ARDSNet01 version 2 Annotated CRFs
Table of Contents

Part 01:04 ALI SCREENING NHLBI-9404 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

COMPLETE FOR PATIENTS MEETING CRITERIA 1-3 IN DESIGNATED ICU'S

+1. Acute Onset 1=Yes,2=No: SCRE1

2. Within past 24 hrs patient had ALL of the following? 1=Yes,2=No: SCRE2
   - 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?

3. No clinical evidence of left Atrial hypertension (if measured pulmonary arterial wedge pressure < or = 18 mmHg)? 1=Yes,2=No: SCRE3

4. PaO2: PAO2

5. FiO2: FIO2

6. First date that all these criteria exist simultaneously: FDATE

Part 02:04 ALI SCREENING NHLBI-9404 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

7. Patient Hospital ID #: NOTE: hospid field removed from database HOSPID

8. Gender 1=Male,2=Female: GENDER

9. Ethnicity 1=White, not of Hispanic Origin,2=Black, not of Hispanic Origin,3=Hispanic,4=Asian/Pacific Islander, 5=American Indian/Alaskan Native,6=Other: ETHNIC

10. Age: AGE

11. Location 1=MICU,2=SICU,3=Cardiac SICU,4=CCU,5=Neuro ICU, 6=Burn,7=Trauma,8=Cancer Unit,9=MICU/SICU,10=Other LOCAT LOCOTH

+12. Regularly Screened ICU 1=Yes,2=No: RSICU

Electronic Table Name = SCREEN

Part 03:04 ALI SCREENING NHLBI-9404 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

+13. Primary Reason for Exclusion: REASON
0=Not Excluded, 1=MD Refuses, 2=Patient/Family Refuses,
3=Patient Unable/Surrogate Unavailable, 4=Patient < 18 Years,
5=Other Trial 30 days, 6=Inclusion Criteria > 36 hours,
7=Neuromuscular Disease, 8=Patient Pregnant, 9=Increased ICP,
10=Chronic Lung Disease, 11=Burns > 30%, 12=Terminal Illness,
13=Bone/Lung Transplant, 14=Not Committed to Full Support,
15=Treated with Itraconazole,Ketoconazole,Fluconazole Past 7 days,
16=Treated with Astemizole,Terfenadine,Cisapride Past 3 days,
17=Chronic Liver Disease, 18=Acute Liver Disease, 19=Morbid Obesity,
20=Imidazole Allergy

13b. Comments: COMMENT

NOTE that variable 'COMMENT' is not included in the limited access dataset, in compliance with non-identifiability requirements.

Part 04:04 ALI SCREENING NHLBI-9404 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

+14. Lung Injury Category (0=None, 1=Primary, 2=Secondary)
Trauma: TRAUMA Sepsis: SEPSIS Multiple Transfusion: MULTRAN
Aspiration: ASPIR Pneumonia: PNEUM Other: OTHER
Other Description: OTHTXT

FOLLOWING ITEMS ARE NOT REQUIRED FOR PATIENTS ENTERED IN KARMA

15. Date of unassisted breathing if unassisted breathing sustained for greater than 48 hours UNASSIS

16. Date of Discharge from Study Hospital DISCH

17. Status at Discharge from Study Hospital 1=Alive,2=Dead: DISSTAT

NOTE that some of the data originally entered into 'OTHTXT' (item 14 Other Description) have been masked, due to the sensitive nature of these data. Please refer to page 2 item 8 of the Change Descriptions document (01-03_changes.pdf) for further detail.

Electronic Table Name = SCREEN

Part 01:01 INCLUSION CRITERIA NHLBI-9404 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

1=Yes,2=No: Date: VDATE

INCL1 1. Acute Onset

INCL2 2. Within the past 24 hours did patient have ALL of the following?
- 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?

INCL3 3. No clinical evidence of left atrial hypertension (if measured pulmonary arterial wedge pressure < or = 18 mmHg)

IF ANSWERS TO 1-3 YES, CONTINUE TO EXCLUSION CRITERIA

INCLUDE

Part 01:04 EXCLUSION CRITERIA NHLBI-9404 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

1=Yes,2=No: Date: VDATE

EXCL1 1. Attending physician unwilling to participate?
EXCL2 2. Patient unwilling to participate?
EXCL3 3. Unable to obtain informed consent?
EXCL4 4. Is patient less than 18 years old?
EXCL5 5. Has patient participated in other intervention trials in ALI, ARDS or Sepsis within the past 30 days?
EXCL6 6. Has it been > 36 hours since all inclusion criteria were met?
EXCL7 7. Does the patient have neuromuscular disease that impairs the ability to ventilate spontaneously?
EXCL8 8. Is patient pregnant?
EXCL9 9. Does the patient have elevated ICP, tricyclic antidepressant overdose, HGBSS, HGBSC, or other conditions where hypercapnia would be contraindicated?
EXCL10 10. Does patient have severe chronic respiratory disease?

