

Layout of CRFs across Days in ARDSNet05 (FACTT) Study

Day -->	0	1-4	5-6	7	8-10	11-13	14	15-20	21	22-27	28
Subject	A										
ALI Screening	A										
Enrollment	A										
APACHE III Demographics	A										
APACHE III Physiology	A										
Apache ABG PART OR FULL version	A										
Pre-Rand Vital Signs	A										
Baseline Vent. Parameters	A										
Baseline Chest X-Ray	A										
Baseline Labs	A										
Pre-Fluid Mngment Vitals	A										
PAC/CVC	A	A	A	A							
Baseline Diagnostic Studies	A										
Baseline Rand Protocol Check	A										
OS Vital Signs		A	A	A							
OS Labs		A	A	A							
OS Ventilator Parameters		A		A			A		A		A
OS Chest X-Ray		A	A	A							
OS Diagnostic Studies		A	A	A							
Random Protocol Check		A	A	A							
Weaning		A	A	A	A	A	A	A	A	A	A
Blood Cultures	A	A	A	A	A						
Glasgow Coma	A			A	A	A	A	A	A	A	A
Brussels Day 0-7 8-14 15-21 22-28	A	A	A	A	A	A	A	A	A	A	A
Adverse Event	A	A	A	A	A	A	A	A	A	A	A
Specimen Collection	A	A	A	A							
Study Termination	Appears on discontinuation day ----- --->										
Day -->	0	1-4	5-6	7	8-10	11-13	14	15-20	21	22-27	28

Subject

METATRIAL

Subject

Visit Date:

Patient Randomization Number:	<input type="text"/>
Screening Number:	<input type="text"/>
Initials:	<input type="text"/>

ALI Screening -

Visit Date:

METATRIAL

COMPLETE FOR PATIENTS MEETING CRITERIA 1-3 IN DESIGNATED ICU'S	
1. Acute Onset:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
2. Within past 24 hrs patient had ALL of the following: <ul style="list-style-type: none"> • PaO₂/FiO₂ less than or equal to 300 mmHg? • Bilateral infiltrates consistent with pulmonary edema on frontal chest radiograph? • Receiving positive pressure ventilation via endotracheal tube? 	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) Date of Qualifying CXR: <input type="text"/> <input type="button" value="Date"/> Time of Qualifying CXR: <input type="text"/> hh:mm
3. No clinical evidence of left atrial hypertension (if measured pulmonary arterial wedge pressure less than or equal to 18 mmHg)?	<input type="radio"/> No Answer <input type="radio"/> Yes (no evidence of LA HTN) (1) <input type="radio"/> No (2)
4. PaO ₂ :	<input type="text"/>
5. FiO ₂ :	<input type="text"/>
6. First date that all these criteria exist simultaneously:	<input type="text"/> <input type="button" value="Date"/>
7. Gender:	<input type="radio"/> No Answer <input type="radio"/> Male (1) <input type="radio"/> Female (2)
8. Ethnicity:	<input type="radio"/> No Answer <input type="radio"/> White (1) <input type="radio"/> Black (2) <input type="radio"/> Hispanic (3) <input type="radio"/> Asian/Pacific Islander (4) <input type="radio"/> American Indian/Alaskan Native (5) <input type="radio"/> Other (6)
9. Age:	<input type="text"/>
10. Location:	<input type="radio"/> No Answer <input type="radio"/> MICU (1) <input type="radio"/> SICU (2) <input type="radio"/> Cardiac SICU (3)

	<input type="radio"/> CCU (4) <input type="radio"/> Neuro ICU (5) <input type="radio"/> Burn (6) <input type="radio"/> Trauma (7) <input type="radio"/> Cancer Unit (8) <input type="radio"/> MICU/SICU (9) <input type="radio"/> Other (10)
Other Location:	<input type="text"/>
11. Regularly Screened ICU:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
12a. Reason for Exclusion:	
Not excluded (0):	<input type="checkbox"/>
No central access (1):	<input type="checkbox"/>
No MD intent to place central access (2):	<input type="checkbox"/>
Presence of a PAC since ALI (3):	<input type="checkbox"/>
> 48 hours since ALI onset (4):	<input type="checkbox"/>
Patient <13 years (5):	<input type="checkbox"/>
Burns >=40% (6):	<input type="checkbox"/>
Not committed to full support (7):	<input type="checkbox"/>
Bone Marrow Transplant (8):	<input type="checkbox"/>
Acute Myocardial Infarction last 30 days (9):	<input type="checkbox"/>
Chronic Lung Disease (10):	<input type="checkbox"/>
Neuromuscular Disease (e.g. C5 spinal injury, neuropathy) (11):	<input type="checkbox"/>
Morbid Obesity (12):	<input type="checkbox"/>
Estimated 6 month mortality >50% (13):	<input type="checkbox"/>
Vasculitis/hemorrhage (14):	<input type="checkbox"/>
MD refuses (15):	<input type="checkbox"/>
Patient/Family Refuses (16):	<input type="checkbox"/>
Patient Unable/Surrogate Unable (17):	<input type="checkbox"/>
Patient Pregnant (18):	<input type="checkbox"/>

Renal Failure (19):	<input type="checkbox"/>
Chronic Liver Disease (20):	<input type="checkbox"/>
Lasix (Furosimide) Allergy (21):	<input type="checkbox"/>
Lung Transplant (22):	<input type="checkbox"/>
12b. Not excluded, not enrolled, explain:	<input type="text"/>
12c. If M.D. refuses, reason(s) for M.D. refusal (select ALL that apply):	
12c-1. Unwilling to withhold PAC:	<input type="checkbox"/>
12c-2. Unwilling to place PAC:	<input type="checkbox"/>
12c-3. Unwilling to use ventilator protocol:	<input type="checkbox"/>
12c-4. Unwilling to use fluid management algorithm:	<input type="checkbox"/>
12c-5. Other:	<input type="checkbox"/>
Other Description:	<input type="text"/>
13. Lung Injury Category	
Trauma:	<input type="radio"/> No Answer <input type="radio"/> none (0) <input type="radio"/> primary (1) <input type="radio"/> secondary (2)
Sepsis:	<input type="radio"/> No Answer <input type="radio"/> none (0) <input type="radio"/> primary (1) <input type="radio"/> secondary (2)
Multiple Transfusion:	<input type="radio"/> No Answer <input type="radio"/> none (0) <input type="radio"/> primary (1) <input type="radio"/> secondary (2)
Aspiration:	<input type="radio"/> No Answer <input type="radio"/> none (0) <input type="radio"/> primary (1) <input type="radio"/> secondary (2)
Pneumonia:	<input type="radio"/> No Answer <input type="radio"/> none (0) <input type="radio"/> primary (1) <input type="radio"/> secondary (2)
Other Lung Injury Category:	<input type="radio"/> No Answer <input type="radio"/> none (0) <input type="radio"/> primary (1) <input type="radio"/> secondary (2)
Other Description:	<input type="text"/>
13a. If Primary Lung Injury Category = Sepsis, indicate site of infection:	<input type="radio"/> No Answer <input type="radio"/> Skin/soft tissue (1) <input type="radio"/> CNS (2) <input type="radio"/> Lung/pleura (3) <input type="radio"/> Peritoneum (4) <input type="radio"/> GI/biliary tract (5) <input type="radio"/> Urinary tract (6) <input type="radio"/> Female GU tract (7) <input type="radio"/> Vascular line infection (8) <input type="radio"/> Bacteremia, site unknown (9) <input type="radio"/> Sepsis site unknown (10)

