



# eClinicalOS Blank Pages

Study Name:	Collaborative Learning
Study Revision	3
Language	English (US)

# 1. Schedule

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	Protocol Deviation	Repeat Visit Instructions : This form should be completed if a deviation from the protocol took place.

# Enrollment

## General Information

(Visit ID = 20, Page ID = 60)

Unique Identifier page-65991-75050-20-60

### GENERAL INFORMATION

***Subjects should only be added to the database once Inclusion Criteria has been met. Screened only subjects who do NOT meet Inclusion Criteria should be recorded on the Screening Log, but NOT added to the database.***

Subject ID number (format 9999999)

Site ID (format 999) Your site ID is the first 3 digits of the subject ID

Collaborative vs Control (auto calculated) (format 9)

# Demographics

(Visit ID = 20, Page ID = 70)

Unique Identifier page-59850-75050-20-70

**SUBJECT INFORMATION**

Subject ID (format 9999999)

Site ID (remote value)

**DEMOGRAPHICS**

1. Birth Weight Known  Yes (select only one)  
 No

1a. Birth Weight (kg) (format 99.99)

2. Gender  Male (select only one)  
 Female

3. Gestational Age at Birth Known  Yes Indicate whether the patient's gestational age at birth is known.(select only one)  
 No

3a. Gestational age at birth (weeks) (format 99.99)

4. Race Data Known  Yes (select only one)  
 No

**Please answer YES or NO for all questions.**

4a. White / Caucasian  Yes Indicate whether the subject's race includes Caucasian. This includes a person having origins in any of the original peoples of Europe, the Middle East, or North Africa.(select only one)  
 No

4b. Black / African American  Yes Indicate whether the subject's race includes Black / African American. This includes a person having origins in any of the black racial groups of Africa.(select only one)  
 No

4c. Asian  Yes Indicate whether the subject's race includes Asian. This includes a person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.(select only one)  
 No

4d. American Indian or Alaska Native  Yes Indicate whether the subject's race includes American Indian / Alaskan Native. This includes a person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment.(select only one)  
 No

4e. Native Hawaiian or Other Pacific Islander  Yes Indicate whether the subject's race includes Native Hawaiian / Pacific Islander. This includes a person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.(select only one)  
 No

4f. Other  Yes Indicate whether the subject's race includes any other race.(select only one)  
 No

4f1. Other, specify

5. Ethnicity  Hispanic or Latino/Latina Hispanic or Latino ethnicity includes patient report of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race.(select only one)  
 Not Hispanic or Latino/Latina  
 Unknown

# Medical Review

(Visit ID = 20, Page ID = 80)

Unique Identifier page-65131-75050-20-80

## SUBJECT INFORMATION

Subject ID (format 9999999)

Site ID (remote value)

## MEDICAL REVIEW

1. Date of procedure (DD-MMM-YYYY) Indicate the date the subject entered the operating room.

1a. Age on date of procedure (days) (format 999) Calculate the subject's age in days at the time of the procedure. The subject's age will be calculated from the date of birth and the date of procedure.

2. Procedure  Tetralogy of Fallot Repair (select only one)  
 Coarctation of Aorta Repair

2a. Specific procedure for this operation (select only one)

- TOF repair, No ventriculotomy
- TOF repair, Ventriculotomy, Nontransannular patch
- TOF repair, Ventriculotomy, Transannular patch
- TOF repair, RV-PA conduit
- TOF - AVC (AVSD) repair
- TOF - Absent pulmonary valve repair

2a. Specific procedure for this operation (select only one)

- Coarctation repair, End to end
- Coarctation repair, End to end, Extended
- Coarctation repair, Subclavian flap
- Coarctation repair, Other

2a1. Coarctation Repair Other, Specify

2b. Fundamental Diagnosis  Pulmonary stenosis Indicate the most complex cardiac anomaly or condition (congenital or acquired) which requires cardiothoracic intervention.(select only one)  
 AVC (AVSD)  
 Absent pulmonary valve

2b. Fundamental Diagnosis  Isolated Coarctation Indicate the most complex cardiac anomaly or condition (congenital or acquired) which required cardiothoracic intervention.(select only one)  
 Isolated Coarctation + VSD (not requiring intervention)  
 Coarctation + Other Lesion

### 3. Prior Palliative Surgery

3a. Status post - Shunt, Systemic to pulmonary. Modified Blalock-Taussig Shunt (MBTS)  Yes Placement of a tube graft from a branch of the aortic arch to the pulmonary artery with or without bypass, from any approach (thoracotomy, sternotomy).(select only one)  
 No

3b. Status post - Shunt, Systemic to pulmonary. Central (from aorta to main pulmonary)  Yes A direct anastomosis or placement of a tube graft from the aorta to the pulmonary artery with or without bypass, from any approach (thoracotomy, sternotomy).(select only one)  
 No

### 4. Noncardiac Congenital Anatomic Abnormalities

**Please answer YES or NO for all questions.**

4a. Major abnormality of head or brain

4a1. Birth Asphyxia	<input type="radio"/> Yes <input type="radio"/> No	The term "asphyxia" should not be used unless the subject met all of the following conditions: (1) umbilical cord arterial pH less than 7 (whether metabolic or mixed), (2) Apgar score of 0 to 3 for longer than 5 minutes, (3) neurologic manifestations (eg, seizures, coma, or hypotonia), and (4) multisystemic organ dysfunction (select only one)
4a2. Hypoxic-ischemic brain injury from cardiogenic shock	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4a3. Seizures requiring medication	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4a4. Porencephaly	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4a5. Polymicrogyria	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4a6. Multicystic Encephalomalacia	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4a7. Pachygyria	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4a8. Lissencephaly	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4a9. Hydranencephaly	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4a10. Holoprosencephaly	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4a11. Anencephaly	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4a12. Hydrocephaly	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4b. Major abnormality of spine or spinal cord	<input type="radio"/> Yes <input type="radio"/> No	Indicate whether the subject had a documented Spine or Spinal cord abnormality that would impact respiratory status immediately following surgical repair. If selected YES, the PI must confirm. (select only one)
4c. Major abnormality of larynx - trachea - or bronchus		
4c1. Laryngeal/esophageal atresia/stenosis	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4c2. Tracheal/bronchial atresia/stenosis	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4c3. Bronchogenic cysts	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4c4. TE Fistula	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4c5. Tracheal-bronchial malacia	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4d. Major abnormality of lung		
4d1. Pulmonary/lobar atresia	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4d2. Extralobar sequestration	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4d3. Pulmonary hypoplasia (oligohydraminos)	<input type="radio"/> Yes <input type="radio"/> No	(select only one)

4d4. Intralobar sequestration	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4d5. Cysts, cystic adenomatoid malformations	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4d6. Pulmonary lymphangiectasis	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4d7. Diaphragmatic hernia	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4d8. Alveolar capillary dysplasia	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4d9. Pulmonary immaturity and surfactant deficiency	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4d10. Pulmonary hyperplasia	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4d11. Surfactant deficiency, respiratory distress syndrome (RDS)	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4d12. Pulmonary hypertension	<input type="radio"/> Yes <input type="radio"/> No	Receiving vasodilator therapy (excluding O2) at time of surgery (select only one)
4d13. Bronchopulmonary dysplasia	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4d14. Lobar emphysema	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4d15. Pleural effusions	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4d16. Meconium aspiration, infection	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4d17. Alveolar simplification	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
<b>5. Reported Chromosomal Abnormalities</b>		
<b>Please answer YES or NO for all questions.</b>		
5a. 22q11 deletion	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
5b. Trisomy 13	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
5c. Trisomy 18	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
5d. Trisomy 21	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
5e. Pierre-Robin sequence	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
5f. Cri-du-chat	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
5g. Other Chromosomal Abnormality or Syndrome	<input type="radio"/> Yes <input type="radio"/> No	Indicate whether the subject had documented Other Chromosomal abnormality or syndrome that would impact respiratory status immediately following surgical repair. If selected YES, the PI must confirm. (select only one)