Part 02:04 EXCLUSION CRITERIA NHLBI-9404 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

1=Yes,2=No:

EXCL11 11. Does patient have burns greater than or equal to 30% total body surface area?
EXCL12 12. Does patient have a malignancy or other chronic irreversible disease or condition for which 6 month mortality is estimated at greater than 50%?
EXCL13 13. Has the patient had either a bone marrow transplant or lung transplant?
EXCL14 14. Not committed to full support?
EXCL15 15. Has the patient been treated with ketoconazole, itraconazole, fluconazole within the past 7 days?
EXCL16 16. Has the patient been treated with astemizole, terfenadine, or cisapride within the past 3 days?

NOTE that the data from the 'EXCLUDE' table have not been included in the limited access dataset, in compliance with non-identifiability requirements.

EXCLUDE

Part 03:04 EXCLUSION CRITERIA NHLBI-9404 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

A. Ascites 1=None,2=Present,3=Tense: PUGHA
B. Encephalopathy 1=None,2=Grade I or II,3=Grade III or IV: PUGHB
No Abnormality
Grade I or II - trivial lack of awareness; shortened attention span; lethargy; disorientation in time; clear personality change or inappropriate behavior
Grade II or IV - very drowsy; semicomatose but responsive to stimuli; confused; gross disorientation in time or space; bizarre behavior; coma; unresponsive to painful stimuli with or without abnormal movements
C. Bilirubin (mg/dl) 1=[<2],2=[2-3],3=[>3]: PUGHC
D. Albumin (g/dl) 1=[>3.5],2=[2.8-3.5],3=[<2.8]: PUGHD
E. Prothrombin time (sec. prolonged) 1=[<=4],2=[5-10],3=[>10]: PUGHE
Total: PUGHTOT

1=Yes,2=No:

EXCL17 17. Is patient known to have severe, chronic liver disease? (If Child-Pugh score is greater than or equal to 10 enter yes)

Part 04:04 EXCLUSION CRITERIA NHLBI-9404 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

1=Yes,2=No:

EXCL18 18. Does the patient have evidence of acute viral, ischemic, or toxic hepatitis with moderate or severe hepatocellular injury?

EXCL19 19. Does patient have known allergy to imidazole or its derivatives?

EXCL20 20. Is the patient morbidly obese? (weight(kg)/height(cm)>1)

IF ANY OF THE ABOVE ANSWERS ARE YES PATIENT SHOULD NOT BE ENROLLED

EXCL21 21. Has informed consent been obtained?
If patient is eligible for the study and consent has been obtained, please call for randomization number.

EXCL21B 22. Is patient randomized? (If Yes, system prompts for number)

23. Patient randomized to (1=6 ml/kg,2=12 ml/kg): EXCL22
24. Date/time of initial ventilator change: EXCL23DT EXCL23TM

EXCLUDE

Page ID: [103] Print Count: [5]

NOTE that the data from the 'EXCLUDE' table have not been included in the limited access dataset, in compliance with non-identifiability requirements.

Part 01:02 APACHE III DEMOGRAPHICS NHLBI-9404 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

Date: VDATE

1. Hospital Admission Date:	HADMDT
2. ICU Admission Date:	ICUDT
3. Time of ICU Admission:	ICUTM
4. Patient Admitted Directly From 1=OR,2=Recovery Room, 3=ER, 4=Floor, 5=Another Special Care Unit, 6=Another Hospital, 7=Direct Admit, 8=Stepdown Unit:	ADMFRM
	1=Yes,2=No:
5. If immediately post-operative, was surgery elective?:	SURGEL
6. ICU Readmit:	ICURE
7. ICU Readmit within 24 hours:	ICURE2
8a. Is chronic health information available?:	CHRNC
8b. Is the patient on chronic dialysis or peritoneal dialysis?:	DIALY
9a. AIDS (do not include HIV positive without AIDS criteria):	AIDS
9b. Leukemia (AML,CML,all lymphocytic leuk.,multiple myeloma):	LEUK

Part 02:02 APACHE III DEMOGRAPHICS NHLBI-9404 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

1=Yes,2=No:

9c. Non-Hodgkin's Lymphoma:	LYMPH
9d. Solid tumor with metastasis:	TUMOR
9e. Immune suppression (radiation, chemotherapy or greater than or equal to 0.3 mg/kg/day prednisone or equivalent) within the past 6 months:	IMMUNE
9f. Hepatic failure with coma or encephalopathy:	HEPA
9g. Cirrhosis:	CIRR
9h. Diabetes Mellitus:	DIAB

DEMO

Part 01:02 APACHE III PHYSIOLOGY NHLBI-9404 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