FOLLOWING ITEMS ARE FOR SCREENED PATIENTS ONLY - DO NOT COMPLETE FOR ENROLLED PATIENTS	
14. Patient able to sustain a period of continuous unassisted breathing for at least 48 hours during first 60 days:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
15a. If yes, enter the first calendar date of the first period of UAB that lasted for >= 48 hours:	<input type="text"/> <input type="button" value="Date"/>
16. Was patient discharged from study hospital during first 90 days?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
16a. If Yes, date of discharge from study hospital:	<input type="text"/> <input type="button" value="Date"/>
17. Status at discharge from study hospital:	<input type="radio"/> No Answer <input type="radio"/> Alive (1) <input type="radio"/> Dead (2)
18. If patient was screened for ALVEOLI, please enter ALVEOLI screening number here:	<input type="text"/>

Enrollment

Visit Date:

1. Has informed consent been obtained:	
a. For the participation in the PAC study?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
b. For genetic testing related to ALI/ARDS?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
c. For genetic testing related to future studies?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
d. For participation in the Cost/Effectiveness Study?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
If patient is eligible and consent for the study has been obtained, please call for randomization number.	
2. Patient randomization number:	Please enter the enrollment number into the Day0 Subject form.
3. Patient randomized to:	<input type="radio"/> No Answer <input type="radio"/> PAC/Fluid Liberal (1) <input type="radio"/> PAC/Fluid Conservative (2) <input type="radio"/> CVC/Fluid Liberal (3) <input type="radio"/> CVC/Fluid Conservative (4)
4. Date/Time of randomization:	Date: <input type="text"/> <input type="button" value="Date"/> Time: <input type="text"/>
5. Footnote version number:	<input type="text"/>

Apache III Demographics

Visit Date:

METATRIAL

1. Hospital Admission date:	<input type="text"/> <input type="button" value="Date"/>
1a. Hospital Admission Type:	<input type="radio"/> No Answer <input type="radio"/> Medical (1) <input type="radio"/> Surgical, scheduled (2) <input type="radio"/> Surgical, unscheduled (3) <input type="radio"/> Other (4)
2. ICU Admission date:	<input type="text"/> <input type="button" value="Date"/>
3. Time of ICU Admission:	<input type="text"/> hh:mm
4. Patient Admitted Directly From:	<input type="radio"/> No Answer <input type="radio"/> OR (1) <input type="radio"/> Recovery Room (2) <input type="radio"/> ER (3) <input type="radio"/> Floor (4) <input type="radio"/> Another Special Care Unit (5) <input type="radio"/> Another Hospital (6) <input type="radio"/> Direct Admit (7) <input type="radio"/> Stepdown Unit (8)
4a. What was the patient's place of residence prior to hospitalization:	<input type="radio"/> No Answer <input type="radio"/> Home Independently (1) <input type="radio"/> Home with help (supervision, direction, or personal assistance)(2) <input type="radio"/> Home with professional help (nurse/nursing service)(3) <input type="radio"/> An intermediate care or rehabilitation center (4) <input type="radio"/> Skilled nursing facility (5) <input type="radio"/> Another acute hospital (6) <input type="radio"/> Other (7)
Specify:	<input type="text"/>
5. Is patient immediately post-operative from elective surgery?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
6. ICU Readmit:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
7. ICU Readmit within 24 hours:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
8a. Is chronic health information available?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
8b. Is the patient on chronic dialysis or peritoneal dialysis?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)

9a. AIDS (do not include HIV positive without AIDS criteria):	<input type="radio"/> No Answer	<input type="radio"/> Yes (1)	<input type="radio"/> No (2)
9b. Leukemia (AML, CML, all lymphocytic leuk., multiple myeloma):	<input type="radio"/> No Answer	<input type="radio"/> Yes (1)	<input type="radio"/> No (2)
9c. Non-Hodgkin's Lymphoma:	<input type="radio"/> No Answer	<input type="radio"/> Yes (1)	<input type="radio"/> No (2)
9d. Solid tumor with metastasis:	<input type="radio"/> No Answer	<input type="radio"/> Yes (1)	<input type="radio"/> No (2)
9e. Immune suppression (radiation, chemotherapy, or ≥ 0.3 mg/kg/day prednisone or equivalent) within the past 6 months:	<input type="radio"/> No Answer	<input type="radio"/> Yes (1)	<input type="radio"/> No (2)
9f. Hepatic failure with coma or encephalopathy:	<input type="radio"/> No Answer	<input type="radio"/> Yes (1)	<input type="radio"/> No (2)
9g. Cirrhosis:	<input type="radio"/> No Answer	<input type="radio"/> Yes (1)	<input type="radio"/> No (2)
9h. Diabetes Mellitus:	<input type="radio"/> No Answer	<input type="radio"/> Yes (1)	<input type="radio"/> No (2)
9i. Hypertension	<input type="radio"/> No Answer	<input type="radio"/> Yes (1)	<input type="radio"/> No (2)
9j. Prior myocardial infarction	<input type="radio"/> No Answer	<input type="radio"/> Yes (1)	<input type="radio"/> No (2)
9k. Congestive heart failure	<input type="radio"/> No Answer	<input type="radio"/> Yes (1)	<input type="radio"/> No (2)
9l. Peripheral vascular disease	<input type="radio"/> No Answer	<input type="radio"/> Yes (1)	<input type="radio"/> No (2)
9m. Prior stroke with sequelae	<input type="radio"/> No Answer	<input type="radio"/> Yes (1)	<input type="radio"/> No (2)
9n. Dementia	<input type="radio"/> No Answer	<input type="radio"/> Yes (1)	<input type="radio"/> No (2)
9o. Chronic pulmonary disease	<input type="radio"/> No Answer	<input type="radio"/> Yes (1)	<input type="radio"/> No (2)
9p. Arthritis	<input type="radio"/> No Answer	<input type="radio"/> Yes (1)	<input type="radio"/> No (2)
9q. Peptic ulcer disease	<input type="radio"/> No Answer	<input type="radio"/> Yes (1)	<input type="radio"/> No (2)
10. Vasopressors last 24 hours?	<input type="radio"/> No Answer	<input type="radio"/> Yes (1)	<input type="radio"/> No (2)
11. Protocol defined ethanol use:	<input type="radio"/> No Answer	<input type="radio"/> Yes (1)	<input type="radio"/> No (2)

Apache III Physiology

Visit Date:

