does not entail a systemic disturbance.
    - ASA 2 patients are those with mild to moderate systemic disturbance caused either by the condition to be treated surgically or by other pathophysiologic processes.
    - As a reference, an otherwise healthy child with cleft lip or palate with no other medical problems would typically fall into an ASA 1 or 2 classification. Children with underlying syndromes often fall into an ASA 3 classification or higher.

Requirement 2.2: Patient Evaluation:

- Every surgical patient must receive a complete and thorough preoperative history, physical examination and health clearance from a primary care provider (ideally a pediatrician) familiar with the average health status and common local health problems.
- Smile Train will ONLY fund surgery for any patient who:
    - During history and physical exam, is found to be at low-risk of developing surgical or anesthetic perioperative complications.
    - Is over three months of age for lip surgery and over six months of age for palate surgery.
    - Is at least 5 kg and demonstrates age appropriate weight.
- Informed consent for the surgical procedure must be obtained by a member of the cleft team.

Requirement 2.3: Scheduling of Patients:

- Children under 2 years of age must NOT have surgery scheduled later than 14:00.
- Combined lip and palate surgical procedures, where both surgeries are performed during the same anesthesia, must NOT take place for patients under 1 year of age.
- There must be a gap of 90 days between two Smile Train-sponsored surgeries to allow time for proper healing following surgery. This directive does not apply to emergencies requiring an urgent return to the operating theater.

PART 3: SPECIFIC PREOPERATIVE REQUIREMENTS

Requirement 3.1: Patient Evaluation:

- A detailed history and physical examination must be completed by a pediatrician or anesthesiologist prior to patients being scheduled for surgery. This assessment must include:
    - History of Present Illness.
    - Past medical history including birth history (estimated gestational age and any known complications at birth that might complicate anesthesia care) and congenital abnormalities.
    - Patient's known allergies (e.g. medications and reactions).
    - Past surgical history including any complications.
    - Previous anesthetic complications including any family history of adverse reactions to anesthesia.
    - A detailed physical exam must be performed and documented with specific attention paid to any obvious congenital abnormalities and airway abnormalities. A detailed heart and lung exam must be performed to assess for any heart murmurs or respiratory abnormalities.
    - Chest x-ray (CXR) and Electrocardiogram (ECG) must be obtained if the patient's history or physical exam suggest cardiac or pulmonary abnormalities.
    - Laboratory work:
        - All patients must receive a complete blood count (CBC).
        - All patients must have a minimum preoperative hemoglobin level of 10g/dL.
        - Patients must not receive blood transfusions prior to surgery to meet hemoglobin requirement.
        - Cleft palate patients must have additional PT/PTT.

Requirement 3.2: Preoperative Anesthesia Evaluation:

- A preoperative assessment must be performed and documented.
- This assessment should occur the day before surgery and not in the operating theater.
- The anesthesia provider must:
    - Review the pediatrician's patient history and physical exam, noting specifically:
        - Past surgical history including any complications.
        - Previous anesthetic complications including any family history of adverse reactions to anesthesia.
        - Review of any implications of prematurity if present.
    - Discuss any new medical issues the patient presents with since being seen by patient's pediatrician or family practitioner.
    - Review patient's current list of medications.
    - Review patient's known allergies (e.g. medications and reactions).
    - Conduct a directed physical exam that includes current vital signs including oxygen saturation and weight. Particular attention should be paid to the patient's airway, cardiac and respiratory status exams.
        - A child identified to have an active lower respiratory infection (LRI) or upper respiratory infection (URI) with constitutional symptoms (e.g. fever or malaise) must have surgery delayed by 4-6 weeks until their health status is optimized. A child identified to have a URI but no constitutional symptoms should be evaluated by an anesthesia provider on a case by case basis regarding the appropriateness for surgery. These cases may need to be delayed by 2 weeks until the URI symptoms have resolved.
    - Review lab data.
    - Discuss general anesthetic plan with the patient and/or parents.
    - Review NPO guidelines for surgery with patient and parents. Every effort should be made to prevent prolonged fasting.