5g1. Other Chromosomal Abnormality or Syndrome,  
Specify

# Eligibility Confirmation

(Visit ID = 20, Page ID = 90)

Unique Identifier page-59830-75050-20-90

## SUBJECT INFORMATION

Subject ID (format 9999999)

Site ID (remote value)

## Eligibility Confirmation

### Exclusion Criteria

1. Known Primary Lung Disease or Airway Anomalies  Yes (select only one)  
 No

*The Medical Review form reports that there is a major abnormality of the lung, larynx - trachea - or bronchus that would exclude this patient from being enrolled.*

2. Corrected Gestational Age at Time of Surgery of < 36 weeks  Yes Gestational Age at Birth plus Age at Date of Surgery(select only one)  
 No  
 Unknown

*The Demographics form reports that gestational age at birth is unknown which would exclude this patient from being enrolled.*

Age on date of procedure (days) (remote value)

Date of Surgery (remote value)

Gestational Age at birth (weeks) (remote value)

3. Patient receiving mechanical ventilation immediately prior to surgery.  Yes This criteria is not exclusive if the medical record explicitly states mechanical ventilation performed solely for purpose prostaglandin-related apnea or hypoapnea. (select only one)  
 No

4. Known Congenital or Acquired Neurologic Injury causing respiratory depression.  Yes Neurologic condition known to produce decreased level of consciousness or apnea/hypoapnea that requires respiratory support greater than cannula oxygen such as CPAP or mechanical ventilation. (select only one)  
 No

*The Medical Review form reports that there is a major abnormality of the head or brain that would exclude this patient from being enrolled.*

5. Patients with Known Chromosomal Abnormality or Syndrome likely to Impact Airway or Lung Function  Yes (select only one)  
 No

*The Medical Review form reports that there is a major chromosomal abnormality that would exclude this patient from being enrolled.*

6. Pulmonary Hypertension  Yes Receiving vasodilator therapy (excluding O2) at time of surgery(select only one)  
 No

7. Planned Concomitant Surgical Procedures Requiring Cardiopulmonary Bypass  Yes (select only one)  
 No

6. Enrollment in the Dexmedetomidine Bolus and Infusion in Corrective Infant Cardiac Surgery: Safety and Pharmacokinetics  Yes (select only one)  
 No

**After filling in the questions above, please press SAVE.**

Eligibility Confirmation (auto calculated) (format 9)

If the Eligibility Confirmation value = 0, the subject status will change to Enrolled.

If the Eligibility Confirmation value = 1, the subject status will change to Not Enrolled.

## Eligibility

(Visit ID = 20, Page ID = 110)

Unique Identifier page-81310-75050-20-110

### SUBJECT INFORMATION

Subject ID (format 9999999)

Site ID (remote value)

### Eligibility Confirmation

#### Exclusion Criteria

1. Known Primary Lung Disease or Airway Anomalies  Yes (select only one)  
 No

*The Medical Review form reports that there is a major abnormality of the lung, larynx - trachea - or bronchus that would exclude this patient from being enrolled.*

2. Corrected Gestational Age at Time of Surgery of < 36 weeks  Yes Gestational Age at Birth plus Age at Date of Surgery (select only one)  
 No  
 Unknown

*The Demographics form reports that gestational age at birth is unknown which would exclude this patient from being enrolled.*

Age on date of procedure (days) (remote value)

Date of Surgery (remote value)

Gestational Age at birth (weeks) (remote value)

3. Patient receiving mechanical ventilation immediately prior to surgery.  Yes This criteria is not exclusive if the medical record explicitly states mechanical ventilation performed solely for purpose prostaglandin-related apnea or hypoapnea. (select only one)  
 No

4. Known Congenital or Acquired Neurologic Injury causing respiratory depression.  Yes Neurologic condition known to produce decreased level of consciousness or apnea/hypoapnea that requires respiratory support greater than cannula oxygen such as CPAP or mechanical ventilation. (select only one)  
 No

*The Medical Review form reports that there is a major abnormality of the head or brain that would exclude this patient from being enrolled.*

5. Patients with Known Chromosomal Abnormality or Syndrome likely to Impact Airway or Lung Function  Yes (select only one)  
 No

*The Medical Review form reports that there is a major chromosomal abnormality that would exclude this patient from being enrolled.*

6. Pulmonary Hypertension  Yes Receiving vasodilator therapy (excluding O2) at time of surgery(select only one)  
 No

7. Planned Concomitant Surgical Procedures Requiring Cardiopulmonary Bypass  Yes (select only one)  
 No

6. Enrollment in the Dexmedetomidine Bolus and Infusion in Corrective Infant Cardiac Surgery: Safety and Pharmacokinetics  Yes (select only one)  
 No

**After filling in the questions above, please press SAVE.**

Enrollment Confirmation (auto calculated) (format 9)

If the Eligibility Confirmation value = 0, the subject status will change to Enrolled.

If the Enrollment Confirmation value = 1, the subject status will change to Not Enrolled.

# Data Collection

## Preoperative Information

(Visit ID = 30, Page ID = 10)

Unique Identifier page-63810-93233-30-10

### SUBJECT INFORMATION

Subject ID

(format 9999999)

Site ID

(remote value)

### PREOPERATIVE INFORMATION

1. Date of Hospital Admission

(DD-MMM-YYYY) Indicate the Date of Admission for this procedure. For those subjects who originally entered the hospital in an out-patient capacity, but were not discharged, the admit date is the date of the subjects entry into the hospital.

2. Preoperative Factors

**Please answer YES or NO for all questions.**

2a. Cardio-pulmonary resuscitation required between date of hospital admission and OR entry time

- Yes  
 No

An attempt to restore spontaneous circulation by performing chest compressions with or without ventilations.(select only one)

2b. Complete AV block - new onset occurring between date of hospital admission and OR entry time

- Yes  
 No

Complete AV block (congenital or acquired) present by clinical documentation.(select only one)

2c. Shock, Persistent at time of surgery

- Yes  
 No

Indicate whether the subject was in a clinical state of hypoperfusion on the operating room according to any of the following criteria:  
(1) hypotension as defined by systolic blood pressure:  
neonates (0-28 days) SBP < 60mmHg  
infants (1-12 months) SBP < 70 mmHg  
(2) IV inotropes, IV vasoactive agents, or mechanical support required to maintain blood pressure as defined above.  
(3) Cardiac index < 1.8 L/min/M2  
(4) Patient in a state of compensated shock as evidenced by all of the following:  
- decreased peripheral pulses  
- decreased capillary refill  
- cool skin temperature  
(5) pH < 7.2 and/or lactate > 4 mmol/L(select only one)

2d. Shock, Resolved at time of surgery

- Yes  
 No

Indicate whether the subject was in a clinical state of hypoperfusion but not on entry to the OR, according to any of the following criteria:  
(1) hypotension as defined by systolic blood pressure:  
neonates (0-28 days) SBP < 60mmHg  
infants (1-12 months) SBP < 70 mmHg  
(2) IV inotropes, IV vasoactive agents, or mechanical support required to maintain blood pressure as defined above.  
(3) Cardiac index < 1.8 L/min/M2  
(4) Patient in a state of compensated shock as evidenced by all of the following:  
- decreased peripheral pulses  
- decreased capillary refill  
- cool skin temperature  
(5) pH < 7.2 and/or lactate > 4 mmol/L(select only one)