METATRIAL

USE VALUES FROM 24HRS PRECEDING RANDOMIZATION		
VITAL SIGNS	Lowest	Highest
1. Temperature:	<input type="text"/> C <input type="text"/> F	<input type="text"/> C <input type="text"/> F
2. Systolic BP:	<input type="text"/> mmHg	<input type="text"/> mmHg
3. Mean Arterial Pressure:	<input type="text"/> mmHg	<input type="text"/> mmHg
4. Heart Rate:	<input type="text"/> beats/min	<input type="text"/> beats/min
5. Respiratory Rate:	<input type="text"/> breaths/min	<input type="text"/> breaths/min
6a. Was patient ventilated when the lowest respiratory rate occurred?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	
6b. Was patient ventilated when the highest respiratory rate occurred?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	
7. Urine output /24 hours:	<input type="text"/> ml	
USE VALUES FROM 24HRS PRECEDING RANDOMIZATION		
HEMATOLOGY	Lowest	Highest
8. HCT:	<input type="text"/> %	<input type="text"/> %
9. WBC:	<input type="text"/> /mm ³	<input type="text"/> /mm ³
10. Platelets (lowest):	<input type="text"/> X 1000 / mm ³	
CHEMISTRY	Lowest	Highest
11. Serum Sodium:	<input type="text"/> mEq/L	<input type="text"/> mEq/L
12. Serum Potassium:	<input type="text"/> mEq/L	<input type="text"/> mEq/L
13. Serum BUN (highest):		<input type="text"/> mg/dL
14. Serum Creatinine:	<input type="text"/> mg/dL	<input type="text"/> mg/dL
15. Serum Glucose:	<input type="text"/> mg/L	<input type="text"/> mg/dL
16. Serum Albumin:	<input type="text"/> g/dL	<input type="text"/> g/dL
17. Serum Bilirubin (highest):		<input type="text"/> mg/dL
18. Serum Bicarbonate (lowest):	<input type="text"/> mEq/L	

Pre-Randomization Vital Signs

Visit Date:

METATRIAL

RECORD VALUES CLOSEST TO THE TIME PRECEDING RANDOMIZATION	
1. Heart Rate:	<input type="text"/> bpm
2. Systolic BP:	<input type="text"/> mmHg
3. Diastolic BP:	<input type="text"/> mmHg
4. Mean Arterial Pressure:	<input type="text"/> mmHg
5. Temperature:	<input type="text"/> C <input type="text"/> F
6. Height:	<input type="text"/> cm <input type="text"/> in
7. Predicted Body Weight:	<input type="text"/> kg
8. Measured Weight:	<input type="text"/> kg <input type="text"/> lbs
9. Anasarca:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
10. Fluid intake last 24h:	<input type="text"/> ml
11. Fluid Output last 24h:	<input type="text"/> ml
12. Central Venous Pressure:	<input type="text"/> mmHg
13. Vasopressors or Inotropic Agents: If yes, enter the infusion rate at time of randomization for all that apply	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
13 -1. Dopamine:	<input type="text"/> mcg/kg/min
13-2. Norepinephrine:	<input type="text"/> mcg/min
13-3. Epinephrine:	<input type="text"/> mcg/min
13-4. Neosynephrine:	<input type="text"/> mcg/min
13-5. Dobutamine:	<input type="text"/> mcg/kg/min
13-6. Dopexamine:	<input type="text"/> mcg/kg/min
13-7. Milrinone:	<input type="text"/> mcg/kg/min
13-8. Amrinone:	<input type="text"/> mcg/kg/min
13-9. Vasopressin:	<input type="text"/> units/min
13-10. Other:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
14. Diuretics? If yes, enter total dose administered last 24 hours	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)

14-1. Furosemide (Lasix):	<input type="text"/>	mg
14-2. Chlorthiazide (Diuril):	<input type="text"/>	mg
14-3. Ethacrynic acid (Edecrin):	<input type="text"/>	mg
14-4. Other:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	

Baseline Ventilator Parameters

Visit Date:

METATRIAL

Date/Time of Initial Vent Change:	Date: <input type="text"/>	Date	Time: <input type="text"/>
Date/Time of Current Intubation:	Date: <input type="text"/>	Date	Time: <input type="text"/>
MOST RECENT VALUES PRIOR TO RANDOMIZATION			
1. Ventilator Mode (check all that apply)			
1.1 SIMV:	<input type="checkbox"/>		
1.2 Pressure Support:	<input type="checkbox"/>		
1.3 Assist/Control:	<input type="checkbox"/>		
1.4 Pressure Control:	<input type="checkbox"/>		
1.5 PC IRV:	<input type="checkbox"/>		
1.6 Other: <input type="text"/>	<input type="checkbox"/>		
2. Calculated Delivered Tidal Volume:	<input type="text"/>	ml	
3. Pressure Control level (If on Pressure Control Ventilation):	<input type="text"/>	cm H ₂ O	
4. Pressure Support level (If on Pressure Support Ventilation):	<input type="text"/>	cm H ₂ O	
5. Set Rate:	<input type="text"/>	breaths/min.	
6. Total Respiratory Rate:	<input type="text"/>	breaths/min.	
7. Total Minute Ventilation:	<input type="text"/>	L/min	
8. PEEP:	<input type="text"/>	cm H ₂ O	
9. Plateau Pressure:	<input type="text"/>	cm H ₂ O	
10. Peak Inspiratory Pressure:	<input type="text"/>	cm H ₂ O	
11. I:E Ratio a. Set I:E 1:	<input type="text"/>	b. True I:E 1:	<input type="text"/>
12. Mean Airway Pressure:	<input type="text"/>	cm H ₂ O	
13. FiO ₂ :	<input type="text"/>		
14. PaO ₂ :	<input type="text"/>	mmHg	
15. PaCO ₂ :	<input type="text"/>	mmHg	
16. Arterial pH:	<input type="text"/>		
17. SpO ₂ :	<input type="text"/>	%	

AFTER INITIAL VENT CHANGE, IF ANY, ON A TIDAL VOLUME OF 6 TO 8 ML/KG PBW	
18. Calculated Delivered Tidal Volume:	<input type="text"/> ml
19. Plateau Pressure:	<input type="text"/> cm H ₂ O
20. PEEP:	<input type="text"/> cm H ₂ O

Baseline Chest X-Ray

Visit Date:

METATRIAL

USE MOST RECENT CXR PRIOR TO TIME OF RANDOMIZATION	
1. Number of quadrants with infiltrates:	<input type="text"/>
2. Barotrauma:	
Pneumothoraces:	<input type="radio"/> No Answer <input type="radio"/> Right (1) <input type="radio"/> Left (2) <input type="radio"/> Bilateral (3) <input type="radio"/> None (4)
Subcutaneous emphysema:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
Pneumomediastinum:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
Pneumatocoles > 2 cm diam:	<input type="radio"/> No Answer <input type="radio"/> Right (1) <input type="radio"/> Left (2) <input type="radio"/> Bilateral (3) <input type="radio"/> None (4)
3. Chest tube:	<input type="radio"/> No Answer <input type="radio"/> Right (1) <input type="radio"/> Left (2) <input type="radio"/> Bilateral (3) <input type="radio"/> None (4)

Baseline Labs

Visit Date:

RECORD VALUES CLOSEST TO THE TIME PRECEDING RANDOMIZATION	
1. Hgb:	<input type="text"/> g/dL
2. WBC:	<input type="text"/> /mm ³
3. Platelets:	<input type="text"/> x 1000 /mm ³
4. Sodium:	<input type="text"/> mEq/L
5. Potassium:	<input type="text"/> mEq/L
6. Glucose:	<input type="text"/> mg/dL
7. Creatinine:	<input type="text"/> mg/dL
8. BUN:	<input type="text"/> mg/dL
9. Chloride:	<input type="text"/> mEq/L
10. Serum Bicarbonate:	<input type="text"/> mEq/L
11. Total Protein:	<input type="text"/> g/dL
12. Albumin:	<input type="text"/> g/dL
FOR ITEMS 13-20, ENTER VALUES CLOSEST TO THE TIME PRECEDING THE INITIAL FLUID MANAGEMENT INSTRUCTION	
MIXED VENOUS (mv) BLOOD GASES (from distal PA port)	
13. PmvO ₂ :	<input type="text"/> mmHg
14. PmvCO ₂ :	<input type="text"/> mmHg
15. mv pH:	<input type="text"/>
16. mvO ₂ Sat (from blood sample):	<input type="text"/> %
CENTRAL VENOUS (cv) BLOOD GASES (from CVP or RA port)	
17. PcvO ₂ :	<input type="text"/> mmHg
18. PcvCO ₂ :	<input type="text"/> mmHg
19. cv pH:	<input type="text"/>
20. cvO ₂ Sat:	<input type="text"/> %

