SAILS/EDEN Paper CRF
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Annotated CRF

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Study Form

1. Study ID#	______________________
2. Date and time of randomization (**Local** time from randomization confirmation)	randomdtm
3. Study Enrollment **(make certain that selection is correct before saving in system)**	☐ SAILS Only

Screening/Enrollment Form I

Complete for enrolled patients meeting criteria in designated ICUs	
Patient initials:	
1. Did patient meet the following 3 criteria: i. Acute onset? ii. Within 24hrs patient had ALL of the following: o PaO2/FiO2 ≤ 300mm Hg o Bilateral infiltrates consistent with pulmonary edema on frontal chest radiograph? o Receiving positive pressure ventilation via endotracheal tube? iii. No clinical evidence of left atrial hypertension?	☐ Yes ☐ No allcrit
2. Date & time of qualifying CXR:	_____/_____/_____ _____:_____ (24hr clock) qualdtm
3. Patient met SIRS criteria? Defined as meeting at **least the WBC or temperature criteria** for a systemic inflammatory response within the window of time **72 hours before to 24 hours after** the date and time of after ALI onset?	☐ Yes ☐ No If Yes, indicate all SIRS criteria met: sirs ❑ White blood cell count >12,000 or <4,000 or >10% band forms ❑ Body temperature >38°C (any route) or <36°C (by core temperatures only: indwelling catheter, esophageal, rectal) ❑ Heart rate (> 90 beats/min) or receiving medications that slow heart rate or paced rhythm
4. Patient has suspected or proven infection?	☐ Yes ☐ No Site of infection: inf ❑ Thorax ❑ Abdomen ❑ Skin or soft tissue ❑ Bacterial meningitis ❑ Urinary tract ❑ Central line ❑ Sinuses ❑ Osteomyelitis ❑ Confirmed Swine Influenza A (H1N1) ❑ Other ___________
5. If qualifying CK level is > 5 times ULN, do the following apply? -Patient has an identifiable cause of CK elevation other than statin therapy -Value has fallen at least 10 % in the two most recent measurements -Most recent value at time of Randomization less than 10 times ULN at randomization -Patient has not received statins in the 30 days prior to randomization	☐ Yes ☐ No ☐ Not applicable ck5uln
6. Date & time of qualifying CXR:	_____/_____/_____ _____:_____ (24hr clock) qualdtm

7. Number of quadrants with opacities (2-4):	_____	quads
8. Date & time of current intubation:	______/______/______ ______:______(24hr clock)	intubdtm
9. PaO2:	______mm Hg	paO2screen
10. FiO2:	_____	fiO2screen
11. Date & time of qualifying P/F:	______/______/______ ______:______(24hr clock)	qualpfdtm
12. First date that all these criteria exist simultaneously (ALI onset):	______/______/______	critdt
13. Gender:	☐ Male ☐ Female	gender
14. Ethnicity:	☐ Hispanic or Latino ☐ Not Hispanic or Latino	ethnic
15. Race (check all that apply) If coordinator cannot obtain the race(s) from the patient, the patient's family, or from a source document, select "not reported".	☐American Indian or Alaskan Native ☐Asian ☐White ☐Black or African American ☐Native Hawaiian or other Pacific Islander ☐Not reported	native asian white afamer island norace
16. Age as appears on screening form (in years):	_____	age
17. Is patient's true age > 89?	☐ Yes; True age is ___________ ☐ No	agegt89
18. Location	☐MICU ☐SICU ☐Cardiac SICU ☐CCU ☐Neuro ICU ☐Burn ☐Trauma ☐Cancer Unit ☐MICU/SICU ☐Other	locat
19. Reason for Exclusion: Select **"Exclusions"** if patient meets exclusion(s) to study. Choose all that apply. Select **"Not Excluded"** if patient meets no exclusions and is enrolled. Select **"Not Excluded Not Enrolled"** if patient meets no exclusions, but is not entered in trial. Indicate reason not enrolled in text box.	☐**Exclusions:** ❑ No consent/inability to obtain consent ❑ More than 7 days since initiation of mechanical ventilation ❑ More than 48 hours since meeting ALI inclusion criteria ❑ Patient, surrogate, or physician not committed to full support ❑ Pregnancy or breast feeding ❑ Severe chronic liver disease (Child-Pugh Score 12-15) ❑ Moribund patient not expected to survive 24 hours ❑ Diffuse alveolar hemorrhage from vasculitis ❑ Burns > 40% total body surface area ❑ Unwillingness or inability to utilize the ARDS network 6ml / kg PBW ventilation protocol ❑ Age less than 18 years ❑ Receiving a statin medication within 48 hours of randomization ❑ Allergy or intolerance to statins ❑ Physician insistence on use of statins during the ICU stay ❑ Physician insistence on AVOIDANCE of statins during the ICU stay ❑ CK, ALT or AST > 5 times the upper limit of normal (ULN)	