2e. Sepsis or Sepsis with positive blood culture between date of hospital admission and OR entry time

- Yes  
 No

Documented (positive blood culture(s)) septicemia.(select only one)

2f. Seizure within 48 hours prior to surgery

- Yes  
 No

Documented (clinical or EEG) seizure activity or chronic seizure disorder requiring medication.(select only one)

2g. Stroke,CVA,or Intracranial hemorrhage > Grade 2 within 48 hrs prior to surgery

- Yes  
 No

Neurologic symptom or symptom complex caused by cerebral ischemia or hemorrhage. (select only one)

2h. Pacemaker present

- Yes  
 No

(select only one)

3. Preoperative Medication and Sedation

**Preoperative Medication and Sedation is defined as anything given within 6 hours of OR entry time.**

**Please answer YES or NO for all questions.**

3a. Dobutamine

- Yes  
 No

(select only one)

3b. Dopamine	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
3c. Epinephrine	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
3d. Milrinone	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
3e. Nitroprusside	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
3f. Prostaglandin Infusion	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
3g. Vasopressin	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
3h. Demerol	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
3h1. Demerol Dose (mg)		(format 999.9)
3i. Dexmedetomidine	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
3i1. Dexmedetomidine Dose (mcg)		(format 999.9)
3j. Ketamine	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
3j1. Ketamine Dose (mg)		(format 999.9)
3k. Diazepam	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
3k1. Diazepam Dose (mg)		(format 999.9)
3l. Lorazepam	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
3l1. Lorazepam Dose (mg)		(format 999.9)
3m. Midazolam	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
3m1. Intravenous/Intramuscular Administration	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
3m1i. Midazolam Dose (mg)		(format 999.9)
3m2. Oral Administration	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
3m2i. Midazolam Dose (mg)		(format 999.9)
3n. Morphine	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
3n1. Intravenous/Intramuscular Administration	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
3n1i. Morphine Dose (mg)		(format 9999.9)
3n2. Oral Administration	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
3n2i. Morphine Dose (mg)		(format 999.9)
3o. Pentobarbital	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
3o1. Pentobarbital Dose (mg)		(format 999.9)

3p. Fentanyl	<input type="radio"/> Yes	(select only one)
	<input type="radio"/> No	
3p1. Fentanyl Dose (mcg)		(format 9999.9)

## Operative Information

(Visit ID = 30, Page ID = 20)

Unique Identifier page-63830-93233-30-20

### SUBJECT INFORMATION

Subject ID (format 9999999)

Site ID (remote value)

### Procedure

1. Date of Procedure (remote value)

2. Weight at surgery (kg) (format 99.99) Indicate the weight of the subject in kilograms at the time of surgery.

3. OR Entry Time (00:00 - 23:59) \_\_\_\_\_ : \_\_\_\_\_ (HH24:MI) Indicate to the nearest minute (24-hour clock) the time the subject entered the operating room.

4. Endotracheal Intubation performed prior to Operating Room arrival?  Yes  No Indicate whether the subject was intubated during the time frame from date of hospital admission but prior to operating room arrival. (select only one)

4a. Initial Intubation Date (DD-MMM-YYYY) Indicate the date the subject was initially intubated prior to operating room arrival.

4b. Initial Intubation Time (00:00 - 23:59) \_\_\_\_\_ : \_\_\_\_\_ (HH24:MI) Indicate the time (24 hour clock) ventilatory support initially started.

4c. Re-intubated in Operating Room for procedure?  Yes  No Indicate whether the patient was re-intubated in operating room. (select only one)

4c1. Intubation Time in Operating Room (00:00 - 23:59) \_\_\_\_\_ : \_\_\_\_\_ (HH24:MI) Indicate the time (24 hour clock) ventilatory support started in operating room.

4a. Intubation Time in Operating Room (00:00 - 23:59) \_\_\_\_\_ : \_\_\_\_\_ (HH24:MI) Indicate the time (24 hour clock) ventilatory support started in operating room.

5. Skin Incision Start Time (00:00 - 23:59) \_\_\_\_\_ : \_\_\_\_\_ (HH24:MI) Indicate to the nearest minute (24-hour clock) the time the skin incision was made.

6. Skin Closure in Operating Room?  Yes  No (select only one)

6a. Skin Closure Time (00:00 - 23:59) \_\_\_\_\_ : \_\_\_\_\_ (HH24:MI) Indicate to the nearest minute (24-hour clock) the time the skin incision was closed.

7. Cardiopulmonary bypass?  Yes  No (select only one)

7a. Cross Clamp Time - No CPB (minutes) (format 999) Indicate the total number of minutes the aorta was completely cross-clamped during this surgical procedure. Enter zero if no cross-clamp was used.

7b. Cross Clamp Time - on CPB (minutes) (format 999) Indicate the total number of minutes the aorta was completely cross-clamped during this surgical procedure. Enter zero if no cross-clamp was used.

7c. CPB Time (minutes) (format 999) Indicate the total number of minutes on cardiopulmonary bypass. If more than one run of cardiopulmonary bypass (CPB) required during this surgical procedure, the sum of the bypass runs will equal the total number of CPB minutes.

8. Patient extubated in OR?  Yes  No Indicate whether the endotracheal tube was removed in the operating room.(select only one)

8a. Extubation Time (00:00 - 23:59) \_\_\_\_\_ : \_\_\_\_\_ (HH24:MI) Indicate the time (24 hour clock) ventilatory support initially ceased after surgery.

9. OR Exit Date (DD-MMM-YYYY) Indicate the date the subject exited the operating room.

10. OR Exit Time (00:00 - 23:59) \_\_\_\_\_ : \_\_\_\_\_ (HH24:MI) Indicate to the nearest minute (24-hour clock) the time the subject exited the operating room.

### Medications given in OR

#### 1. Induction

1a. Date of Induction (DD-MMM-YYYY)

1b. Time of Induction \_\_\_\_\_ : \_\_\_\_\_ (HH24:MI)

1c. Inhalation Induction  Yes  No (select only one)

1c1. Isoflurane	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
1c2. Sevoflurane	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
1c3. Desflurane	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
1d. Intravenous Induction	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
1d1. Dexmedetomidine	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
1d1i. Dexmedetomidine Dose (mcg)		(format 99.999)
1d2. Etomidate	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
1d2i. Etomidate Dose (mg)		(format 99.999)
1d3. Fentanyl	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
1d3i. Fentanyl Dose (mcg)		(format 9999.999)
1d4. Ketamine	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
1d4i. Ketamine Dose (mg)		(format 99.999)
1d5. Midazolam	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
1d5i. Midazolam Dose (mg)		(format 999.999)
1d6. Propofol	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
1d6i. Propofol Dose (mg)		(format 999.999)
1d7. Remifentanyl	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
1d7i. Remifentanyl Dose (mcg)		(format 99.9999)
1d8. Sodium Thiopental	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
1d8i. Sodium Thiopental Dose (mg)		(format 999.999)
1d9. Sufentanil	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
1d9i. Sufentanil Dose (mcg)		(format 999.99)
1e. Intramuscular Induction	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
1e1. Ketamine	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
1e1i. Ketamine Dose (mg)		(format 99.999)
1e2. Midazolam	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
1e2i. Midazolam Dose (mg)		(format 999.999)