Pre Fluid Management Vital Signs

Visit Date:

RECORD VALUES CLOSEST TO THE TIME PRECEDING THE FIRST FLUID MANAGEMENT PROTOCOL INSTRUCTION	
1. Date/Time of first fluid management instruction:	Date: <input type="text"/> <input type="button" value="Date"/> Time: <input type="text"/>
2. Mean Arterial Pressure:	<input type="text"/> mmHg
3. Temperature:	<input type="text"/> C <input type="text"/> F
4. Capillary refill time:	<input type="radio"/> No Answer <input type="radio"/> <= 2 sec (1) <input type="radio"/> > 2 sec (2)
5. Knee mottling:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
6. Cold extremities:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
7. Fluid in since randomization:	<input type="text"/> ml
8. Fluid out since randomization:	<input type="text"/> ml
9. Central Venous Pressure:	<input type="text"/> mmHg
10. Pulmonary Artery Systolic:	<input type="text"/> mmHg
11. Pulmonary Artery Diastolic:	<input type="text"/> mmHg
12. Pulmonary Artery Occlusion Pressure:	<input type="text"/> mmHg
13. Cardiac Index:	<input type="text"/> L/min/m2
14. Mixed venous O2 sat (if applicable):	<input type="text"/> %
15. Average 4 hour urine output prior to time of data collection:	<input type="text"/> ml/kg/hr
16. Vasopressors or Inotropic Agents?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
16-1. Dopamine:	<input type="text"/> mcg/kg/min
16-2. Norepinephrine:	<input type="text"/> mcg/min
16-3. Epinephrine:	<input type="text"/> mcg/min
16-4. Neosynephrine:	<input type="text"/> mcg/min
16-5. Dobutamine:	<input type="text"/> mcg/kg/min
16-6. Dopexamine:	<input type="text"/> mcg/kg/min
16-7. Milrinone:	<input type="text"/> mcg/kg/min

16-8. Amrinone:	<input type="text"/>	mcg/kg/min
16-9. Vasopressin:	<input type="text"/>	units/min
Other:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	
17. Diuretics given since randomization? If yes, enter total dose administered since randomization.	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	
17-1. Furosemide (Lasix):	<input type="text"/>	mg
17-2. Chlorthiazide (Diuril):	<input type="text"/>	mg
17-3. Ethacrynic acid (Edecrin):	<input type="text"/>	mg
17-4. Other:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	



Day 0 & On-Study PAC/CVC

Visit Date:

COMPLETE THIS FORM FOR ALL PAC OR CVC INSERTION/CHANGES TO DAY 7. USE ONLY ONE FORM FOR EACH CATHETER.	
1. Catheter Number (First study catheter = number 1):	<input type="text"/>
2. Catheter type:	<input type="radio"/> No Answer <input type="radio"/> PAC (1) <input type="radio"/> CVC (2) <input type="radio"/> Introducer (3) <input type="radio"/> PICC (4)
3. Date and Time catheter inserted:	Date: <input type="text"/> <input type="button" value="Date"/> Time: <input type="text"/>
4. CVC/PAC placed through existing vascular access site:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
5. CVC/PAC placed through new vascular access site:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
6. Catheter antibiotic coated?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
7. Number of lumens:	<input type="text"/>
8a. Manufacturer:	<input type="text"/>
8b. Model number:	<input type="text"/>
9. Location of catheter:	<input type="radio"/> No Answer <input type="radio"/> subclavian (1) <input type="radio"/> internal jugular (2) <input type="radio"/> antecubital (3) <input type="radio"/> femoral (4) <input type="radio"/> other (5)
10. Date/Time catheter removed:	Date: <input type="text"/> <input type="button" value="Date"/> Time: <input type="text"/>
11. Reason catheter removed:	<input type="radio"/> No Answer <input type="radio"/> catheter complication (1) <input type="radio"/> catheter malfunction (2) <input type="radio"/> routine line change (3) <input type="radio"/> PAC removed per study protocol (4) <input type="radio"/> central access no longer needed (5) <input type="radio"/> other (6)
11a. Other Specify:	<input type="text"/>

	12. Insertion Complications (check all that apply):	13. Late Complications (>24 hrs from placement to 3 days after removal; check all that apply):
None:	<input type="checkbox"/>	<input type="checkbox"/>
Atrial arrhythmia requiring Rx:	<input type="checkbox"/>	<input type="checkbox"/>
PVCs requiring Rx:	<input type="checkbox"/>	<input type="checkbox"/>
ventricular tachycardia:	<input type="checkbox"/>	<input type="checkbox"/>
ventricular fibrillation:	<input type="checkbox"/>	<input type="checkbox"/>
right bundle branch block:	<input type="checkbox"/>	<input type="checkbox"/>
complete heart block:	<input type="checkbox"/>	<input type="checkbox"/>
pneumothorax:	<input type="checkbox"/>	<input type="checkbox"/>
hemothorax:	<input type="checkbox"/>	<input type="checkbox"/>
hemoptysis:	<input type="checkbox"/>	<input type="checkbox"/>
inadvertent arterial puncture:	<input type="checkbox"/>	<input type="checkbox"/>
excessive bleeding at insertion site:	<input type="checkbox"/>	<input type="checkbox"/>
local site infection:	<input type="checkbox"/>	<input type="checkbox"/>
local venous thrombosis:	<input type="checkbox"/>	<input type="checkbox"/>
venous thromboembolism:	<input type="checkbox"/>	<input type="checkbox"/>
air embolism:	<input type="checkbox"/>	<input type="checkbox"/>
other:	<input type="checkbox"/>	<input type="checkbox"/>

14. Catheter tip cultured?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	
15. If yes, catheter tip culture results:	Organism 1	Organism 2
	<input type="radio"/> No Answer <input type="radio"/> Staph aureus (1) <input type="radio"/> Staph epidermis (2) <input type="radio"/> Strep pneumoniae (3) <input type="radio"/> Enterococcus (4) <input type="radio"/> Other Gram Positive coccus (5) <input type="radio"/> Pseudomonas Species (6) <input type="radio"/> Hemophilus influenza (7) <input type="radio"/> Other Gram Negative rod (8) <input type="radio"/> Candida or Torulopsis Species (9) <input type="radio"/> Aspergillus Species (10) <input type="radio"/> Other (11) <input type="radio"/> No Growth (12)	<input type="radio"/> No Answer <input type="radio"/> Staph aureus (1) <input type="radio"/> Staph epidermis (2) <input type="radio"/> Strep pneumoniae (3) <input type="radio"/> Enterococcus (4) <input type="radio"/> Other Gram Positive coccus (5) <input type="radio"/> Pseudomonas Species (6) <input type="radio"/> Hemophilus influenza (7) <input type="radio"/> Other Gram Negative rod (8) <input type="radio"/> Candida or Torulopsis Species (9) <input type="radio"/> Aspergillus Species (10) <input type="radio"/> Other (11) <input type="radio"/> No Growth (12)
CFU/ml (if available):	<input type="text"/>	<input type="text"/>