	❑ Diagnosis of hypothyroidism and not on thyroid replacement therapy ❑ Receiving niacin, fenofibrate, cyclosporine, gemfibrozil, lopinavir, ritonavir, atazanavir during the ICU stay ❑ Home mechanical ventilation (noninvasive ventilation or via tracheotomy) except for CPAP/BIPAP used solely for sleep-disordered breathing ❑ Chronic respiratory failure defined as $PaCO_2$ > 60 mm Hg in the outpatient setting ❑ Interstitial lung disease of severity sufficient to require continuous home oxygen therapy ❑ Cardiac disease classified as NYHA class IV ❑ Unable to receive or unlikely to absorb enteral study drug (e.g. patients with partial or complete mechanical bowel obstruction, intestinal ischemia, infarction, and short bowel syndrome) ❑ Myocardial infarction within past 6 months ❑ Intraparenchymal CNS bleed within 6 mos ❑ Patient refusal for SAILS ❑ MD refusal for SAILS (specify reason) ___Refusal to use conservative fluid protocol ___Refusal to use 6ml ventilator protocol ___Other: ☐ Not Excluded (Select if enrolled in SAILS and EDEN) ☐ Not Excluded and not enrolled, explain: ____________________________________
Lung Injury Category:	
17. Trauma	☐ None ☐ Primary ☐ Secondary trauma
18. Sepsis	☐ None ☐ Primary (indicate site):__________ ☐ Secondary sepsis
19. Multiple transfusion	☐ None ☐ Primary ☐ Secondary tranf
20. Aspiration	☐ None ☐ Primary ☐ Secondary aspir
21.Pneumonia	☐ None ☐ Primary ☐ Secondary pneumo
22.Other	☐ None ☐ Primary(describe:__________ ☐ Secondary(describe:__________) otherlung

Enrollment II

Complete for all enrolled subjects.

1. Has informed consent been obtained for participation in SAILS?	☐Yes	☐No	sailconsent
2. For genetic research in this study?	☐Yes	☐No	genconsent
3. For genetic testing related to future ARDS studies?	☐Yes	☐No	genconsenta
4. For future genetic research involved with other conditions?	☐Yes	☐No	futconsento
5. To contact subject for future studies?	☐Yes	☐No	contconsent

Apache III Demographics

1. Hospital admission date:	_____/_____/_____	hasddt
2. Hospital admission type:	☐ Medical ☐ Surgical scheduled ☐ Surgical unscheduled ☐ Other_______________	admtype
3. ICU admission date:	_____/_____/_____	icudt
4. ICU admission time:	_____:_____ (24 hr clock)	icutm
5. Patient admitted directly from:	☐ OR ☐ Recovery Room ☐ ER ☐ Floor ☐ Another special care unit ☐ Another hospital ☐ Direct admit ☐ Stepdown unit	admitfrom
6. What was the patient's place of residence prior to hospitalization?	☐ Home independently ☐ Home w/ help (supervision, c[...]al assistance) ☐ Home w/ professional help (nursing/nursing service) ☐ Intermediate care or rehab facility ☐ Skilled nursing facility ☐ Other (please specify)_______________________	reside
7. Is patient immediately post-operative from elective surgery?	☐ Yes ☐ No	surgel
8. ICU Readmit:	☐ Yes ☐ No	icureadmit
9. ICU readmit within 24 hrs?	☐ Yes ☐ No	readmit24
10. Is chronic health information available?	☐ Yes ☐ No	healthinfo
11. Is the patient on chronic dialysis or peritoneal dialysis?	☐ Yes ☐ No	chrondial
12. AIDS (do not include HIV positive without AIDS criteria)	☐ Yes ☐ No	aids
13. Leukemia (AML, CML, ALL, multiple myeloma):	☐ Yes ☐ No	leuk
14. Non-Hodgkin's lymphoma:	☐ Yes ☐ No	lymph
15. Solid tumor w/ metastasis:	☐ Yes ☐ No	tumor
16. Immune suppression (radiation, chemo, or ≥ 0.3mg/kg/day prednisone or equivalent) w/in past 6 mos:	☐ Yes ☐ No	immune
17. Hepatic failure w/ coma or encephalopathy	☐ Yes ☐ No	hepa