<b>2. Regional Anesthetic?</b>		
	<input type="radio"/> Yes <input type="radio"/> No	Regional anesthesia is anesthesia affecting a large part of the body. For the purposes of this study, regional anesthesia is confined to the central techniques, which include so called neuraxial blockade (epidural anesthesia, spinal anesthesia). (select only one)
2a. Thoracic Epidural Catheter	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
2b. Lumbar Epidural - Single shot	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
2c. Lumbar Intrathecal - Single Shot	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
2d. Lumbar Epidural Catheter	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
2e. Caudal Epidural - Single shot	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
2f. Caudal Epidural Catheter	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
3. Intercostal Nerve Infiltration by Surgeon or Anesthesiologist?	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4. Regional Field Block by Surgeon or Anesthesiologist?	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
<b>5. Intraoperative Medication</b> <i>Intraoperative Medication is defined as medication given from when Induction ends until ICU arrival.</i> <b>Please answer Yes or No to ALL questions.</b>		
5a. Acetaminophen	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
5b. Ketorolac	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
5c. Desflurane	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
5d. Isoflurane	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
5e. Sevoflurane	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
5f. Nitric Oxide Inhalation	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
5g. Dexmedetomidine (Precedex)	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
5g1. Dexmedetomidine (Precedex) Cumulative Dose (mcg)		(format 99.999)
5h. Fentanyl	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
5h1. Fentanyl Cumulative Dose (mcg)		(format 9999.999)
5i. Ketamine	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
5i1. Ketamine Cumulative Dose (mg)		(format 99.999)
5j. Midazolam	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
5j1. Midazolam Cumulative Dose (mg)		(format 999.999)

5k. Diazepam	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
5k1. Diazepam Cumulative Dose (mg)		(format 999.999)
5l. Propofol (Diprivan) Infusion	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
5l1. Propofol (Diprivan) Infusion Cumulative Dose (mg)		(format 999.999)
5m. Remifentanil	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
5m1. Remifentanil Cumulative Dose (mcg)		(format 999.9999)
5n. Sufentanil	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
5n1. Sufentanil Cumulative Dose (mcg)		(format 999.99)
5o. Esmolol	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
5o1. Esmolol Highest Dose (mcg/kg/min)		(format 999.999)
5p. Epinephrine	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
5p1. Epinephrine Highest Dose (mcg/kg/min)		(format 99.999)
5q. Milrinone	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
5q1. Milrinone Highest Dose (mcg/kg/min)		(format 99.9999)
5r. Dopamine	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
5r1. Dopamine Highest Dose (mcg/kg/min)		(format 999.9)
5s. Vasopressin Infusion	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
5s1. Vasopressin Infusion Highest Dose (units/kg/hr)		(format 99.9999)

## Postoperative Information

(Visit ID = 30, Page ID = 30)

Unique Identifier page-92910-93233-30-30

### SUBJECT INFORMATION

Subject ID (format 9999999)

Site ID (remote value)

### POSTOPERATIVE ICU CARE

- |   |   |  |
|---|---|--|
| 1. Date of ICU Arrival                                  |   | (DD-MMM-YYYY) The date the subject arrived in the ICU bed space.   |
| 2. Time of ICU Arrival (00:00 - 23:59)                  | _____ : _____   | (HH24:MI) The time (24 hour clock) the subject arrived in the ICU bed space.   |
| 3. Time of ICU Handoff (00:00 - 23:59)                  | _____ : _____   | (HH24:MI) Indicate the time (24 hour clock) that the anesthesiologist completed the report to attending physician in ICU.  |
| 4. Initial Extubation within 30 minutes of ICU arrival? | <input type="radio"/> Yes<br><input type="radio"/> No | Indicate whether the Initial Extubation was within 30 minutes of ICU arrival. (select only one)  |
| 4a. Initial Extubation Time (00:00 - 23:59)             | _____ : _____   | (HH24:MI) Indicate the time (24 hour clock) ventilatory support initially ceased after surgery.  |
| 5. Initial Extubation within 6 hours of ICU arrival?    | <input type="radio"/> Yes<br><input type="radio"/> No | Indicate whether the Initial Extubation was within 6 hours of ICU arrival. (select only one)   |
| 5a. Initial Extubation Time (00:00 - 23:59)             | _____ : _____   | (HH24:MI) Indicate the time (24 hour clock) ventilatory support initially ceased after surgery.  |
| 6. Initial Extubation Date                              |   | (DD-MMM-YYYY) Indicate the date ventilatory support initially ceased after surgery.<br>If the subject expired while intubated, capture the date of expiration.<br>If subject discharged on chronic ventilatory support, capture the date of discharge. |
| 7. Initial Extubation Time (00:00 - 23:59)              | _____ : _____   | (HH24:MI) Indicate the time (24 hour clock) ventilatory support initially ceased after surgery.  |

### Medications given in ICU

**Medications given in ICU is defined as anything given from ICU arrival to Initial ICU discharge.**

**Please answer YES or NO for all questions.**

- |  |   |   |
|--|---|---|
| 1. Acetaminophen   | <input type="radio"/> Yes<br><input type="radio"/> No | (select only one)   |
| 2. Dexmedetomidine (Precedex) infusion                             | <input type="radio"/> Yes<br><input type="radio"/> No | (select only one)   |
| 2a. Cumulative Dose within the first 6 hours of arrival (mcg)      |   | (format 9999.9999) For calculation of cumulative doses, Use continuous doses AND bolus doses. |
| 2b. Cumulative Dose between hour 6 and hour 48 (mcg)               |   | (format 9999.9999) For calculation of cumulative doses, Use continuous doses AND bolus doses. |
| 3. Fentanyl  | <input type="radio"/> Yes<br><input type="radio"/> No | (select only one)   |
| 3a. Cumulative Dose within the first 6 hours of arrival (mcg)      |   | (format 9999.9999) For calculation of cumulative doses, Use continuous doses AND bolus doses. |
| 3b. Cumulative Dose between hour 6 and hour 48 (mcg)               |   | (format 9999.9999) For calculation of cumulative doses, Use continuous doses AND bolus doses. |
| 4. Ketorolac   | <input type="radio"/> Yes<br><input type="radio"/> No | (select only one)   |
| 4a. Cumulative Dose within the first 6 hours of arrival (mg)       |   | (format 9999.9999) For calculation of cumulative doses, Use continuous doses AND bolus doses. |
| 4b. Cumulative Dose between hour 6 and hour 48 (mg)                |   | (format 9999.9999) For calculation of cumulative doses, Use continuous doses AND bolus doses. |
| 5. Local Anesthetic infusion via catheter (On-Q, Pleural catheter) | <input type="radio"/> Yes<br><input type="radio"/> No | (select only one)   |
| 6. Midazolam   | <input type="radio"/> Yes<br><input type="radio"/> No | (select only one)   |