+USE VALUES FROM 24HRS PRECEDING INITIAL VENT CHANGES Date: VDATE

VITAL SIGNS	Lowest	Highest		Lowest	Highest
+1. Temperature:	TEMPCL	TEMPCH	C	TEMPFL	TEMPFH F
2. Systolic BP:	SYSBPL	SYSBPH	mmHg		
3. Mean Arterial Pressure:	MEANAPL	MEANAPH	mmHg		
4. Heart Rate:	HRATEL	HRATEH	beats/min		
5. Respiratory Rate:	RESPL	RESPH	breaths/min		

6a. Was patient ventilated when the lowest respiratory rate occured? 1=Yes,2=No: LVENT

6b. Was patient ventilated when the highest respiratory rate occured? 1=Yes,2=No: HVENT

+7. Urine Output/24 hours: URINE ml

Part 02:02 APACHE III PHYSIOLOGY NHLBI-9404 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

USE VALUES FROM 24HRS PRECEDING INITIAL VENT CHANGES

HEMATOLOGY	Lowest	Highest	
*8. Hct:	HCTL	HCTH	%
*9. WBC:	WBCL	WBCH	/mm^3
*10.Platelets (lowest):	PLATE		X1000 /mm^3

CHEMISTRY			
*11. Serum Sodium:	SODIUML	SODIUMH	meq/L
*12. Serum Potassium:	POTASL	POTASH	meq/L
*13. Serum BUN (highest):		BUN	mg/dl
*14. Serum Creatinine:	CREATL	CREATH	mg/dl
*15. Serum Glucose:	GLUCL	GLUCH	mg/dl
*16. Serum Albumin:	ALBUML	ALBUMH	g/dl
*17. Serum Bilirubin (highest):		BILI	mg/dl
*18. Serum Bicarbonate (lowest):	BICAR		meq/L

Electronic Table Name = PHYSIO

Part 01:02 APACHE - ABG NHLBI-9404 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

Visit Date: VDATE

REPORT ALL ABG'S IN THE 24HRS PRECEDING INITIAL VENT CHANGE

	FiO2	PaO2 mmHg	PaCO2 mmHg	pH	Intubated when ABG obtained 1=Yes,2=No
1.	FIO21	PAO21	PACO21	PH1	INTUBAT1
2.	FIO22	PAO22	PACO22	PH2	INTUBAT2
3.	FIO23	PAO23	PACO23	PH3	INTUBAT3
4.	FIO24	PAO24	PACO24	PH4	INTUBAT4
5.	FIO25	PAO25	PACO25	PH5	INTUBAT5
6.	FIO26	PAO26	PACO26	PH6	INTUBAT6
7.	FIO27	PAO27	PACO27	PH7	INTUBAT7
8.	FIO28	PAO28	PACO28	PH8	INTUBAT8
9.	FIO29	PAO29	PACO29	PH9	INTUBAT9
10.	FIO210	PAO210	PACO210	PH10	INTUBAT10

NOTE: in the database, the 'copnum' variable represents the rows shown here

Part 02:02 APACHE - ABG NHLBI-9404 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

	FiO2	PaO2 mmHg	PaCO2 mmHg	pH	Intubated when ABG obtained 1=Yes,2=No
11.	FIO211	PAO211	PACO211	PH11	INTUBAT11
12.	FIO212	PAO212	PACO212	PH12	INTUBAT12
13.	FIO213	PAO213	PACO213	PH13	INTUBAT13
14.	FIO214	PAO214	PACO214	PH14	INTUBAT14
15.	FIO215	PAO215	PACO215	PH15	INTUBAT15
16.	FIO216	PAO216	PACO216	PH16	INTUBAT16
17.	FIO217	PAO217	PACO217	PH17	INTUBAT17
18.	FIO218	PAO218	PACO218	PH18	INTUBAT18
19.	FIO219	PAO219	PACO219	PH19	INTUBAT19
20.	FIO220	PAO220	PACO220	PH20	INTUBAT20

Electronic Table Name = BABG

NOTE: the original production of the data extract tables combined the above variables into: fio2, pao2, paco2, ph, and intubate, as you can see in the electronic 'babg' table you have received. No data were altered as a result of this restructuring.