18. Cirrhosis:	☐ Yes ☐ No	cirr
19. Diabetes Mellitus:	☐ Yes ☐ No	diab
20. History of hypertension:	☐ Yes ☐ No	hyper
21. Prior MI:	☐ Yes ☐ No	hyper
22. Congestive heart failure:	☐ Yes ☐ No	heart
23. Peripheral vascular disease:	☐ Yes ☐ No	vascular
24. Prior stroke with sequelae:	☐ Yes ☐ No	aestroke
25. Dementia:	☐ Yes ☐ No	dementia
26. Chronic pulmonary disease:	☐ Yes ☐ No	chrpulm
27. Arthritis:	☐ Yes ☐ No	arthritis
28. Peptic ulcer disease:	☐ Yes ☐ No	ulcer
29. Vasopressors in the 24 hrs prior to randomization?	☐ Yes ☐ No	vasol24

Apache III Physiology

VITAL SIGNS	
USE VALUES FROM 24 HRS PRECEDING RANDOMIZATION If no values were obtained for clinical purposes during the 24hrs preceding randomization, **the lab tests must be obtained (after obtaining pt/surrogate consent) before initiating study procedures.**	
1. Temperature: templ temph	Lowest ______ Highest ______ ☐°C ☐°F
2. Systolic BP: sysbpl sysbpl	Lowest ______ Highest ______ mm Hg
3. Mean arterial pressure: mapl mapl	Lowest ______ Highest ______ mm Hg
4. Heart rate: hratel hratel	Lowest ______ Highest ______ beats/min
5. Respiratory rate: respl respl	Lowest ______ Highest ______ breaths/min
6. Was pt. ventilated when the lowest resp rate occurred?	☐ Yes ☐ No ventl
7. Was pt. ventilated when the highest resp rate occurred?	☐ Yes ☐ No venth
8. **Urine** output for 24 hrs preceding randomization:	________ml urineout
9. **Total fluid** output for 24 hrs pre randomization:	________ml (**includes negative CVVH ba**[...]) fluidout
10. **Total fluid intake** for the 24 hrs preceding randomization:	________ml (**includes positive CVVH ba**[...]) fluidin
Hematology	
11. Hct:	Only hcto Lowest hctl Highest hcth
12. WBC:	Only wbco Lowest wbcl Highest wbch [...]m3
13. Platelets (lowest):	Lowest ______ X 1000/mm3 plate
Chemistry	
14. Serum Sodium:	Only sodiumo Lowest sodiuml [...]/L Highest sodiumh
15. Serum Potassium:	Only potaso Lowest potasl [...]Eq/L Highest potash
16. Serum BUN (highest):	Highest ______ mg/dL bun
17. Serum Creatinine:	Only creato Lowest creatl Highest creath
18. Serum Glucose:	Only gluco Lowest glucl Highest gluch
20. Serum Albumin: 21.	Only albumo Lowest albuml Highest albumh

20. Serum Bilirubin (highest):	Highest _______ mg/dL bilih
21. Serum Bicarbonate (lowest):	Lowest _______ mEq/L bicarbl

Apache III ABG (all)

Report all ABG's in the 24 hrs preceding randomization

FI02	PaO2	PaCO2	pH	Intubated when ABG obtained?
1. fio2abg	pao2abg	paco2abg	phabg	☐ intubat
2.				☐ Yes ☐ No
3.				☐ Yes ☐ No
4.				☐ Yes ☐ No
5.				☐ Yes ☐ No
6.				☐ Yes ☐ No
7.				☐ Yes ☐ No
8.				☐ Yes ☐ No
9.				☐ Yes ☐ No
10.				☐ Yes ☐ No
11.				☐ Yes ☐ No
12.				☐ Yes ☐ No