6a. Intravenous/Intramuscular Administration	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
6a1. Cumulative Dose within the first 6 hours of arrival (mg)		(format 9999.9999) For calculation of cumulative doses, Use continuous doses AND bolus doses.
6a2. Cumulative Dose between hour 6 and hour 48 (mg)		(format 9999.9999) For calculation of cumulative doses, Use continuous doses AND bolus doses.
6b. Oral Administration	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
6b1. Cumulative Dose within the first 6 hours of arrival (mg)		(format 9999.9999) For calculation of cumulative doses, Use continuous doses AND bolus doses.
6b2. Cumulative Dose between hour 6 and hour 48 (mg)		(format 9999.9999) For calculation of cumulative doses, Use continuous doses AND bolus doses.
7. Morphine	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
7a. Intravenous/Intramuscular Administration	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
7a1. Cumulative Dose within the first 6 hours of arrival (mg)		(format 9999.9999) For calculation of cumulative doses, Use continuous doses AND bolus doses.
7a2. Cumulative Dose between hour 6 and hour 48 (mg)		(format 9999.9999) For calculation of cumulative doses, Use continuous doses AND bolus doses.
7b. Oral Administration	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
7b1. Cumulative Dose within the first 6 hours of arrival (mg)		(format 9999.9999) For calculation of cumulative doses, Use continuous doses AND bolus doses.
7b2. Cumulative Dose between hour 6 and hour 48 (mg)		(format 9999.9999) For calculation of cumulative doses, Use continuous doses AND bolus doses.
8. Nitroprusside	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
8a. Highest Dose in first 48 hours (mcg/kg/min)		(format 9999.9999)
9. Esmolol infusion	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
9a. Highest Dose in first 48 hours (mcg/kg/min)		(format 9999.9999)
10. Propofol (Diprivan) infusion	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
10a. Highest Dose in first 48 hours (mg)		(format 9999.9999)
11. Vasoactive Infusion within first 48 hours?	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
<b>Please answer YES or NO for all questions.</b>		
11a. Dobutamine infusion	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
11a1. Start Date of Dobutamine infusion		(DD-MMM-YYYY)
11a2. Start Time of Dobutamine infusion (00:00 - 23:59)	_____ : _____	(HH24:MI)
11b. Dopamine infusion	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
11c. Epinephrine (Adrenalin) infusion	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
11c1. Start Date of Epinephrine (Adrenalin) infusion		(DD-MMM-YYYY)
11c2. Start Time of Epinephrine (Adrenalin) infusion (00:00 - 23:59)	_____ : _____	(HH24:MI)

11d. Isoproterenol infusion	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
11e. Milrinone infusion	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
11f. Norepinephrine (Levophed) infusion	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
11f1. Start Date of Norepinephrine (Levophed) infusion		(DD-MMM-YYYY)
11f2. Start Time of Norepinephrine (Levophed) infusion(00:00 - 23:59)	_____ : _____	(HH24:MI)
11g. Vasopressin infusion	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
11g1. Start Date of Vasopressin infusion		(DD-MMM-YYYY)
11g2. Start Time of Vasopressin infusion (00:00 - 23:59)	_____ : _____	(HH24:MI)
11h. Date patient off all Vasoactive Infusions		(DD-MMM-YYYY)
11i. Time patient off all off all Vasoactive Infusions (00:00 - 23:59)	_____ : _____	(HH24:MI)
12. Date patient off all continuous infusions of sedative and analgesic		(DD-MMM-YYYY) If subject was not on continuous IV, leave date blank.
13. Time patient off all continuous infusions of sedative and analgesic (00:00 - 23:59)	_____ : _____	(HH24:MI) If subject was not on continuous IV, leave time blank.

**Assessments**

**RETROSPECTIVE DATA COLLECTION - If the information below in the assessment section is not available/cannot be determined, please select 'Unknown'.**  
**PROSPECTIVE DATA COLLECTION - The information below in the assessment section is either documented or not documented, please select YES or NO.**  
**Please refer to the CPG diagram, the medical record and/or other source documents.**

**1. Staffing Resources**

1a. ICU census on date of surgery		(format 99) Defined as number of patients physically in the ICU at 1500 on date of surgery
1b. Number of clinical care ICU nurses scheduled on day of surgery		(format 99) Defined as number of nurses providing direct clinical care to patients in the ICU from 0700 of the day of surgery until 0700 the day after surgery
1c. In addition to primary nurse in ICU, was there a resource nurse?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	(select only one)
1c1. Resource nurse total support time at bedside	<input type="radio"/> < 30 minutes <input type="radio"/> 30 - 60 minutes <input type="radio"/> > 60 minutes <input type="radio"/> Unknown	(select only one)
1c2. Additional (3rd nurse) needed to provide direct patient care at bedside?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	(select only one)

**2. Documentation**

**2a. Anesthetic/Sedation Plan**

2a1. Is there documentation of a preoperative anesthetic plan to allow early extubation?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	(select only one)
2a2. Is there documentation of a postoperative analgesia/sedation plan to allow early extubation?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	(select only one)
2a3. Time of initiation of post-operative IV fluids (00:00 - 23:59)	_____ : _____	(HH24:MI) The time the medicine started flowing into subject.
2b. Communication		

2b1. Is there documented communication that the ICU staff was informed of early extubation plan?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	(select only one)
2b2. Is there documented communication from the anesthesiologist with the ICU care team regarding ability to receive potential early extubation patient?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	(select only one)
<b>2c. Vitals</b>		
2c1. Time that initial vital sign assessment documented in ICU (00:00 - 23:59)	_____ : _____	(HH24:MI)
2c2. Time that 4th complete vital sign assessment documented in ICU (00:00 - 23:59)	_____ : _____	(HH24:MI) Complete vital assessment: 1) Respiratory Rate 2) Blood Pressure 3) Pulse 4) Temperature 5) Pain assessment
2c3. Is there documentation of blood gases, or pulse oximetry, or EtCO <sub>2</sub> , or ventilator settings, or oxygen at least twice within the first 6 hours of ICU arrival?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	If one or more of the described assessments were documented at least twice within the first 6 hours after arrival to ICU.(select only one)
2c4. Is there documentation of significant hypertension?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	Significant Hypertension: If there were 2 or more systolic blood pressure values within a minimum of 60 minutes that exceed the 99th percentile in the first 48 hours after arrival in the ICU. Please refer to the Blood Pressure Chart.(select only one)
<b>3. First Lab Tests in ICU</b>		
<b>3a. Arterial Blood Gases</b>		
3a1. pH	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	(select only one)
3a1i. pH value		(format 99.99)
3a2. PaCO <sub>2</sub>	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	(select only one)
3a2i. PaCO <sub>2</sub> value (mm Hg)		(format 999)
3a3. PaO <sub>2</sub>	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	(select only one)
3a3i. PaO <sub>2</sub> value (mm Hg)		(format 999)
3a4. SaO <sub>2</sub>	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	(select only one)
3a4i. SaO <sub>2</sub> value (%)		(format 999)
3a5. Base	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	(select only one)
3a5i. Base value		(format 99)
3a6. Date of Arterial Blood Gas Draw		(DD-MMM-YYYY)
3a7. Time of Arterial Blood Gas Draw (00:00 - 23:59)	_____ : _____	(HH24:MI)
3b. Lactate	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	(select only one)
3b1. Lactate value (mmol/l)		(format 99.99)
3b2. Date of Lactate Blood Draw		(DD-MMM-YYYY)

3b3. Time of Lactate Blood Draw (00:00 - 23:59)	_____ : _____	(HH24:MI)
3c. Hematocrit	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	(select only one)
3c1. Hematocrit value		(format 99.99)
3c2. Date of Hematocrit Blood Draw		(DD-MMM-YYYY)
3c3. Time of Hematocrit Blood Draw (00:00 - 23:59)	_____ : _____	(HH24:MI)