Part 01:02 VITAL SIGNS NHLBI-9404 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

Date: VPATE

1. Date and time of current intubation: INTUBDT INTUBTM
+ITEMS 2-5 ARE MOST RECENT IN THE 4HRS PRECEDING INITIAL VENT CHANGE

2. Heart Rate:	HRATE	bpm	
3. Systolic BP:	SYSBP	mmHg	
4. Diastolic BP:	DIABP	mmHg	
5. Temperature:	TEMPCL	C	TEMPFL F
6. Height	HEIGHTC	cm	HEIGHTI in
7. Gender:	GENDER	1=Male, 2=Female	
8. IBW:	IBW	kg (computed)	
9. Weight:	WEIGHTK	kg	WEIGHTL lbs
10. Fluid Intake/24 hours:	FLUIDI	ml	
11. Urine Output/24 hours:	FLUIDO	ml	

Part 02:02 VITAL SIGNS NHLBI-9404 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

+ITEMS 11-16 ARE MOST RECENT IN 24HRS

11. Hct:	HCT	%
12. WBC:	WBC	/mm^3
13. Total Bilirubin:	BILI	mg/dl
14. AST:	AST	Units/L
15. ALT:	ALT	Units/L
16. Alkaline Phosphatase:	ALKAL	Units/L

+Collect blood for cytokines and urine for thromboxane metabolites prior to initial vent change

NOTE that this baseline 'Vital' form was joined with the on-study 'Vital' form (page 13) to create the electronic 'vital' table that you have received.

Electronic Table Name = VITAL

Part 01:01 CHEST X-RAY/BAROTRAUMA NHLBI-9404 Day:0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

Date: VDATE

MOST RECENT CXR PRIOR TO INITIAL VENT CHANGE

1. Radiographic Lung Injury Score (# of quadrants 0-4) RADLIS

2. Barotrauma:

Pneumothoraces	1=Right,2=Left,3=Bilateral,4=None:	BARO1
Subcutaneous emphysema	1=Yes,2=No:	BARO2
Pneumomediastinum	1=Yes,2=No:	BARO3
Pneumatoceles > 2 cm diam	1=Right,2=Left,3=Bilateral,4=None:	BARO4

3. Chest Tube 1=Right,2=Left,3=Bilateral,4=None: CTUBE

NOTE that this baseline Chest XRay form was joined with the on-study Chest XRay form (page 15) to create the electronic 'oschest' table that you have received.

OSCHEST

Part 01:01 MEDICATION REPORT NHLBI-9404 Day:0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

MOST RECENT WITHIN 24HRS Date: VDATE

1=Yes,2=No: Initial Vent Change Time: VENTCHTM

SEDAT 1. Sedative/Tranquilizers (benzodiazepines,narcotics,barbiturates,propofol)

BLOCKER 2. Neuromuscular Blocking Agents

H2BLOCK 3. H2 Blockers?

ANTBIO 4. Erythromycin, clarithromycin, or other macrolide antibiotics

VASOP 5. Has patient received any vasopressors in the past 24 hrs.?

STUDY DRUG MUST BE ADMINISTERED WITHIN 4HRS OF RANDOMIZATION

6. Date first dose of study drug administered: STDRUGDT

7. Time first dose of study drug administered: STDRUGTM

NOTE that this baseline 'med' form was joined with the on-study 'med' form (page 15) to create the electronic 'med' table that you have received.

MED

Part 01:01 GLASGOW COMA NHLBI-9404 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

Date: VDATE

1. Is patient on a sedative or neuromuscular blocker? 1=Yes,2=No: SEDATE
   If yes, use best estimate

2. Eye Opening Score 4=Spontaneous, 3=To Voice, 2=To Pain, 1=None: EYE

3. Motor Response Score MOTOR
   6=Obeys Commands, 5=Localizes to Pain, 4=Flexor Withdrawal,
   3=Abnormal Flexion, 2=Extension, 1=Flaccid:

4. Verbal Response Score OR On Ventilator VERBAL
   5=Oriented, 5=Appears Oriented,
   4=Confused, 3=Quesionably Oriented,
   3=Inappropriate, 1=Generally Unresponsive
   2=Incomprehensible,
   1=None

Total: TOTAL

GLASGOW

Part 01:02 VENTILATOR PARAMETERS NHLBI-9404 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

MOST RECENT IN 4HR INTERVAL BEFORE INITIAL VENT CHANGE Date: VDATE
Initial Vent Change Time: VENTCHTM

1. Ventilator Manufacturer and Model: VMODEL
   1=Puritan-Bennett 7200, 2=Servo 9000,
   3=Servo 300, 4=Hammilton Veolar/Amadeus,
   5=Bird 8400, 6=Bear 1000, 7=Other
2. Ventilator Mode
   2.1 SIMV 1=Yes,2=No: 2.2 Pressure Support 1=Yes,2=No: PSUPP
   2.3 Assist/Control 1=Yes,2=No: 2.4 Pressure Control 1=Yes,2=No: PCON
   2.5 PC IRV 1=Yes,2=No: 2.6 Other 1=Yes,2=No: OTHERSP
+3. Calculated Delivered Tidal Volume: TIDAL ml OTHER
   (If on Volume Cycled Mode)
4. Pressure Control Level: PCONL cm H2O
   (If on Pressure Control Ventilation)
+5. Pressure Support: PSUPL cm H2O
   (If on Pressure Support Ventilation)