For non-intubated gases, use the following rule for determining FiO2:
FiO2 = 0.21 + .03N (where N= number of liters of O2 per minute)

Alcohol & Smoking Assessment

Complete for all enrolled subjects at baseline (Use the form as a source document—have person completing the form sign and date)

The Alcohol Use Disorders Identification Test (AUDIT) Questionnaire		
1. How often do you have a drink containing alcohol?	☐ Never [skip to Q's 9-10] ☐ Monthly or less ☐ 2 to 4 times a month ☐ 2 to 3 times a week ☐ 4 or more times a week	alchfreq
2. How many drinks containing alcohol do you have on a typical day when you are drinking?	☐ 1 or 2 ☐ 3 or 4 ☐ 5 or 6 ☐ 7, 8, or 9 ☐ 10 or more	alchnum
3. How often do you have 6 or more drinks on one occasion?	☐ Never ☐ Less than monthly ☐ Monthly ☐ Weekly ☐ Daily or almost daily	alch6freq
Skip to question 9 if question 2 is '1 to drinks and question 3 is 'never'		
4. How often during the last year have you found you were not able to stop drinking once you had started?	☐ Never ☐ Less than monthly ☐ Monthly ☐ Weekly ☐ Daily or almost daily	alchstop
5. How often during the last year have you failed to do what was normally expected from you because of drinking?	☐ Never ☐ Less than monthly ☐ Monthly ☐ Weekly ☐ Daily or almost daily	alchfail
6. How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?	☐ Never ☐ Less than monthly ☐ Monthly ☐ Weekly ☐ Daily or almost daily	alchmorn
7. How often during the last year have you had a feeling of guilt or remorse after drinking?	☐ Never ☐ Less than monthly ☐ Monthly ☐ Weekly ☐ Daily or almost daily	alchguilt
8. How often during the last year have you been unable to remember what happened the night before because you had been drinking?	☐ Never ☐ Less than monthly ☐ Monthly ☐ Weekly ☐ Daily or almost daily	alchmemory
9. Have you or someone else been injured as a result of your drinking?	☐ No ☐ Yes, but not in the last year ☐ Yes, during the last year	alchinjury
10. Has a relative or friend or a doctor or another health worker been concerned about your drinking or suggested you cut down?	☐ No ☐ Yes, but not in the last year ☐ Yes, during the last year	alchconcern
Smoking history: 11. Ever smoker? (> 100 cigarettes in lifetime)	☐ Yes (if yes, answer 12 & 13) ☐ No	smoker
12. If ever smoker, estimate # pack years=#pk/day X #yrs	____________pk years	packyr
13. Current smoker?	☐ Yes ☐ No, when quit ____	smokequitdt

Baseline Creatinine-SAILS

Collect all creatinine values in the 48 hours prior to randomization

Date	Time (24 hr clock)	Creatinine Value
		mg/dL
creatbasedt		creatbase dL
		mg/dL
		mg/dL
		mg/dL
		mg/dL

Baseline Labs-SAILS

All required (enter most recent values prior to randomization--may use values up to 24 hours prior to randomization). If NOT available in the 24 hours prior to randomization obtain after consent.

1. CK	__________U/L	ck
2. CK ULN for this subject:	__________U/L	
3. ALT	__________U/L	alt
4. ALT ULN for this subject:	__________U/L	
5. AST	__________U/L	ast
6. AST ULN for this subject:	__________U/L	
7. CRP	__________mg/dL Please indicate whether high sensitivity or regular CRP: ☐Regular ☐ High sensitivity	crp crphl

On-Study Labs-SAILS

- Required labs may be collected +/- 2 days **except for DAY 1.**
- **CK and ALT required on days 1, 3, 6, 14, 21.** Record values on additional days **if clinically available.**
- **Additional CK required on day 10.**
- **CRP required on days 6 and 14.**

1. CK	__________U/L	ck
2. ALT	__________U/L	alt
3. AST		ast
4. CRP	__________mg/dL Please indicate whether high sensitivity or regular CRP: ☐Regular ☐ High sensitivity	crp crphl