Fluid:	Recommended fasting time:
Clear fluids	2 hours
Breast milk	4 hours
Cow's milk or solids	6 hours

- Anesthesia approval must be obtained in order to clear patient for surgery.

Requirement 3.3: Day of Surgery:

- Member of cleft team must:
  - Ensure patient is afebrile and has age appropriate vital signs.
  - Verify appropriate NPO status and ensure patient is not dehydrated.
- Premedication:
  - If the use of a mild sedative to relieve anxiety immediately prior to surgery is part of the routine care of preoperative pediatric patients, the patient must be continuously monitored, at a minimum with a functional pulse oximeter. This pulse oximeter should be placed on the patient concurrent with the administration of the medication and continuously monitored by a nurse or a member of the anesthesia team until the patient goes in for surgery.

Requirement 3.4: Operating Theater Equipment & Supplies:

- The following equipment and supplies must be available in each operating theater and used when appropriate:
  - Adequate lighting
  - Well-maintained and sterilized cleft set and related surgical instruments
  - Supply of oxygen (oxygen concentrator, cylinders or pipeline)
  - Airway management equipment:
    - Appropriately sized oropharyngeal and nasopharyngeal airways
    - Appropriately sized facemasks
    - Appropriately sized laryngoscope and blades
    - Appropriately sized endotracheal tubes
    - Intubation aids, e.g. Magill forceps, bougie, stylet
    - Adult and pediatric self-inflating resuscitation bags
    - Tracheostomy tray
  - All functional anesthesia machines should include:
    - Inspired oxygen concentration monitor
    - Anti-hypoxia device to prevent delivery of a hypoxic gas mixture
    - System to prevent misconnection of gas sources (e.g. tank yokes, hose connectors)
    - Vigilance and use of pulse oximetry is critical to prevent hypoxia during surgery
  - Monitoring equipment:
    - Electrocardiogram (ECG)
    - Defibrillator (at least one functioning defibrillator should be available)
    - Stethoscope
    - Pulse oximeter
    - Non-invasive blood pressure monitor with appropriately sized cuffs
  - Suction device and suction catheters
  - Equipment for IV infusions and injection of medications (including burette sets, if available)
  - IV pressure infuser bag
  - Patient warmers
- If available, end tidal carbon dioxide (ETCO2) should be used
- All equipment and supplies must be in good working order. If any of the specified equipment is not functioning properly, surgeries must be deferred or suspended.

PART 4: SURGICAL AND ANESTHESIA CARE REQUIREMENTS

Requirement 4.1: Qualified Clinical Professionals:

- Only qualified, credentialed cleft surgeons registered in Smile Train Express are permitted to perform surgery on Smile Train-sponsored patients. These surgeons must be trained, have current certification in their country, and have ongoing experience in surgery for cleft lip and palate. Qualified surgeons will have:
    - Demonstrated that cleft surgeries occur regularly by sharing of patient lists, surgical schedules, and volume.
    - Demonstrated that the facility has experience in cleft surgery by having performed cleft surgeries in the previous six months.
    - Registered in Smile Train's online patient database Smile Train Express.
- Only qualified credentialed anesthesiologists or anesthesia providers with current certification in their country who have ongoing experience and familiarity in caring for young children may provide anesthesia for Smile Train patients.
    - Smile Train-sponsored patients must be attended by a trained anesthesia provider at all times until fully recovered and transferred to the ward.

PART 5: INTRAOPERATIVE SURGICAL AND ANESTHESIA REQUIREMENTS

Requirement 5.1: Safe Surgical Environment:

- Commitment to using the World Health Organization Surgical Safety Checklist.
- Appropriate number of operating theater personnel experienced in cleft surgery.
- All operating theater personnel must change into sterile garments before entering the operating theater.
- Staff familiar with sterile technique and access to functional sterilizing machines.
- During general anesthesia, care must be taken to protect patient's eyes to avoid corneal injuries
- Appropriate surgical equipment to safely perform cleft lip and palate surgery.
- During use of electrocautery, care must be taken by the team for proper use to avoid burns to the patient
- For palate surgeries, blood and blood transfusion capabilities must be readily available.
- Temperature modality should be available in operating theater.