**4. Pain Scores (FLACC)**

*Record the highest pain score per hour for 12 hours post extubation time*

1st hour	2nd hour	3rd hour	4th hour	5th hour	6th hour	7th hour	8th hour	9th hour	10th hour	11th hour	12th hour
<input type="radio"/> 0	(select only one)										
<input type="radio"/> 1		<input type="radio"/> 1		<input type="radio"/> 1		<input type="radio"/> 1		<input type="radio"/> 1		<input type="radio"/> 1	
<input type="radio"/> 2		<input type="radio"/> 2		<input type="radio"/> 2		<input type="radio"/> 2		<input type="radio"/> 2		<input type="radio"/> 2	
<input type="radio"/> 3		<input type="radio"/> 3		<input type="radio"/> 3		<input type="radio"/> 3		<input type="radio"/> 3		<input type="radio"/> 3	
<input type="radio"/> 4		<input type="radio"/> 4		<input type="radio"/> 4		<input type="radio"/> 4		<input type="radio"/> 4		<input type="radio"/> 4	
<input type="radio"/> 5		<input type="radio"/> 5		<input type="radio"/> 5		<input type="radio"/> 5		<input type="radio"/> 5		<input type="radio"/> 5	
<input type="radio"/> 6		<input type="radio"/> 6		<input type="radio"/> 6		<input type="radio"/> 6		<input type="radio"/> 6		<input type="radio"/> 6	
<input type="radio"/> 7		<input type="radio"/> 7		<input type="radio"/> 7		<input type="radio"/> 7		<input type="radio"/> 7		<input type="radio"/> 7	
<input type="radio"/> 8		<input type="radio"/> 8		<input type="radio"/> 8		<input type="radio"/> 8		<input type="radio"/> 8		<input type="radio"/> 8	
<input type="radio"/> 9		<input type="radio"/> 9		<input type="radio"/> 9		<input type="radio"/> 9		<input type="radio"/> 9		<input type="radio"/> 9	
<input type="radio"/> 10		<input type="radio"/> 10		<input type="radio"/> 10		<input type="radio"/> 10		<input type="radio"/> 10		<input type="radio"/> 10	
<input type="radio"/> Pain Assessed (Not FLACC)		<input type="radio"/> Pain Assessed (Not FLACC)		<input type="radio"/> Pain Assessed (Not FLACC)		<input type="radio"/> Pain Assessed (Not FLACC)		<input type="radio"/> Pain Assessed (Not FLACC)		<input type="radio"/> Pain Assessed (Not FLACC)	
<input type="radio"/> Unknown		<input type="radio"/> Unknown		<input type="radio"/> Unknown		<input type="radio"/> Unknown		<input type="radio"/> Unknown		<input type="radio"/> Unknown	

**5. Ventilator support settings**

*Report the values that are closest to extubation time.*

5a. Mode

SIMV-PC (select only one)  
 SIMV-VC  
 Pressure Support  
 CPAP + Pressure Support  
 CPAP  
 Other  
 Unknown

5a1. Other ventilation mode, Specify

**5b. Parameters**

5b1. Ventilator Rate  Yes (select only one)  
 No  
 Unknown

5b1i. Ventilator Rate (minutes) (format 99)

5b2. Spontaneous Breathing Rate  Yes (select only one)  
 No  
 Unknown

5b2i. Spontaneous Breathing Rate (minutes) (format 99)

5b3. Peak inspiratory pressure (PIP)  Yes (select only one)  
 No  
 Unknown

5b3i. Peak inspiratory pressure (cmH2O) (format 999)

5b4. Positive end-expiratory pressure (PEEP)  Yes (select only one)  
 No  
 Unknown

5b4i. Positive end-expiratory pressure (cmH2O) (format 99)

5b5. Mean airway pressure (MAP)  Yes (select only one)  
 No  
 Unknown

5b5i. Mean airway pressure (cmH2O) (format 99)

5b6. Pressure support (PS)  Yes (select only one)  
 No  
 Unknown

5b6i. Amount of pressure support (cmH2O) (format 99)

5b7. Tidal Volume  Yes (select only one)  
 No  
 Unknown

5b7i. Tidal Volume (ml) (format 999)

**5. Lab Tests 6 hours post ICU arrival**

*Report the values that are closest to 6 hours after ICU arrival time.*

**5a. Arterial Blood Gases**

5a1. pH  Yes (select only one)  
 No  
 Unknown

5a1i. pH value (format 99.99)

5a2. PaCO2  Yes (select only one)  
 No  
 Unknown

5a2i. PaCO2 value (mm Hg) (format 999)

5a3. PaO2	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	(select only one)
5a3i. PaO2 value (mm Hg)		(format 999)
5a4. SaO2	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	(select only one)
5a4i. SaO2 value (%)		(format 999)
5a5. Base	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	(select only one)
5a5i. Base value		(format 999)
5a6. Date of Arterial Blood Gas Draw		(DD-MMM-YYYY)
5a7. Time of Arterial Blood Gas Draw (00:00 - 23:59)	_____ : _____	(HH24:MI)
5b. Lactate	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	(select only one)
5b1. Lactate value (mmol/l)		(format 99.99)
5b2. Date of Lactate Blood Draw		(DD-MMM-YYYY)
5b3. Time of Lactate Blood Draw (00:00 - 23:59)	_____ : _____	(HH24:MI)

**6. Lab Tests closest to Extubation Time**

*Report the values that are closest to but before extubation time.*

**6a. Arterial Blood Gases**

6a1. pH	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> Same As <b>3. First Lab Tests in ICU</b>	(select only one)
6a1i. pH value		(format 99.99)
6a2. PaCO2	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> Same As <b>3. First Lab Tests in ICU</b>	(select only one)
6a2i. PaCO2 value (mm Hg)		(format 999)
6a3. PaO2	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> Same As <b>3. First Lab Tests in ICU</b>	(select only one)
6a3i. PaO2 value (mm Hg)		(format 999)
6a4. SaO2	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> Same As <b>3. First Lab Tests in ICU</b>	(select only one)
6a4i. SaO2 value (%)		(format 999)

6a5. Base	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> Same As <b>3. First Lab Tests in ICU</b>	(select only one)
6a5i. Base value		(format 999)
6a6. Date of Arterial Blood Gas Draw		(DD-MMM-YYYY)
6a7. Time of Arterial Blood Gas Draw (00:00 - 23:59)		(HH24:MI)
6b. Lactate	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> Same As <b>3. First Lab Tests in ICU</b>	(select only one)
6b1. Lactate value (mmol/l)		(format 99.99)
6b2. Date of Lactate Blood Draw		(DD-MMM-YYYY)
6b3. Time of Lactate Blood Draw (00:00 - 23:59)		(HH24:MI)
<b>6. Ventilator support settings 6 hours post ICU arrival</b>		
<i>Report the values that are closest to 6 hours after ICU arrival time.</i>		
6a. Mode	<input type="radio"/> SIMV-PC <input type="radio"/> SIMV-VC <input type="radio"/> Pressure Support <input type="radio"/> CPAP + Pressure Support <input type="radio"/> CPAP <input type="radio"/> Other <input type="radio"/> Unknown	(select only one)
6a1. Other ventilation mode, Specify		
<b>6b. Parameters</b>		
6b1. Ventilator rate	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	(select only one)
6b1i. Ventilator Rate (minutes)		(format 99)
6b2. Spontaneous Breathing Rate	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	(select only one)
6b2i. Spontaneous Breathing Rate (minutes)		(format 99)
6b3. Peak inspiratory pressure (PIP)	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	(select only one)
6b3i. Peak inspiratory pressure (cmH2O)		(format 999)
6b4. Positive end-expiratory pressure (PEEP)	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	(select only one)
6b4i. Positive end-expiratory pressure (cmH2O)		(format 99)

6b5. Mean airway pressure (MAP)	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	(select only one)
6b5i. Mean airway pressure (cmH2O)		(format 99)
6b6. Pressure support (PS)	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	(select only one)
6b6i. Amount of pressure support (cmH2O)		(format 99)
6b. Tidal Volume	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	(select only one)
6b7i. Tidal Volume (ml)		(format 999)