Baseline Ventilator Parameters-ALL

Collect most recent values prior to randomization	
1. Ventilator Target:	☐Pressure Ventilation (PCV) ☐Volume Ventilation ☐Dual Mode
1. Ventilator mode (select all that apply) simv prvc pressup volassist presassist pcirv aprv hvocv vc autof othervent	☐SIMV **(volume targeted)** ☐PRVC (pressure regulated volume control)or equivalent **(volume targeted)** ☐Pressure Support _________cm H2O **(pressure targeted)** pressupcmh2o ☐Volume Assist/Control **(volume targeted)** ☐Pressure Assist ________cm H2O presascmh2o ☐PC IRV (pressure targeted) ☐Airway Pressure Release Ventilation (APRV) **(pressure targeted)** ☐HFO ☐VC+ **(dual mode)** ☐Auto Flow **(dual mode)** ☐Other ___________
2. Calculated delivered tidal volume: **Complete ONLY if subject on Volume Targeted Mode**	_________ml tidal
3. Inspiratory Time: **Complete ONLY if on a pressure targeted or dual mode**	________seconds insptime
4. Set rate:	________breaths/min setrate
5. Total respiratory rate:	________breaths/min resp
6. Total minute ventilation:	________L/min minvent
7. PEEP:	________cm H2O peep
8. FiO2 prior to randomization:	________ fio2
9. SpO2 prior to randomization:	________% spo2
10. Plateau pressure:	________cm H2O pplat
11. Peak inspiratory pressure:	________cm H2O pip
12. Mean airway pressure:	________cm H2O meanair
Enter ABG closest to time of randomization	
13. FiO2 at time of ABG	fio2abg
14. PaO2	_______mmHg pao2abg
15. PaCO2	_______mmHg paco2abg
16. Arterial pH	phabg
17. SpO2	_______ % spo2abg

After initial vent change, if any, on a tidal volume of 6-8 ml/kg PBW		
18. Calculated delivered tidal volume:	________ml	tidalpost
19. Plateau pressure:	________cm H2O	pplatpost
20. PEEP:	________cm H2O	peeppost

Baseline Vital Signs-ALL

Record values closest to the time preceding randomization	
1. Heart rate: hrate	________beat/min
2. Systolic BP: sysbp	________mm Hg
3. Diastolic BP: diabp	________mm Hg
4. CVP: cvp	________mm Hg
5. Mean Arterial Pressure (MAP only map art line present)	________mm Hg
6. Temperature: temp	________ ☐ °C ☐ °F
7. Measured height: height	________ ☐cm ☐in
8. Measured weight: weigh	________ ☐kg ☐lbs
Predicted body weight pbw	________kg
9. Intravenous vasopressor support or inotrope in 24 hrs preceding randomization? vaso If yes, enter infusion rates at time of randomization for items to the right. **If YES above, but NO infusions at time of randomization, enter "none" under "other"**	☐No ☐Yes o Dobutamine:______☐µg/kg dobut ...in o Dopamine:________☐µg/kg dopa ...in o Norepinephrine:________☐ norepi ☐µg/min o Epinephrine:_________ ☐µ epi ...g/min o Vasopressin:_________units vasorate o Neosynephrine:_______ ☐µ neosyn ...µg/min o Other (specify)__________ vasoother ______ __________________________________

On-study Vital Signs-SAILS

Complete on days 1-7 or until 48 hours UAB.

1. Heart rate: hrate	_________beat/min
2. Systolic BP: sysbp	_________mm Hg
3. Diastolic BP: diabp	_________mm Hg
4. Temperature: temp	_________ ☐ °C ☐ °F
5. CVP: cvp	_________mm Hg
6. Max temp this day maxtemp	
7. CXR: Enter the number of quadrants with infiltrates if CXR clinically available this calendar day.	_________ quadrants cxrquads
8. IV or PO corticosteroids totaling ≥ 20 mg methylprednisolone equivalents given this calendar date? 20 mg methylprednisolone equivalents: ≥3.75 mg dexamethasone ≥20 mg methylprednisolone ≥25 mg prednisone ≥100mg hydrocortisone	☐ Yes ☐ No cort

On-Study Ventilator Parameters-ALL

Required on days 1-4, 7, 12, 21, 28 (if on mechanical ventilation)