Requirement 5.2: Intraoperative Medication/Intravenous Fluids/Gases:

- A selection of these medications must be available in the operating theater at all times:
    - Ketamine
    - Diazepam or midazolam
    - Narcotic analgesia: morphine or fentanyl
    - Local anesthetic (e.g. lidocaine or bupivacaine)
    - Thiopentone or propofol
    - Appropriate inhalational anesthetic (e.g. halothane, isoflurane, sevoflurane)
    - Suxamethonium/Succinylcholine
    - Appropriate nondepolarizing muscle relaxant
    - Neostigmine
    - Dexamethasone
    - Tranexamic acid
- These resuscitative medications must be available in the operating theater at all times:
    - Oxygen (supplemental oxygen must be available for all patients undergoing general anesthesia)
    - Epinephrine (adrenaline)
    - Inhaled racemic epinephrine
    - Atropine
    - Ephedrine or phenylephrine
    - Inhaled bronchodilators
    - Hydrocortisone
    - Dextrose
- Normal saline or Ringer's lactate must be available in the operating theater at all times.
    - Hypotonic IV solutions should be avoided during surgery.

- All medications and IV fluids must be clearly labelled and dated.
- If procurable, dantrolene sodium should be available for treatment of cases of malignant hyperthermia.

Requirement 5.3: Intraoperative Anesthesia Monitoring:

- Anesthesia provider must be in the operating theater with the patient at all times.
- Clinical observation by a trained anesthesia provider intraoperatively should include:
    - Pulse rate and quality:
        - ECG must be monitored throughout each anesthetic.
    - Tissue oxygenation and perfusion:
        - Continuously monitored by clinical observation and a pulse oximeter. Clinical observation of oxygenation requires exposure of part of the patient (e.g. face or hand, and adequate lighting).
    - Respiratory rate and quality/breathing system bag movement:
        - The adequacy of the airway and ventilation must be monitored by auscultation and continuous clinical observation. Where a breathing circuit is used, the reservoir bag or peak airway pressures should be observed. A precordial stethoscope must be used when only a pulse oximeter and ECG is available for intraoperative monitoring.
    - Breath sounds:
        - In some environments, continuous use of a precordial or esophageal stethoscope may be appropriate. If an endotracheal tube is used, correct placement must be verified by auscultation. If possible, confirmation of correct placement by carbon dioxide detection is useful.
    - Heart sounds:
        - Palpation or auscultation with a precordial stethoscope may be useful. Display of the pulse and/or auscultation of the heart sounds must be continuous. Continuous monitoring and display of the heart rate must be done with a pulse oximeter.
- Timings of all medications administered and vital signs must be recorded contemporaneously on intraoperative anesthesia record including:
    - Non-invasive arterial blood pressure, heart rate, temperature, respiratory rate, O2 sat (and ETCO2, if available) every 5 minutes.

PART 6: POSTOPERATIVE SURGICAL AND ANESTHESIA CARE REQUIREMENTS

Requirement 6.1: Safe Postoperative Environment:

- It is expected that the operating surgeon remain in the operating theater suite until the patient is extubated and breathing spontaneously with stable vital signs.
- The patient is the responsibility of the anesthesia provider until he/she is cleared to be moved to the ward.
- All patients must be awake, breathing spontaneously, and administered supplemental oxygen by facemask when transported from the operating theater to the post anesthesia care unit (PACU).
- A crash cart with all emergency and resuscitation materials should be easily accessible to the PACU and ward. It must include medications and equipment required for defibrillation, intubation, intravenous medication, and passage of central lines. Care should be taken to regularly replenish materials after use.
- It is important for anesthesiologists to work with the surgeons to determine what medications should be administered to pediatric patients to appropriately manage their pain without causing respiratory compromise. Consider using local anesthesia blocks when appropriate.