**ICU Stay**

1. Re-Intubation after Initial Extubation?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	Indicate whether the subject was re-intubated after the initial postoperative extubation.(select only one)
1a. Re-Intubation Date		(DD-MMM-YYYY) Indicate the date ventilatory support restarted.
1b. Re-Intubation Time (00:00 - 23:59)	_____ : _____	(HH24:MI) Indicate the time (24 hour clock) ventilatory support restarted.
1c. Final Extubation Date		(DD-MMM-YYYY) Indicate the date ventilatory support last ceased prior to discharge. If the subject expired while intubated, capture the date of expiration. If the subject was discharged on chronic ventilatory support, capture the date of discharge.
1d. Final Extubation Time (00:00 - 23:59)	_____ : _____	(HH24:MI) Indicate the time (24 hour clock) ventilatory support last ceased prior to discharge. If the subject expired while intubated, capture the time of expiration. If the subject was discharged on chronic ventilatory support, capture the time of discharge.
2. Positive Airway Pressure (CPAP/BIPAP)?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	Indicate whether the subject received Positive Airway Pressure (CPAP/BIPAP) anytime during their ICU stay. (select only one)
2a. at postoperative ICU arrival?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	Indicate whether Positive Airway Pressure (CPAP/BIPAP) was used at ICU Arrival. (select only one)
2b. at postoperative ICU discharge?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	Indicate whether Positive Airway Pressure(CPAP/BIPAP) was used at ICU Discharge. (select only one)
3. High Flow Nasal Cannula (HFNC)?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	Indicate whether the subject received High Flow Nasal Cannula (HFNC) anytime during their ICU stay. (select only one)
3a. at postoperative ICU arrival?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	Indicate whether High Flow Nasal Cannula (HFNC) was used at ICU Arrival. (select only one)
3b. at postoperative ICU discharge?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	Indicate whether High Flow Nasal Cannula (HFNC) was used at ICU Discharge. (select only one)
4. Enteral feeding initiated during ICU stay?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	(select only one)

4a. Date Enteral Feeding Initiated		(DD-MMM-YYYY)
4b. Time Enteral Feeding Initiated (00:00 - 23:59)	_____ : _____	(HH24:MI)
5. Oral feeding initiated during ICU stay?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	(select only one)
5a. Date Oral Feeding Initiated		(DD-MMM-YYYY)
5b. Time Oral Feeding Initiated (00:00 - 23:59)	_____ : _____	(HH24:MI)
6. Critical Care End Date		(DD-MMM-YYYY) Indicate the date the attending deemed the subject ready to leave the ICU.
7. Critical Care End Time (00:00 - 23:59)	_____ : _____	(HH24:MI) Indicate the time (24 hour clock) the attending deemed the subject ready to leave the ICU.
8. ICU Discharge Date		(DD-MMM-YYYY) Indicate the date ICU service was no longer responsible for subject care.
9. ICU Discharge Time (00:00 - 23:59)	_____ : _____	(HH24:MI) Indicate the time (24 hour clock) ICU service was no longer responsible for subject care.
10. Unplanned Return to ICU?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	(select only one)
10a. Unplanned Return to ICU Date		(DD-MMM-YYYY)
10b. Unplanned Return to ICU Time (00:00 - 23:59)	_____ : _____	(HH24:MI)

**Intraoperative and/or Postoperative complications**

*Complications are defined as anything occurring from OR entry time until date of hospital discharge.*

**Please answer YES or NO for all questions.**

1. Multi-System Organ Failure (MSOF) = Multi-Organ Dysfunction Syndrome (MODS)	<input type="radio"/> Yes <input type="radio"/> No	Clinical entity with failure of two or more vital organ Systems associated with high fever, thrombocytopenia, and cardiocirculatory insufficiency. (select only one)
2. Unexpected Cardiac arrest	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
3. Cardiac dysfunction resulting in low cardiac output	<input type="radio"/> Yes <input type="radio"/> No	Low cardiac output is defined as persistent postoperative decrease in blood pressure, decrease in peripheral perfusion (e.g., reduced pulses; cool, mottled skin), or reduced end organ perfusion (e.g., decreased urine output).(select only one)
4. Arrythmia(s) Requiring Therapy	<input type="radio"/> Yes <input type="radio"/> No	Any cardiac rhythm other than normal sinus rhythm requiring therapy. Therapy is defined as either Drug Therapy, Electrical Cardioversion/Defibrillation, Permanent or Temporary Pacemaker.(select only one)
4a. Foci	<input type="radio"/> Atrial <input type="radio"/> Ventricular <input type="radio"/> Junctional <input type="radio"/> Complete Heart Block	(select only one)
4b. Start Date of Arrythmia(s) Requiring Therapy		(DD-MMM-YYYY)
4c. Start Time of Arrythmia(s) Requiring Therapy (00:00 - 23:59)	_____ : _____	(HH24:MI)
5. Bleeding, Requiring reoperation	<input type="radio"/> Yes <input type="radio"/> No	Operative re-intervention was required for bleeding.(select only one)
5a. Start Date of Bleeding, Requiring reoperation		(DD-MMM-YYYY)
5b. Start Time of Bleeding, Requiring reoperation (00:00 - 23:59)	_____ : _____	(HH24:MI)
6. Sternum left open	<input type="radio"/> Yes <input type="radio"/> No	Sternum was left open postoperatively (i.e., planned or unplanned).(select only one)

7. Unplanned cardiac reoperation, exclusive of reoperation for bleeding	<input type="radio"/> Yes <input type="radio"/> No	Any additional unplanned operation prior to discharge. The following operations will always be coded as "Unplanned Reoperation": (1) Mediastinal exploration for infection (2) Mediastinal exploration for hemodynamic instability (3) Emergent mediastinal exploration for initiation of ECMO or VAD (4) Reoperation for residual or recurrent lesion.(select only one)
8. Unplanned interventional therapeutic cardiovascular catheterization	<input type="radio"/> Yes <input type="radio"/> No	Any unplanned interventional cardiovascular catheterization.(select only one)
9. Unplanned non-cardiac reoperation	<input type="radio"/> Yes <input type="radio"/> No	Any additional unplanned operation prior to discharge.(select only one)
10. Mechanical circulatory support (IABP, VAD, ECMO, or CPS)	<input type="radio"/> Yes <input type="radio"/> No	Any additional procedure that required mechanical circulatory support following major surgery prior to discharge of the hospitalization.(select only one)
11. Pleural effusion, Requiring drainage	<input type="radio"/> Yes <input type="radio"/> No	Postoperative chest x-ray evidence of fluid (non-chylous) in the pleural space, requiring drainage.(select only one)
12. Pneumonia	<input type="radio"/> Yes <input type="radio"/> No	Postoperative pulmonary infection diagnosed by appropriate clinical findings and one or more of the following: positive cultures of sputum, pulmonary secretions or empyema fluid and / or pulmonary infiltrate on chest x-ray.(select only one)
13. Pneumothorax, Requiring drainage or evacuation	<input type="radio"/> Yes <input type="radio"/> No	Postoperative chest x-ray evidence of air in the pleural space requiring evacuation or resuscitation.(select only one)
14. Respiratory failure, Requiring tracheostomy	<input type="radio"/> Yes <input type="radio"/> No	Failure to wean from mechanical ventilation necessitating the creation of a surgical airway.(select only one)
15. Acute renal failure Requiring dialysis or hemofiltration	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
16. Sepsis	<input type="radio"/> Yes <input type="radio"/> No	Documented infection with two or more of the following symptoms: (1) temperature instability (core temp > 38.5 / <36) (2) tachycardia / bradycardia (3) tachypnea or mechanical ventilation (4) leukocytosis/leucopenia(select only one)
17. Vocalcord dysfunction (possible recurrent laryngeal nerve injury)	<input type="radio"/> Yes <input type="radio"/> No	Presence of poor or no vocal cord movement assessed by endoscopy. Subject may or may not have stridor, hoarse voice or poor cry, in conjunction with endoscopic findings.(select only one)
18. Wound infection	<input type="radio"/> Yes <input type="radio"/> No	At least one of the following conditions: (1) Wound aspirated or opened with drainage of fluid and / or excision of tissue (I & D) (2) Positive culture (3) Treatment with antibiotics or antifungals.(select only one)
19. Catheter associated bloodstream infection	<input type="radio"/> Yes <input type="radio"/> No	Presence of bacteremia originating from an i.v. catheter(select only one)