Baseline Diagnostic Studies

Visit Date:

METATRIAL

Enter Date for all Diagnostic Cardiovascular Studies Performed on the day of study entry and in the two days prior to randomization.	
1. Trans-thoracic Cardiac Ultrasound?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
If yes, Date:	<input type="text"/> <input type="button" value="Date"/>
2. Transesophageal Cardiac Ultrasound?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
If yes, Date:	<input type="text"/> <input type="button" value="Date"/>
3. Radionuclide Ventriculography?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
If yes, Date:	<input type="text"/> <input type="button" value="Date"/>
4. Left Heart Cardiac Catheterization?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
If yes, Date:	<input type="text"/> <input type="button" value="Date"/>
5. Greene Dye Cardiac Output?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
If yes, Date:	<input type="text"/> <input type="button" value="Date"/>
6. Bioimpedance Cardiac Output?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
If yes, Date:	<input type="text"/> <input type="button" value="Date"/>
7. Other?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
If yes, Date:	<input type="text"/> <input type="button" value="Date"/>

Baseline Random Protocol Check

METATRIAL

Day 0 Random Protocol Check

Visit Date:

2. Record SEQUENCE of all cells identified by ICU team this calendar date: (begin with first cell identified after midnight)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	1st Cell	2nd Cell	3rd Cell	4th Cell	5th Cell	6th Cell	7th Cell
	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	8th Cell	9th Cell	10th Cell	11th Cell	12th Cell	13th Cell	14th Cell

On Study Vital Signs/Hemodynamics

Visit Date:

RECORD VALUES CLOSEST TO 8 A.M.	
1. Heart Rate:	<input type="text"/> bpm
2a. Systolic BP:	<input type="text"/> mmHg
2b. Diastolic BP:	<input type="text"/> mmHg
3. Mean Arterial Pressure:	<input type="text"/> mmHg
4. Temperature:	<input type="text"/> C <input type="text"/> F
5. Measured weight:	<input type="text"/> kg <input type="text"/> lbs
6. Has patient achieved protocol-specified hemodynamic stability this calendar date?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) <input type="radio"/> Not Applicable (3)
If patient is still on fluid management portion of Protocol, complete items 7-10.	
7. Capillary Refill Time:	<input type="radio"/> No Answer <input type="radio"/> <= 2 sec (1) <input type="radio"/> >2 sec (2)
8. Knee mottling:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
9. Cold extremities:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
10. Anasarca:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
11. Fluid Intake last 24h:	<input type="text"/> ml
11-1. PRBC:	<input type="text"/> units
11-2. FFP:	<input type="text"/> units
11-3. 25% Albumin:	<input type="text"/> ml
11-4. 5% Albumin:	<input type="text"/> ml
11-5. Other colloid (specify):	<input type="text"/> ml
11-6. Enteral:	<input type="text"/> ml
12. Fluid Output last 24h:	<input type="text"/> ml
13. Central Venous Pressure:	<input type="text"/> mmHg
14. Pulmonary Artery Systolic:	<input type="text"/> mmHg
15. Pulmonary Artery Diastolic:	<input type="text"/> mmHg
16. Pulmonary Artery Occlusion Pressure:	<input type="text"/> mmHg

17. Cardiac Index:	<input type="text"/> L/min/m ²
18. Mixed venous O ₂ sat (if available):	<input type="text"/> %
19. Vasopressors or Inotropic Agents? If yes, enter infusion rate at 8 a.m.:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
19-1. Dopamine:	<input type="text"/> mcg/kg/min
19-2. Norepinephrine:	<input type="text"/> mcg/min
19-3. Epinephrine:	<input type="text"/> mcg/min
19-4. Neosynephrine:	<input type="text"/> mcg/min
19-5. Dobutamine:	<input type="text"/> mcg/kg/min
19-6. Dopexamine:	<input type="text"/> mcg/kg/min
19-7. Milrinone:	<input type="text"/> mcg/kg/min
19-8. Amrinone:	<input type="text"/> mcg/kg/min
19-9. Vasopressin:	<input type="text"/> units/min
19-10. Other:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
20. Diuretics given this calendar date? If yes, enter total dose administered this calendar day:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
20-1. Furosemide (Lasix):	<input type="text"/> mg
20-2. Chlorthiazide (Diuril):	<input type="text"/> mg
20-3. Ethacrynic acid (Edecrin):	<input type="text"/> mg
20-4. Other:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
21. Recombinant human APC (xigris or drotrecogin alfa) administered this calendar date?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)

On-Study Labs

Visit Date:

SELECTED LABS required day 1, 3, 5, and 7; enter if available days 2, 4, and 6.	
1. Hgb:	<input type="text"/> g/dL
2. Sodium:	<input type="text"/> mEq/L
3. Potassium:	<input type="text"/> mEq/L
4. Glucose:	<input type="text"/> mg/dL
5. Creatinine:	<input type="text"/> mg/dL
6. BUN:	<input type="text"/> mg/dL
7. Chloride:	<input type="text"/> mEq/L
8. Serum Bicarbonate:	<input type="text"/> mEq/L
9. Total Protein:	<input type="text"/> g/dL
10. Albumin:	<input type="text"/> g/dL

On-Study Ventilator Parameters

Visit Date:



IF ON ASSISTED BREATHING DURING REFERENCE PERIOD 0600-1000. IF MORE THAN ONE VALUE, USE VALUES CLOSEST TO 0800. IF BLOOD GASES NOT AVAILABLE IN REFERENCE PERIOD, USE CLOSEST TO REFERENCE PERIOD ON SAME CALENDAR DATE.	
1. Calculated Delivered Tidal Volume (If on Assist/Control):	<input type="text"/> ml
2. Pressure Support level (If on Pressure Support Ventilation):	<input type="text"/> cm H ₂ O
3. Set Rate:	<input type="text"/> breaths/min.
4. Total Respiratory Rate:	<input type="text"/> breaths/min.
5. Total Minute Ventilation:	<input type="text"/> L/min
6. PEEP:	<input type="text"/> cm H ₂ O
7. Plateau Pressure (0.5 second end-inspiratory pause):	<input type="text"/> cm H ₂ O
8. Peak Inspiratory Pressure:	<input type="text"/> cm H ₂ O
9. I:E Ratio: a. Set I:E 1:	<input type="text"/> or b. True I:E 1: <input type="text"/>
10. Mean Airway Pressure:	<input type="text"/> cm H ₂ O
ARTERIAL BLOOD GASES	
11. FiO ₂ :	<input type="text"/>
12. PaO ₂ :	<input type="text"/> mmHg
13. PaCO ₂ :	<input type="text"/> mmHg
14. Arterial pH:	<input type="text"/>
15. SpO ₂ :	<input type="text"/> %
MIXED VENOUS (mv) BLOOD GASES (from distal PA port)	
16. PmvO ₂ :	<input type="text"/> mmHg
17. PmvCO ₂ :	<input type="text"/> mmHg
18. mv pH:	<input type="text"/>
19. mvO ₂ Sat:	<input type="text"/> %
CENTRAL VENOUS (cv) BLOOD GASES (from CVP or RA port)	
20. PcvO ₂ :	<input type="text"/> mmHg

21. PcvCO ₂ :	<input type="text"/> mmHg
22. cv pH:	<input type="text"/>
23. cvO ₂ sat:	<input type="text"/> %

On-Study Chest X-Ray

Visit Date:

METATRIAL

USE FIRST CXR IN THE REFERENCE PERIOD 04:00-10:00. If unavailable in the reference period, use first CXR this calendar day.	
1. Number of quadrants with infiltrates:	<input style="width: 50px; height: 20px;" type="text"/>
2. Barotrauma:	
Pneumothoraces: (4)	<input type="radio"/> No Answer <input type="radio"/> Right (1) <input type="radio"/> Left (2) <input type="radio"/> Bilateral (3) <input type="radio"/> None
Subcutaneous emphysema:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
Pneumomediastinum:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
Pneumatoceles > 2 cm diam: (4)	<input type="radio"/> No Answer <input type="radio"/> Right (1) <input type="radio"/> Left (2) <input type="radio"/> Bilateral (3) <input type="radio"/> None
3. Chest tube: (4)	<input type="radio"/> No Answer <input type="radio"/> Right (1) <input type="radio"/> Left (2) <input type="radio"/> Bilateral (3) <input type="radio"/> None

On-Study Diagnostic Studies

Visit Date:

METATRIAL

Indicate all Diagnostic Cardiovascular Studies performed on this calendar date.		
1. Trans-thoracic Cardiac Ultrasound?	<input type="radio"/> No Answer	<input type="radio"/> Yes (1) <input type="radio"/> No (2)
2. Transesophageal Cardiac Ultrasound?	<input type="radio"/> No Answer	<input type="radio"/> Yes (1) <input type="radio"/> No (2)
3. Radionuclide Ventriculography?	<input type="radio"/> No Answer	<input type="radio"/> Yes (1) <input type="radio"/> No (2)
4. Left Heart Cardiac Catheterization?	<input type="radio"/> No Answer	<input type="radio"/> Yes (1) <input type="radio"/> No (2)
5. Greene Dye Cardiac Output?	<input type="radio"/> No Answer	<input type="radio"/> Yes (1) <input type="radio"/> No (2)
6. Bioimpedance Cardiac Output?	<input type="radio"/> No Answer	<input type="radio"/> Yes (1) <input type="radio"/> No (2)
7. Other?	<input type="radio"/> No Answer	<input type="radio"/> Yes (1) <input type="radio"/> No (2)

Random Protocol Check

Visit Date:

Time of random cath check:	<input type="text"/>																								
1. Fluid management protocol still in effect?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)																								
1a. If no, give reason:	<input type="radio"/> No Answer <input type="radio"/> Achieved 12 hours of UAB (1) <input type="radio"/> Withdrawn from fluid management arm of the protocol (2) <input type="radio"/> Other (3)																								
Other specify:	<input type="text"/>																								
2. Record SEQUENCE of all cells identified by ICU team this calendar date: (begin with first cell identified after midnight)	<table border="1"> <tr> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> </tr> <tr> <td>1st Cell</td> <td>2nd Cell</td> <td>3rd Cell</td> <td>4th Cell</td> <td>5th Cell</td> <td>6th Cell</td> </tr> <tr> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> </tr> <tr> <td>8th Cell</td> <td>9th Cell</td> <td>10th Cell</td> <td>11th Cell</td> <td>12th Cell</td> <td>13th Cell</td> </tr> </table>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	1st Cell	2nd Cell	3rd Cell	4th Cell	5th Cell	6th Cell	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	8th Cell	9th Cell	10th Cell	11th Cell	12th Cell	13th Cell
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>																				
1st Cell	2nd Cell	3rd Cell	4th Cell	5th Cell	6th Cell																				
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>																				
8th Cell	9th Cell	10th Cell	11th Cell	12th Cell	13th Cell																				
3. Was free water (PO or IV) administered to treat hyponatremia on this calendar date?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)																								
ENTER VALUES CLOSEST TO THE TIME PRECEDING THE RANDOM CATH CHECK.																									
4. Time of data collection:	<input type="text"/> (closest to computer-selected time of random cath check)																								
5. MAP:	<input type="text"/> mmHg																								
5a. On vasopressor?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)																								
6. Adequate circulation?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)																								
7. CVP:	<input type="text"/> mmHg																								
8. PAOP:	<input type="text"/> mmHg																								
9. If PAOP invalid, enter assumed PAOP based on PAD:	<input type="text"/> mmHg																								
10. PAD:	<input type="text"/> mmHg																								
11. CI:	<input type="text"/> L/min/m ²																								
12. Mixed venous O ₂ sat:	<input type="text"/> %																								
13. PEEP:	<input type="text"/> cm/H ₂ O																								
14. Average 4 hour urine output prior to time of data collection:	<input type="text"/> ml/kg/hr																								
15. Fluid Management Algorithm Cell Number Selected by ICU team from above data:	<input type="text"/> (range 1-20)																								

16. Enter treatments given in response to the data in 5-11, 14	
16-1. Vasopressor given?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
If not given, why not?	<input type="radio"/> No Answer <input type="radio"/> b/o footnote (1) <input type="radio"/> Declined (2) <input type="radio"/> Not in cell (3)
Please select specific reason not given:	<input type="text" value="No Answer"/>
Other:	<input type="text"/>
16-2. Fluid bolus given?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
If not given, why not?	<input type="radio"/> No Answer <input type="radio"/> b/o footnote (1) <input type="radio"/> Declined (2) <input type="radio"/> Not in cell (3)
Please select specific reason not given:	<input type="text" value="No Answer"/>
Other:	<input type="text"/>
16-3. Dobutamine given?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
If not given, why not?	<input type="radio"/> No Answer <input type="radio"/> b/o footnote (1) <input type="radio"/> Declined (2) <input type="radio"/> Not in cell (3)
Please select specific reason not given:	<input type="text" value="No Answer"/>
Other:	<input type="text"/>
16-4. Lasix given?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
If not given, why not?	<input type="radio"/> No Answer <input type="radio"/> b/o footnote (1) <input type="radio"/> Declined (2) <input type="radio"/> Not in cell (3)
Please select specific reason not given:	<input type="text" value="No Answer"/>
Other:	<input type="text"/>

Footnote/Reason-Declined Code

1=Ineffective circulation reversed; dobutamine being weaned 2=Vasopressor or fluid bolus given last 12 hrs 3= Renal
 4= Oliguria with creatinine >3mg/dL 5= Oliguria with creatinine <= 3mg/dL and urinary studies indicate acute renal
 response to maximum dose furosemide 7= Three fluid boluses given this day 8= Fluid bolus did not produce sustained
 filling pressure last 24 hrs 11= Arrhythmia/tachycardia 12= Out of ICU/diagnostic testing 13= Cardiac output read
 14= Declined because of noninvasive cardiovascular test results 15= Declined because mixed venous O2 sat normal/hi
 because mixed venous O2 sat low 17= PAOP reading questioned 18= CVP reading questioned 19= Active GI bleed
 MI
 21= Suspected myocardial ischemia 22= Acute PE 23= Pericardial disease 24= Other emergency 25= Other 26= C
 27= FiO2 ≥ 0.7 28= wrong cell identified 29= nursing/physician error (pure mistake) 30= elevated sodium 31= UOF
 32=optional (in shock cell) 33=not in cell

Weaning

Visit Date:

METATRIAL

FOR THIS CALENDAR DATE	
1. Did patient meet weaning evaluation criteria?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) <input type="radio"/> Not applicable or undergoing PSV wean (3)
2. If 1 is yes, did patient pass 5 min CPAP trial?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) <input type="radio"/> Not tried/not indicated (3)
3. Did patient tolerate a trial of spontaneous breathing > 2 hours?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) <input type="radio"/> Not tried/not indicated (3)
4. Did patient complete 48 hours of unassisted breathing on this calendar date?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
5. IV or PO Corticosteroids given this calendar date?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
If yes, total daily dose:	<input type="text"/> mg (methylprednisone equivalent)
6. Experimental therapies? If yes, check experimental therapies:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
Nitric Oxide:	<input type="checkbox"/>
Surfactant:	<input type="checkbox"/>
Partial Liquid Ventilation:	<input type="checkbox"/>
ECMO:	<input type="checkbox"/>
IVOX:	<input type="checkbox"/>
HFV or HFO:	<input type="checkbox"/>
Prone Positioning:	<input type="checkbox"/>
Inhaled PGI or PGE:	<input type="checkbox"/>
Intravenous PGI or PGE:	<input type="checkbox"/>

Blood Cultures

Visit Date:

METATRIAL

ENTER ALL POSITIVE BLOOD CULTURES	
Organism:	<input type="radio"/> No Answer <input type="radio"/> Staph aureus (1) <input type="radio"/> Staph epidermidis (2) <input type="radio"/> Strep pneumoniae (3) <input type="radio"/> Enterococcus (4) <input type="radio"/> Other Gram Positive coccus (5) <input type="radio"/> Pseudomonas Species (6) <input type="radio"/> Hemophilus influenza (7) <input type="radio"/> Other Gram Negative rod (8) <input type="radio"/> Candida or Torulopsis Species (9) <input type="radio"/> Aspergillus Species (10) <input type="radio"/> Other (11)
Date:	<input type="text"/> <input type="button" value="Date"/>
Time:	<input type="text"/>

Glasgow Coma

Visit Date:

METATRIAL

Complete this form on study days 0, 7, and study hospital discharge.	
1. Is patient on a sedative or neuromuscular blocker?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
2. Eye Opening Score:	<input type="radio"/> No Answer <input type="radio"/> Spontaneous (4) <input type="radio"/> To voice (3) <input type="radio"/> To pain (2) <input type="radio"/> none (1)
3. Motor Response Score:	<input type="radio"/> No Answer <input type="radio"/> Obeys commands (6) <input type="radio"/> Localizes to pain (5) <input type="radio"/> Flexor withdrawal (4) <input type="radio"/> Abnormal flexion (3) <input type="radio"/> Extension (2) <input type="radio"/> Flaccid (1)
4. Verbal Response Score:	<input type="radio"/> No Answer <input type="radio"/> Oriented, or if on ventilator, appears oriented (5) <input type="radio"/> Confused (4) <input type="radio"/> Inappropriate, or if on ventilator, questionable oriented (3) <input type="radio"/> Incomprehensible (2) <input type="radio"/> None, or if on ventilator generally unresponsive (1)
Total:	<input type="text"/>

Brussels Table 1

Visit Date:

Study Day	Date	Systolic BP	PaO2/ FiO2	Platelets X1000	Creatinine	Bilirubin	Vasopressor
Day 0							<input type="radio"/> No Answer <input type="radio"/> Yes (1)
Day 1							<input type="radio"/> No Answer <input type="radio"/> Yes (1)
Day 2							<input type="radio"/> No Answer <input type="radio"/> Yes (1)
Day 3							<input type="radio"/> No Answer <input type="radio"/> Yes (1)
Day 4							<input type="radio"/> No Answer <input type="radio"/> Yes (1)
Day 5							<input type="radio"/> No Answer <input type="radio"/> Yes (1)
Day 6							<input type="radio"/> No Answer <input type="radio"/> Yes (1)
Day 7							<input type="radio"/> No Answer <input type="radio"/> Yes (1)

Brussels Table 2

Visit Date:

Study Day	Date	Systolic BP	PaO2/ FiO2	Platelets X1000	Creatinine	Bilirubin	Vasopressor
Day 8							<input type="radio"/> No Answer <input type="radio"/> Yes (1)
Day 9							<input type="radio"/> No Answer <input type="radio"/> Yes (1)
Day 10							<input type="radio"/> No Answer <input type="radio"/> Yes (1)
Day 11							<input type="radio"/> No Answer <input type="radio"/> Yes (1)
Day 12							<input type="radio"/> No Answer <input type="radio"/> Yes (1)
Day 13							<input type="radio"/> No Answer <input type="radio"/> Yes (1)
Day 14							<input type="radio"/> No Answer <input type="radio"/> Yes (1)

Brussels Table 3

Visit Date:

Study Day	Date	Systolic BP	PaO2/ FiO2	Platelets X1000	Creatinine	Bilirubin	Vasopressor
Day 15							<input type="radio"/> No Answer <input type="radio"/> Yes (1)
Day 16							<input type="radio"/> No Answer <input type="radio"/> Yes (1)
Day 17							<input type="radio"/> No Answer <input type="radio"/> Yes (1)
Day 18							<input type="radio"/> No Answer <input type="radio"/> Yes (1)
Day 19							<input type="radio"/> No Answer <input type="radio"/> Yes (1)
Day 20							<input type="radio"/> No Answer <input type="radio"/> Yes (1)
Day 21							<input type="radio"/> No Answer <input type="radio"/> Yes (1)

Brussels Table 4

Visit Date:

Study Day	Date	Systolic BP	PaO2/ FiO2	Platelets X1000	Creatinine	Bilirubin	Vasopressor
Day 22							<input type="radio"/> No Answer <input type="radio"/> Yes (1)
Day 23							<input type="radio"/> No Answer <input type="radio"/> Yes (1)
Day 24							<input type="radio"/> No Answer <input type="radio"/> Yes (1)
Day 25							<input type="radio"/> No Answer <input type="radio"/> Yes (1)
Day 26							<input type="radio"/> No Answer <input type="radio"/> Yes (1)
Day 27							<input type="radio"/> No Answer <input type="radio"/> Yes (1)
Day 28							<input type="radio"/> No Answer <input type="radio"/> Yes (1)

Adverse Event

Visit Date:

METATRIAL

CALL CCC IMMEDIATELY FOR SERIOUS, UNEXPECTED AND STUDY RELATED EVENTS	
1. Date of event:	<input type="text"/> <input type="text" value="Date"/>
2. Time of event:	<input type="text"/>
3. Name of event:	<input type="text"/>
4. Describe event or problem:	<input type="text"/>
5. Severity of event:	<input type="radio"/> No Answer <input type="radio"/> Mild (1) <input type="radio"/> Moderate (2) <input type="radio"/> Serious (3)
6. Did AE require therapeutic intervention to prevent permanent impairment/damage?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
7. Was the patient in immediate risk of death due to the event?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
8. Was the event unexpected or more severe or frequent than expected in CVC/PAC managed ALI/ARDS?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) <input type="radio"/> Unknown (3)
9. Causal relationship to PAC/CVC:	<input type="radio"/> No Answer <input type="radio"/> definitely associated (1) <input type="radio"/> probably associated (2) <input type="radio"/> possible association (3) <input type="radio"/> probably not associated (4) <input type="radio"/> definitely not associated (5) <input type="radio"/> uncertain association (6)
10. Causal relationship to fluid management protocol:	<input type="radio"/> No Answer <input type="radio"/> definitely associated (1) <input type="radio"/> probably associated (2) <input type="radio"/> possible association (3) <input type="radio"/> probably not associated (4) <input type="radio"/> definitely not associated (5) <input type="radio"/> uncertain association (6)
11. Was patient withdrawn from the study because of this event? If yes, check all that apply:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
1=PAC vs CVC Trial:	<input type="checkbox"/>