1. Ventilator Target:	☐ Pressure Ventilation (PCV) ☐ Volume Ventilation ☐ Dual Mode
2. Ventilator mode (select all that apply) simv prvc pressup volassist presassist pcirv aprv hvocv vc autof othervent	☐ SIMV **(volume targeted)** ☐ PRVC (pressure regulated volume control)or equivalent **(volume targeted)** ☐ Pressure Support ________ pressupcmh2o **targeted)** ☐ Volume Assist/Control **(volu** ☐ Pressure Assist ________cm presascmh2o ☐ PC IRV **(pressure targeted)** ☐ Airway Pressure Release Ventilation (APRV) **(pressure targeted)** ☐ HFO ☐ VC+ (dual mode) ☐ Auto Flow (dual mode) ☐ Other __________
3. Calculated delivered tidal volume: **Complete ONLY if subject on Volume Targeted Mode**	_________ml tidal
4. Inspiratory Time: **Complete ONLY if on a pressure targeted or dual mode**	________seconds insptime
5. Set rate:	________breaths/min setrate
6. Total respiratory rate:	________breaths/min resp
7. Total minute ventilation:	________L/min minvent
8. PEEP:	________cm H2O peep
9. FiO2 at 0800:	________ fio2
10. SpO2 at 0800:	________% spo2
11. Plateau pressure:	________cm H2O pplat
12. Peak inspiratory pressure:	________cm H2O pip
13. Mean airway pressure:	________cm H2O meanair
Enter ABG closest to 0800	
14. FiO2 at time of ABG	fio2abg
15. PaO2	_______mmHg pao2abg
16. PaCO2	_______mmHg paco2abg
17. Arterial pH	phabg
18. SpO2	_______ % spo2abg

Dosing-SAILS

- ❑ **Complete on days 0-28 until discharged from hospital or 3 days post ICU discharge.**

sailsdosedate0-sailsdosedate28

sailsdose0-sailsdose28

0. Dose received today (select one):	☐40 mg	☐20 mg	☐10 mg	☐ None
1. Do t one):	☐40 mg		mg	☐ None
2. Dose received today (select one):	☐40 mg		mg	☐ None
3. Dose received today (select one):	☐40 mg	☐20 mg	☐10 mg	☐ None
4. Dose received today (select one):	☐40 mg	☐20 mg	☐10 mg	☐ None
5. Dose received today (select one):	☐40 mg	☐20 mg	☐10 mg	☐ None
6. Dose received today (select one):	☐40 mg	☐20 mg	☐10 mg	☐ None
7. Dose received today (select one):	☐40 mg	☐20 mg	☐10 mg	☐ None
8. Dose received today (select one):	☐40 mg	☐20 mg	☐10 mg	☐ None
9. Dose received today (select one):	☐40 mg	☐20 mg	☐10 mg	☐ None
10. Dose received today (select one):	☐40 mg	☐20 mg	☐10 mg	☐ None
11. Dose received today (select one):	☐40 mg	☐20 mg	☐10 mg	☐ None
12. Dose received today (select one):	☐40 mg	☐20 mg	☐10 mg	☐ None
13. Dose received today (select one):	☐40 mg	☐20 mg	☐10 mg	☐ None
14. Dose received today (select one):	☐40 mg	☐20 mg	☐10 mg	☐ None
15. Dose received today (select one):	☐40 mg	☐20 mg	☐10 mg	☐ None
16. Dose received today (select one):	☐40 mg	☐20 mg	☐10 mg	☐ None
17. Dose received today (select one):	☐40 mg	☐20 mg	☐10 mg	☐ None
18. Dose received today (select one):	☐40 mg	☐20 mg	☐10 mg	☐ None
19. Dose received today (select one):	☐40 mg	☐20 mg	☐10 mg	☐ None
20. Dose received today (select one):	☐40 mg	☐20 mg	☐10 mg	☐ None
21. Dose received today (select one):	☐40 mg	☐20 mg	☐10 mg	☐ None
22. Dose received today (select one):	☐40 mg	☐20 mg	☐10 mg	☐ None
23. Dose received today (select one):	☐40 mg	☐20 mg	☐10 mg	☐ None
24. Dose received today (select one):	☐40 mg	☐20 mg	☐10 mg	☐ None
25. Dose received today (select one):	☐40 mg	☐20 mg	☐10 mg	☐ None
26. Dose received today (select one):	☐40 mg	☐20 mg	☐10 mg	☐ None
27. Dose received today (select one):	☐40 mg	☐20 mg	☐10 mg	☐ None
28. Dose received today (select one):	☐40 mg	☐20 mg	☐10 mg	☐ None