Requirement 6.2: Safe Postoperative PACU Care:

- There must be a designated PACU where all patients can be temporarily admitted after surgery to safely regain consciousness from anesthesia and receive appropriate postoperative care.
    - This area must be staffed by healthcare workers (ideally 1:2 practitioner to patient ratio) who are trained in airway management and postoperative monitoring (blood pressure, ECG, and pulse oximetry monitoring).
- All patients must be continuously monitored for:
    - Tissue oxygenation and perfusion with a pulse oximeter
    - Respiratory rate
    - Pulse rate

    - Assessment of pain
- Patients must remain in PACU until they are fully awake, pain is controlled, and there is no evidence of nausea, vomiting or postoperative bleeding. Typically, this will be one to two hours postoperatively. Before any patient is transferred to the ward, an anesthesia provider must evaluate the patient and deem that the patient is stable enough to be moved.
- The PACU must have temperature modality.

Requirement 6.3: Safe Postoperative Ward Care:

- All patients on the ward should have hourly pulse, respiratory rate and O2 sat monitored by ward staff overnight.
- A handover document should be completed by the PACU team for the ward staff with written details of problems to be expected, plan for pain management and instructions on when feeding may be initiated.

Requirement 6.4: High Dependency Care Provisions:

- All partners must have access to a high dependency care unit (e.g. intensive care unit (ICU) for patients with severe and life-threatening illnesses and injuries who require constant, close monitoring. These units can be within the hospital or at a nearby healthcare facility.
- If high dependency care capabilities are not available, a current, functioning transfer agreement with a nearby healthcare facility that can provide this type of intensive care must be in place for Smile Train-sponsored surgeries. The healthcare facility that is providing the intensive care must agree to document care provided and share all medical information with the referring hospital in a timely manner.
- An anesthesia provider, intensivist or pediatrician must oversee ICU management and care provided to patients.
- Trained nurses and technicians must be available to care for and assist with management and monitoring of patients (ideally 1:2 nurse to patient ratio).
- Written protocols must be in place and implemented by the staff for emergency care, triage, CPR, and blood transfusions. The use of regular emergency drills is strongly encouraged.
- A handover document should be completed by the anesthesia provider for the ICU staff.

PART 7: SENTINEL EVENTS

Requirement 7.1: Promptly report all sentinel events. A sentinel event is an unexpected event that results in death, serious permanent physical or psychological injury, or severe temporary harm to a patient. Examples of sentinel events include, but are not limited to, patient death, cardiac arrest, respiratory arrest, stroke, aspiration or aspiration pneumonia, and unanticipated return to the operating theater:

- Within 24 hours of a sentinel event occurrence partner hospital must:
    - Report the occurrence of the sentinel event to Smile Train by emailing medical@smiletrain.org.
    - Complete Smile Train's Sentinel Event Form (Part One) and email to medical@smiletrain.org.
- Within 14 days of the sentinel event occurrence:
    - All sentinel events must be discussed by the cleft team at the healthcare facility so that opportunities for improvement in quality of care can be identified and action plans initiated.
    - Partner hospital must complete Smile Train's Sentinel Event Report (Part Two) and email to medical@smiletrain.org.
    - Partner hospital must prepare and send the patient's medical record (preoperative history & physical, pre-, intra-, and postoperative records including the anesthesia preoperative assessment and intraoperative record, PACU record, all physician and nursing progress notes, lab reports, operative reports, and any additional narratives) to medical@smiletrain.org.
- Within 4-6 weeks of the Sentinel Event occurrence:
    - A member of Smile Train's Medical Advisory Board will review and analyze the medical records received and will provide constructive feedback to the partner hospital in the form of an analysis and memorandum.
    - The partner hospital will send written confirmation of the analysis and plans for inclusion of constructive feedback and recommendations.

- All partner hospitals that experience a sentinel event resulting in the death of a Smile Train-sponsored patient will be required to undergo a safety and quality audit of their facility conducted by an independent pediatric anesthesiologist appointed by Smile Train.

Recognizing that patient safety is always our #1 priority, I have read Smile Train's Safety and Quality Protocol, and certify that _____ (*organization/hospital)* **meets and will adhere to these requirements.**

Signed_____**Name**_____

Title_____**Date**_____