Part 02:02 VENTILATOR PARAMETERS NHLBI-9404 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

6. Set Rate:	SRATE	breaths/min.
7. Total Respiratory Rate:	TRESPR	breaths/min.
8. Total Minute Ventilation:	TMNVNT	L/min
9. PEEP:	PEEP	cm H2O
10. Plateau Pressure		
Pstat #1 0.5 second end-inspiratory pause:	PSTAT1	cm H2O
Pstat #2 0.5 second end-inspiratory pause:	PSTAT2	cm H2O
Pstat #3 0.5 second end-inspiratory pause:	PSTAT3	cm H2O
11. Peak Inspiratory Pressure:	PEAK	cm H2O
12. I:E Ratio Set I:E IRATIO: ERATIO or True I:E TIRATIO: TERATIO		
13. Mean Airway Pressure:	MAPRES	cm H2O
14. FiO2:	FIO2	
15. PaO2:	PAO2	mmHg
16. PaCO2:	PACO2	mmHg
17. Arterial pH:	ARTPH	
18. SpO2:	SPO2	%

Electronic Table Name = VENT

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NOTE that this baseline 'Vent' form was joined with the on-study 'Vent' form (page 14) to create the electronic 'vent' table that you have received.

Part 01:02 ON STUDY VITAL SIGNS NHLBI-9404 Day: 1

Copy ___:___ Investigator: _____ Patient ID: ___ _____

Date: VDATE

+ Data from reference period 06:00 to 10:00. If more than one value, use the value closest to 08:00. If not available in reference period, use closest to reference period on same calendar day.

*1. Heart Rate:	HRATE	bpm		
*2. Systolic BP:	SYSBP	mmHg		
*3. Diastolic BP:	DIABP	mmHg		
*4. Temperature:	TEMPCL	C	TEMPFL	F
5. Weight:	WEIGHTK	kg	WEIGHTL	lbs
6. Fluid Intake/24 hours:	FLUIDI	ml		
7. Urine Output/24 hours:	FLUIDO	ml		

Part 02:02 ON STUDY VITAL SIGNS NHLBI-9404 Day: 1

Copy ___:___ Investigator: _____ Patient ID: ___ _____

8. Hct:	HCT	%
9. WBC:	WBC	/mm^3
10. AST:	AST	Units/L
11. ALT:	ALT	Units/L
12. Alkaline Phosphatase:	ALKAL	Units/L

+Collect blood for cytokines and urine for thromboxane metabolites on Days 1 + 3; collect blood for Keto levels 2 hours after Day 3 dose; complete specimen collection form.

NOTE that this on-study 'Vital' form was joined with the baseline 'Vital' form (page 9) to create the electronic 'vital' table that you have received.

Electronic Table Name = VITAL

Part 01:02 ON STUDY VENTILATOR PARAMETERS NHLBI-9404 Day: 1

Copy ___:___ Investigator: _____ Patient ID: ___ _____

IF ON POSITIVE PRESSURE VENT DURING REFERENCE PERIOD 0600-1000. IF MORE THAN ONE VALUE, USE VALUES CLOSEST TO 0800. IF ABG NOT AVAILABLE IN REFERENCE PERIOD, USE CLOSEST TO REFERENCE PERIOD ON SAME CALENDAR DATE. Date: VDATE

1. Ventilator Manufacturer and Model: VMODEL
   1=Puritan-Bennett 7200, 2=Servo 9000,
   3=Servo 300, 4=Hammilton Veolar/Amadeus,
   5=Bird 8400, 6=Bear 1000, 7=Other
2. Ventilator Mode
   2.1 Assist/Control 1=Yes,2=No: ASSIST
   2.2 Pressure Support 1=Yes,2=No: PSUPP
   2.3 Unassisted Breathing 1=Yes,2=No: VNASIS
+3. Calculated Delivered Tidal Volume: TIDAL ml
   (If on Volume Cycled Mode)
+4. Pressure Support: PSUPL cm H2O
   (If on Pressure Support Ventilation)

Part 02:02 ON STUDY VENTILATOR PARAMETERS NHLBI-9404 Day: 1

Copy ___:___ Investigator: _____ Patient ID: ___ _____

5. Set Rate:	SRATE	breaths/min.
6. Total Respiratory Rate:	TRESPR	breaths/min.
7. Total Minute Ventilation:	TMNVNT	L/min
8. PEEP:	PEEP	cm H2O
9. Plateau Pressure		
Pstat #1 0.5 second end-inspiratory pause:	PSTAT1	cm H2O
Pstat #2 0.5 second end-inspiratory pause:	PSTAT2	cm H2O
Pstat #3 0.5 second end-inspiratory pause:	PSTAT3	cm H2O
10. Peak Inspiratory Pressure:	PEAK	cm H2O
11. I:E Ratio: a.Set I:E IRATIO : ERATIO or b.True I:E TIRATIO : TERATIO		
12. Mean Airway Pressure:	MAPRES	cm H2O
13. FiO2:	FIO2	
+14. PaO2:	PAO2	mmHg
+15. PaCO2:	PACO2	mmHg
+16. Arterial pH:	ARTPH	
17. SpO2:	SPO2	%

Page ID: [202]

Electronic Table Name = VENT

Print Count: [8]

NOTE that this on-study 'Vent' form was joined with the baseline 'Vent' form (page 12) to create the electronic 'vent' table that you have received.