2=Fluid Management Algorithm:	<input type="checkbox"/>
12. Status of this adverse event at the time of initial AE report:	<p><input type="radio"/> No Answer</p> <p><input type="radio"/> Recovered (1)</p> <p><input type="radio"/> AE Present, no treatment (2)</p> <p><input type="radio"/> AE Present, being treated (3)</p> <p><input type="radio"/> Residual effect, no treatment (4)</p> <p><input type="radio"/> Residual effect, being treated (5)</p> <p><input type="radio"/> Deceased as a result of this AE (6)</p>
12.1 Date of recovery:	<input type="text"/> <input type="button" value="Date"/>
13. Final outcome of this adverse event (until resolution or stabilization):	<p><input type="radio"/> No Answer</p> <p><input type="radio"/> Recovered (1)</p> <p><input type="radio"/> AE Present, no treatment (2)</p> <p><input type="radio"/> AE Present, being treated (3)</p> <p><input type="radio"/> Residual effect, no treatment (4)</p> <p><input type="radio"/> Residual effect, being treated (5)</p> <p><input type="radio"/> Deceased as a result of this AE (6)</p>
13.1 Date of recovery:	<input type="text"/> <input type="button" value="Date"/>

Specimen Collection

Visit Date:

METATRIAL

Day 0	
Blood for Cytokine:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) If no, enter reason in comment to field.
Date of Blood Draw:	<input type="text"/> <input type="button" value="Date"/>
Day 1	
Blood for Cytokine:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) If no, enter reason in comment to field.
Date of Blood Draw:	<input type="text"/> <input type="button" value="Date"/>
Day 3	
Blood for Cytokine:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) If no, enter reason in comment to field.
Date of Blood Draw:	<input type="text"/> <input type="button" value="Date"/>
Day 7	
Blood for Cytokine:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) If no, enter reason in comment to field.
Date of Blood Draw:	<input type="text"/> <input type="button" value="Date"/>
Genetics	
Whole Blood :	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) If no, enter reason in comment to field.
Date for Whole Blood:	<input type="text"/> <input type="button" value="Date"/>
Buccal Smear:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) If no, enter reason in comment to field.
Date of Buccal Smear:	<input type="text"/> <input type="button" value="Date"/>

Study Termination

Visit Date:

Begin completion of this form by Day 28. Patients not yet home with unassisted breathing (UAB) should be followed through Day 90.	
1. Patient status (through Day 90):	<input type="radio"/> No Answer <input type="radio"/> Home with unassisted breathing (1) <input type="radio"/> Dead prior to discharge home with UAB (2) <input type="radio"/> Other (3)
1a. If 1, date home with UAB:	<input type="text"/> <input type="button" value="Date"/>
1b. If 2, date of death prior to home with UAB:	<input type="text"/> <input type="button" value="Date"/>
1c. Date of last known patient status if not home with UAB and not dead:	<input type="text"/> <input type="button" value="Date"/>
2. Was patient permanently withdrawn from the fluid management arm of the FACTT trial?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
2a. If yes, give date PAC withdrawal:	<input type="text"/> <input type="button" value="Date"/>
3. Was patient discharged alive from study hospital (through Day 90)?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
3a. If yes, give date:	<input type="text"/> <input type="button" value="Date"/>
3b. If alive, destination at discharge from study hospital:	<input type="radio"/> No Answer <input type="radio"/> Home (1) <input type="radio"/> Home with paid or unpaid help (2) <input type="radio"/> Rehab facility (3) <input type="radio"/> Another acute care facility (4)
ICU HISTORY	
ICU days during study hospitalization to day 90 (days in which patient spent any time in an ICU during study hospitalization).	
4a. Discharged from ICU?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) <input type="radio"/> Unknown (3)
Date of ICU discharge:	<input type="text"/> <input type="button" value="Date"/>
4b. Readmitted to ICU?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) <input type="radio"/> Unknown (3)
Date of ICU readmission:	<input type="text"/> <input type="button" value="Date"/>
Discharged from ICU?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) <input type="radio"/> Unknown (3)
Date of ICU discharge:	<input type="text"/> <input type="button" value="Date"/>
4c. Readmitted to ICU?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) <input type="radio"/> Unknown (3)

Date of ICU readmission:	<input type="text"/> <input type="button" value="Date"/>
Discharged from ICU?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) <input type="radio"/> Unknown (3)
Date of ICU discharge:	<input type="text"/> <input type="button" value="Date"/>
4d. Readmitted to ICU?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) <input type="radio"/> Unknown (3)
Date of ICU readmission:	<input type="text"/> <input type="button" value="Date"/>
Discharged from ICU?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) <input type="radio"/> Unknown (3)
Date of ICU discharge:	<input type="text"/> <input type="button" value="Date"/>
4e. Readmitted to ICU?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) <input type="radio"/> Unknown (3)
Date of ICU readmission:	<input type="text"/> <input type="button" value="Date"/>
Discharged from ICU?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) <input type="radio"/> Unknown (3)
Date of ICU discharge:	<input type="text"/> <input type="button" value="Date"/>
HISTORY ON VENTILATOR	
Ventilator days until UAB at home, death, or day 90. (A ventilator day is any day in which the patient received assisted breathing (AB), except for AB for < 24 hours for a procedure or surgery).	
5a. Patient achieved unassisted breathing:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) <input type="radio"/> Unknown (3)
Date of first UAB (first date with no AB; midnight to midnight):	<input type="text"/> <input type="button" value="Date"/>
5b. Patient returned to assisted breathing:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) <input type="radio"/> Unknown (3)
Date of return to AB:	<input type="text"/> <input type="button" value="Date"/>
5c. Patient achieved unassisted breathing again?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) <input type="radio"/> Unknown (3)
Date of UAB (2nd date with no AB; midnight to midnight):	<input type="text"/> <input type="button" value="Date"/>
5d. Patient returned to assisted breathing:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) <input type="radio"/> Unknown (3)
Date of return to AB:	<input type="text"/> <input type="button" value="Date"/>
5e. Patient achieved unassisted breathing again?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) <input type="radio"/> Unknown (3)
Date of UAB:	<input type="text"/> <input type="button" value="Date"/>
5f. Patient returned to assisted breathing:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) <input type="radio"/> Unknown (3)
Date of return to AB:	<input type="text"/> <input type="button" value="Date"/>
5g. Patient achieved unassisted	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) <input type="radio"/> Unknown (3)

breathing again?	
Date of UAB:	<input type="text"/> <input type="button" value="Date"/>
6. Did patient require dialysis during study hospitalization?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
If yes, date of first dialysis:	<input type="text"/> <input type="button" value="Date"/>
Date of last dialysis during study hospitalization:	<input type="text"/> <input type="button" value="Date"/>
7. End of Life Decision Making:	<input type="radio"/> No Answer <input type="radio"/> No DNR decision made (1) <input type="radio"/> DNR decision made: withhold only CPR (2) <input type="radio"/> DNR decision made: withhold life support in addition to CPR (3) <input type="radio"/> DNR decision made: withdraw life support (4) <input type="radio"/> Diagnosis of brain death (5) <input type="radio"/> Unknown/can't tell (6)