**Discharge/Readmission**

1. Date of Hospital Discharge		(DD-MMM-YYYY) Indicate the date on which the subject was discharged from the hospital. This is intended to capture the total length of stay in your hospital regardless of the medical service managing the subject. If the subject expired prior to hospital discharge, capture the date of expiration.
2. Mortality Status at Hospital Discharge	<input type="radio"/> Alive <input type="radio"/> Dead	Indicate whether the subject was Alive or Dead at discharge from the hospitalization in which this surgical procedure occurred.(select only one)
3. Tube Feeding at Hospital Discharge?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	(select only one)
4. Discharge Location	<input type="radio"/> Home <input type="radio"/> Other Acute Care Center <input type="radio"/> Other Chronic Care Center <input type="radio"/> Unknown	Indicate the location to where the subject was discharged. (select only one)



# Operative Data

## Operative and Postoperative Information

(Visit ID = 40, Page ID = 40)

Unique Identifier page-73556-81150-40-40

SUBJECT INFORMATION		
Subject ID		(format 9999999)
Site ID	(remote value)	
PROCEDURE		
1. Hospital Admission		(DD-MMM-YYYY) Indicate the Date of Admission for this procedure.
2. Date of Procedure	(remote value)	
3. Endotracheal Intubation performed prior to Operating Room arrival?	<input type="radio"/> Yes <input type="radio"/> No	Indicate whether the subject was intubated during the time frame from date of hospital admission but prior to operating room arrival. (select only one)
3a. Initial Intubation Date		(DD-MMM-YYYY) Indicate the date the subject was initially intubated prior to operating room arrival.
3b. Initial Intubation Time (00:00 - 23:59)	_____ : _____	(HH24:MI) Indicate the time (24 hour clock) ventilatory support initially started.
3c. Re-intubated in Operating Room for procedure?	<input type="radio"/> Yes <input type="radio"/> No	Indicate whether the subject was re-intubated in the operating room. (select only one)
3c1. Intubation Time in Operating Room (00:00 - 23:59)	_____ : _____	(HH24:MI) Indicate the time (24 hour clock) ventilatory support started in operating room.
3a. Intubation Time in Operating Room (00:00 - 23:59)	_____ : _____	(HH24:MI) Indicate the time (24 hour clock) ventilatory support started in operating room.
4. Cardiopulmonary bypass?	<input type="radio"/> Yes <input type="radio"/> No	(select only one)
4a. Cross Clamp Time - No CPB (minutes)		(format 999) Indicate the total number of minutes the aorta was completely cross-clamped during this surgical procedure. Enter zero if no cross-clamp was used.
4b. Cross Clamp Time - on CPB (minutes)		(format 999) Indicate the total number of minutes the aorta was completely cross-clamped during this surgical procedure. Enter zero if no cross-clamp was used.
4c. CPB Time (minutes)		(format 999) Indicate the total number of minutes on cardiopulmonary bypass. If more than one run of cardiopulmonary bypass (CPB) required during this surgical procedure, the sum of the bypass runs will equal the total number of CPB minutes.
POSTOPERATIVE ICU CARE		
1. Date of ICU Arrival		(DD-MMM-YYYY) The date the subject arrived in the ICU bed space.
2. Time of ICU Arrival (00:00 - 23:59)	_____ : _____	(HH24:MI) The time (24 hour clock) the subject arrived in the ICU bed space.
3. Initial Extubation Date		(DD-MMM-YYYY) Indicate the date ventilatory support initially ceased after surgery. If the subject expired while intubated, capture the date of expiration. If subject discharged on chronic ventilatory support, capture the date of discharge.
4. Initial Extubation Time (00:00 - 23:59)	_____ : _____	(HH24:MI) Indicate the time (24 hour clock) ventilatory support initially ceased after surgery.
5. Re-Intubation after Initial Extubation?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	Indicate whether the subject was re-intubated after the initial postoperative extubation.(select only one)
5a. Re-Intubation Date		(DD-MMM-YYYY) Indicate the date ventilatory support restarted.
5b. Re-Intubation Time (00:00 - 23:59)	_____ : _____	(HH24:MI) Indicate the time (24 hour clock) ventilatory support restarted.
5c. Final Extubation Date		(DD-MMM-YYYY) Indicate the date ventilatory support last ceased prior to discharge. If the subject expired while intubated, capture the date of expiration. If the subject was discharged on chronic ventilatory support, capture the date of discharge.

5d. Final Extubation Time (00:00 - 23:59)	_____ : _____	(HH24:MI) Indicate the time (24 hour clock) ventilatory support last ceased prior to discharge. If the subject expired while intubated, capture the time of expiration. If the subject was discharged on chronic ventilatory support, capture the time of discharge.
6. Critical Care End Date		(DD-MMM-YYYY) Indicate the date the attending deemed the subject ready to leave the ICU.
7. Critical Care End Time (00:00 - 23:59)	_____ : _____	(HH24:MI) Indicate the time (24 hour clock) the attending deemed the subject ready to leave the ICU.
8. ICU Discharge Date		(DD-MMM-YYYY) Indicate the date ICU service was no longer responsible for subject care.
9. ICU Discharge Time (00:00 - 23:59)	_____ : _____	(HH24:MI) Indicate the time (24 hour clock) ICU service was no longer responsible for subject care.
10. Unplanned return to ICU?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	(select only one)
10a. Unplanned return to ICU Date		(DD-MMM-YYYY)

**DISCHARGE/READMISSION**

1. Date of Hospital Discharge		(DD-MMM-YYYY) Indicate the date on which the subject was discharged from the hospital. This is intended to capture the total length of stay in your hospital regardless of the medical service managing the subject. If the subject expired prior to hospital discharge, capture the date of expiration.
2. Mortality Status at Hospital Discharge	<input type="radio"/> Alive <input type="radio"/> Dead	Indicate whether the subject was Alive or Dead at discharge from the hospitalization in which this surgical procedure occurred.(select only one)
3. Discharge Location	<input type="radio"/> Home <input type="radio"/> Other Acute Care Center <input type="radio"/> Other Chronic Care Center <input type="radio"/> Unknown	Indicate the location to where the subject was discharged. (select only one)

# Protocol Deviation

## Protocol Deviation

(Visit ID = 50, Page ID = 10)

Unique Identifier page-85090-85130-50-10

### SUBJECT INFORMATION

Subject ID (format 9999999)

Site ID (remote value)

### PROTOCOL DEVIATION

1. Date of Protocol Deviation (DD-MMM-YYYY)

2. Initials of person completing form  
Please enter the initials of the person completing this form. The format should be First Initial, Middle Initial and Last Initial. If this person does not have a middle name, please enter this field as first initial-last initial.

### Deviation Description

1. Deviation Description Please enter a description of the deviation.

### 2. Type of Deviation

**Please answer YES or NO for all questions.**

2a. Enrollment of a subject who did not meet all inclusion/exclusion criteria  Yes (select only one)  
 No

2b. Enrolling a subject after IRB approval expired  Yes (select only one)  
 No

2c. Performing study procedure not approved by the IRB  Yes (select only one)  
 No

2d. Failure to perform study procedure as outlined in protocol  Yes (select only one)  
 No

2e. Study procedures and/or assessments performed prior to obtaining or reaffirming written informed consent.  Yes (select only one)  
 No

2f. Obtaining informed consent with outdated / expired consent document  Yes (select only one)  
 No

2g. Other  Yes (select only one)  
 No

2gi. Other, Specify