Part 01:01 CHEST X-RAY/BAROTRAUMA NHLBI-9404 Day:1

Copy ___:___ Investigator: _____ Patient ID: ___ _____

Date: VDATE

Use first CXR in the reference period 06:00-10:00. If unavailable in reference period, use first CXR this calendar day.

1. Radiographic Lung Injury Score (# of quadrants 0-4) RADLIS
2. Barotrauma:
   - Pneumothoraces 1=Right,2=Left,3=Bilateral,4=None: BARO1
   - Subcutaneous emphysema 1=Yes,2=No: BARO2
   - Pneumomediastinum 1=Yes,2=No: BARO3
   - Pneumatoceles > 2 cm diam 1=Right,2=Left,3=Bilateral,4=None: BARO4
3. Chest Tube 1=Right,2=Left,3=Bilateral,4=None: CTUBE

NOTE that this on-study Chest XRay form was joined with the baseline Chest XRay form (page 10) to create the electronic 'oschest' table that you have received.

OSCHEST

Part 01:01 MEDICATION REPORT NHLBI-9404 Day:1

Copy ___:___ Investigator: _____ Patient ID: ___ _____

INDICATE 1=YES,2=NO IF ANY OF THE FOLLOWING MEDICATIONS WERE ADMINISTERED THIS CALENDAR DAY Date: VDATE

SEDAT 1. Sedative/Tranquilizers (benzodiazepines,narcotics,barbiturates,propofol)
BLOCKER 2. Neuromuscular Blocking Agents
H2BLOCK 3. H2 Blockers?

THE FOLLOWING DRUGS ARE DISCOURAGED BY THE PROTOCOL

KETO 4a. Ketoconazole FLUC 4b. Fluconazole ITRA 4c. Itraconazole

THE FOLLOWING DRUGS ARE PROHIBITED BY THE PROTOCOL

ASTEM 5a. Astemizole TERF 5b. Terfenadine CISA 5c. Cisapride

EXPERIMENTAL THERAPIES

NITRIC 6a. Nitric oxide SURF 6b. Surfactant PARTLV 6c. Partial Liquid Vent.
ECMO 7a. ECMO IVOX 7b. IVOX HFVHFO 7c. HFV or HFO
PRONE 7d. Prone Positioning
ANTBIO 8. Erythromycin, clarithromycin, or other macrolide antibiotics

MED

Page ID: [203] Print Count: [15]

NOTE that this on-study 'med' form was joined with the baseline 'med' form (page 10) to create the electronic 'med' table that you have received.

Part 01:04 WEANING/DRUG DISCONTINUATION NHLBI-9404 Day:1

Copy ___:___ Investigator: _____ Patient ID: ___ _____

DURING THE SAME CALENDAR DAY Date: VDATE

+1a. Was the patient permanently withdrawn from the vent arm of the protocol? 1=Yes,2=No: VWDRAW

+1b. Was the patient permanently withdrawn from the keto/placebo arm of the protocol? 1=Yes,2=No: KWDRAW

2. Was study drug administered? 1=Yes,2=No: WEA1N

3. At 0600, was patient on: WEA2N
1=Volume Assist/Control Ventilation 2=Pressure Support Ventilation
3=Unassisted Breathing 4=Other:
WEA2NO

NOTE that variable 'WEA2NO' has been removed from the limited access dataset, to maintain non-identifiability.

1=Yes,2=No
3=Not tried/Evaluated

4. Did patient meet weaning evaluation criteria? WEA3N

4a. If 4 is Yes, did patient pass 5 minute CPAP trial? WEA4N

Part 02:04 WEANING/DRUG DISCONTINUATION NHLBI-9404 Day:1

Copy ___:___ Investigator: _____ Patient ID: ___ _____

5. Were there attempts to wean PS by 5cmH2O? 1=Yes,2=No: WEA5CM
If No, why not:
WEA5TXT

NOTE that variable 'WEA5TXT' has been removed from the limited access dataset, to maintain non-identifiability.

WEANING HISTORY: Record initial and subsequent Pressure Support levels along with their corresponding starting times each time the Pressure Support level is changed.

Pressure Support Level		Time	Pressure Support Level		Time
5a.	LEVELA	TIMEA	5b.	LEVELB	TIMEB
5c.	LEVELC	TIMEC	5d.	LEVELD	TIMED
5e.	LEVELE	TIMEE	5f.	LEVELF	TIMEF
5g.	LEVELG	TIMEG	5h.	LEVELH	TIMEH

Electronic Table Name = WEAN

Part 03:04 WEANING/DRUG DISCONTINUATION NHLBI-9404 Day:1

Copy ___:___ Investigator: _____ Patient ID: ___ _____

6. Did patient tolerate a trial of spontaneous breathing > 2 hours?
1=Yes,2=No,3=Not tried/Evaluated: WEA6N

7. Did patient complete 48 hours of unassisted breathing on this calendar day? 1=Yes,2=No: WEA7N

For items 9 through 13 enter first value in 4 hr interval ON or AFTER time of the ventilator check. If no time appears, skip items 8 - 15.

Selected Time of ventilator check: VENTCKTM

+8. Was patient on assist/control continuously during 4 hrs preceding and 4 hrs following selected ventilator check time? 1=Yes,2=No: ASSIST

9. FiO2: FIO2

10. Calculated Delivered Tidal Volume: TIDAL ml

11. PEEP: PEEP cm H2O

12. Set Rate: SRATE

13. Pplat Mid PPLAT cm H2O

Part 04:04 WEANING/DRUG DISCONTINUATION NHLBI-9404 Day:1

Copy ___:___ Investigator: _____ Patient ID: ___ _____

For items 14 and 15 enter last value in the four hour interval ON OR PRIOR TO time of the ventilator check

14a. pH: PH

14b. If PH available, was set rate changed in the interval between measurement and the time set rate (Item 11) recorded? 1=Yes,2=No: SETCHNG

15a. SpO2: SPO2 %

15b. If SpO2 available, was FiO2 or PEEP changed in the interval between SpO2 measurement and the time FiO2 or PEEP (Items 9 or 11) recorded? 1=Yes,2=No: FIOCHNG

NOTE that the electronic table 'WEAN' also contains the following variables: ventctm2, pao2, peechng, noph, and volin. These were added as the ARDSNet03 CRFs were developed. To view the corresponding questions that were used with these variables, please refer to the annotated Weaning form for ARDSNet03 (ardsnet03_crfs.pdf).

Electronic Table Name = WEAN

Part 01:02 BRUSSELS TABLE DAYS 0-14 NHLBI-9404 Day: ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

24HR WORST VALUE

	Date	Syst BP	PaO2/ FiO2	Platelets X 1000	Creat-inine	Bili-rubin	Vasopressor 1=Y,2=N
Day 0.5	VDATE0	SYSBP0	PAFI0	PLATE0	CREAT0	BILI0	VASO0
Day 1	1	1	1	1	1	1	1
Day 2	2	2	2	2	2	2	2
Day 3	3	3	3	3	3	3	3
Day 4	4	4	4	4	4	4	4
Day 5	5	5	5	5	5	5	5
Day 6	6	6	6	6	6	6	6
Day 7	7	7	7	7	7	7	7
Day 8	8	8	8	8	8	8	8
Day 9	9	9	9	9	9	9	9
Day 10	10	10	10	10	10	10	10
Day 11	11	11	11	11	11	11	11
Day 12	12	12	12	12	12	12	12

Part 02:02 BRUSSELS TABLE DAYS 0-14 NHLBI-9404 Day: ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

24HR WORST VALUE

	Date	Syst BP	PaO2/ FiO2	Platelets X 1000	Creat-inine	Bili-rubin	Vasopressor 1=Y,2=N
Day 13	13	13	13	13	13	13	13
Day 14	14	14	14	14	14	14	14

BRUSS

Part 01:01 BRUSSELS TABLE DAYS 15-28 NHLBI-9404 Day: ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

24HR WORST VALUE	Date	Syst BP	PaO2/ FiO2	Platelets X 1000	Creat-inine	Bili-rubin	Vasopressor 1=Y,2=N
Day 15	VDATE0	SYSBP0	PAFI0	PLATE0	CREAT0	BILI0	VASO0
Day 16	1	1	1	1	1	1	1
Day 17	2	2	2	2	2	2	2
Day 18	3	3			1		
Day 19	4	4					
Day 20	5	5					
Day 21	6	6					
Day 22	7	7					
Day 23	8	8					
Day 24	9	9					
Day 25	10	10					
Day 26	11	11					
Day 27	12	12					
Day 28	13	13					

BRUSS

NOTE: the original production of the data extract tables combined the above variables into: vdate, sysbp, pafi, plate, creat, bili, and vaso, as you can see in the electronic 'bruss' table you have received. No data were altered as a result of this restructuring.

Part 01:01 SPECIMEN COLLECTION NHLBI-9404 Day: ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

Date: VDATE

	1=Yes,2=No	Date
Day 0		
Blood for cytokine	BLOOD1	BLDT1
Urine for Thromboxane Metab	URINE1	URDT1
Day 1		
Blood for cytokine	BLOOD2	BLDT2
Urine for Thromboxane Metab	URINE2	URDT2
Day 3		
Blood for cytokine	BLOOD3	BLDT3
Urine for Thromboxane Metab	URINE3	URDT3
Study Drug given	STDRUG	STDRUGDT
Time Study Drug given		STDRUGTM
Blood for Ketoconazole	BLOODK	BLDKDT
Time		BLDKTM

SPEC

Part 01:02 ADVERSE EVENT REPORT NHLBI-9404 Day: ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

Date: VDATE

1. Date of event: EVDATE 2. Time of event: EVTM
3. Specified event: SPEVNT
   1=Increased Intracranial Pressure 2=Gastrointestinal Bleed
   3=Arrhythmia 4=Hepatitis 5=Other adverse event
   Other Specify: OTHER
4. Describe event or problem:
   DESC

NOTE that variables 'OTHER' and 'DESC' are not included in the limited access dataset, in compliance with non-identifiability requirements.

5. Severity of event (1=mild,2=moderate,3=severe): SEVER
6. Did AE require therapeutic intervention to prevent permanent impairment/damage? (1=Yes,2=No): THERAP

Part 02:02 ADVERSE EVENT REPORT NHLBI-9404 Day: ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

1=Yes,2=No

7. Was the patient in immediate risk of death due to the event? RISKDE
8. Did the patient die as a result of the event? DIE
9. Was the event unexpected in ARDS or more severe or frequent than expected in ARDS? (1=yes, 2=no, 3=unknown): EXPECT
10. Causal relationship to study drug: CAUSAL
    1=definitely associated 2=probably associated
    3=possible association 4=probably not associated
    5=definitely not associated 6=uncertain association
11. Was study drug discontinued as a result of this event? DISC
12. Was patient withdrawn from the ventilator because of event? WDRAW
13. Outcome to date: OUTCOME
    1=recovered - date: RECDT 2=AE present, no treatment
    3=AE present/being treated 4=residual effect/no treatment
    5=residual effect/being treated 6=deceased

AER

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NOTE that the electronic database 'AER' also contains the following variables: system1, system2, failure, msof, and death. Please refer to the Summary of Changes document (01-03_changes.pdf) for a description of these variables.

Part 01:02 STUDY TERMINATION NHLBI-9404 Day:ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

Date: VDATE

Complete this form when the patient: 1) goes home with unassisted breathing or sustains unassisted breathing at home for more than 48 hours or 2) dies (whichever comes first). For patients alive after day 28 who have not been discharged home or are on assisted breathing, check on the patient's status at intervals of at most 30 days until 1 or 2 occurs or the patient survives 180 days at any location with or without assisted breathing.

1. Patient Status:_ variable name = 'status'
   1=Home with unassisted breathing
   2=Dead prior to discharge home with unassisted breathing or dead prior to achieving unassisted breathing at home for 48 hrs
   3=Other

1a. If 1, date discharged home on unassisted breathing: ST1DT
1b. If 2, date of death: ST2DT
1c. If 3, date of last patient contact: ST3DT

Part 02:02 STUDY TERMINATION NHLBI-9404 Day:ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

2. Patient able to sustain a period of continuous unassisted breathing for at least 48 hrs during first 28 days? 1=Yes,2=No: UNASSIST
2a. If Yes, beginning date of period of unassisted breathing: UNADT
3. Did the patient return to assisted breathing during the first 28 days? 1=Yes,2=No: ASSIST
3a. If Yes, number of calendar dates on which the patient required assisted breathing between the date 2a and day 28: ASDAYS
4. Was the patient discharged alive from ICU during the first 28 days after enrollment? 1=Yes,2=No: ICU
4a. If Yes, date of discharge: ICUDT
5. Did the patient return to an ICU during the first 28 days? 1=Yes,2=No: RICU
5a. If Yes, number of calendar dates on which the patient received any ICU-care between the date 4a and day 28: RICUDAYS
6. Patient discharged alive from study hospital? 1=Yes,2=No: ALIVE
6a. If Yes, date of discharge alive from hospital: ALIVEDT

TERM

Part 01:01 ADDITIONAL COMMENTS NHLBI-9404 Day: ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

Form Name: FRNAME
Item Number: ITEMNUM
Day Number: DAYNUM

Date: VDATE

Comment:
COMMENT

COMMENT

NOTE that the data from the 'COMMENT' table have not been included in the limited access dataset, in compliance with non-identifiability requirements.