On Study Intake and Output-ALL

Complete on days 1-8 or until UAB (values should be taken from the <u>previous 24 hours</u>)

1. Total intake last 24 hours fluidin	__________ ml
2. PRBC last 24 hours prbc24	__________ units
3. FFP last 24 hours ffp24	__________ units
4. Total output last 24 hours fluidout	__________ ml
5. Urine output last 24 hours urineout	__________ ml
Total enteral <u>feedings</u> last 24 hours	entfeedvol ____________ ml

Random Protocol Check

Question	Response
1. Did subject have a central venous catheter in place for any portion of this day?	☐ Yes ☐ No cathprior
2. In the **12 hours prior** to the random check time, did patient receive vasopressors?	☐ Yes ☐ No vaso12prior
3. In the **12 hours prior** to the random check time, did MAP fall below 60 mmHg?	☐ Yes ☐ No map60
4. In the **4 hours prior** to the random check time, were IV maintenance fluids running?	☐ Yes ☐ No maintflu
5. In the **4 hours prior** to the random check time, was Lasix given?	☐ Yes ☐ No lasix4
6. In the **12 hours prior** to the random check time, was fluid bolus (> 15 ml/kg PBW) given?	☐ Yes ☐ No bolus12
7. Average UOP in the **4 hours prior** to the random check time < 0.5 ml/kg/hr?	☐ Yes ☐ No avupo4
8. On **this calendar day**, was patient in acute renal failure or receiving renal replacement therapy?	☐ Yes ☐ No renal
9. CVP or PAOP (most recent value in the 4 hours PRIOR to but not on the random check time). **Example:** if random time is 1200, and you have values at 1100, 1200 and 1300, you should enter the value from 1100.	cvp_rc paop_rc

Concomitant Medications-SAILS

Complete on days 1-10

Question	Response
1. Please select all medications administered this calendar day:	❑ None this day ❑ Niacin ❑ Fenofibrate ❑ Cyclosporin ❑ Gemfibrozil ❑ Lopinavir ❑ Ritonavir ❑ Atazanavir ☐ Daptomycin (administratio is NOT prohibited) nosailscm niacin fenofib cyclo genfib lopin riton atazanavir daptomycin
2. Did subject receive non-study statin this calendar day? nsstatin	☐ Yes ☐ No If YES, select statin administered: ❑ Rosuvastatin ❑ Atorvastatin ❑ Lovastatin ❑ Simvastatin ❑ Pravastatin nsstatyn Daily dose of statin prescribed: ❑ 5 mg ❑ 10 mg ❑ 20 mg ❑ 40 mg ❑ 80 mg nsstatdose

Brussels-ALL

Collect **"worst"** value of calendar day (midnight to midnight):

LOWEST SBP
LOWEST P/F
LOWEST Platelets
HIGHEST creatinine and bilirubin

Vasopressors yes/no: (Yes) to indicate that one or more vasopressors were used on the calendar date. (No) if no vasopressors were used on the calendar date. "Vasopressor" is defined as: Dopamine ≥ 6 mcg/kg/min and Neo-Synephrine, epinephrine, or Levophed at any rate. Dobutamine is NOT considered a vasopressor.

Day/date	SBP	P/F	platelets x 1000	creatinine	bilirubin	vasopressor?
0	systbp0- systbp14					yes / no
1.						yes / no
2.		pf0-pf14				yes / no
3.						yes / no
4.						yes / no
5.			plate0- plate14			yes / no
6.						yes / no
7.				creat0- creat14		yes / no
8.						yes / no
9.						yes / no
10.					bili0-bili14	yes / no
11.						yes / no
12.						vaso0- vaso14
13.						
14.						yes / no

Glasgow Coma Score-ALL

Complete on day 0, 7, 14 (or day of discharge, whichever comes first) **GCS total score=** gcs

1. Is patient on a sedative or neuromuscular blocker?	☐ Yes ☐ No	sedate
2. Eye opening score:	☐ None (1) ☐ To pain (2) ☐ To voice (3) ☐ Spontaneous (4)	eye
3. Motor response score:	☐ Flaccid (1) ☐ Abnormal Extension (2) ☐ Abnormal flexion (3) ☐ Flexion withdrawal (4) ☐ Localizes to pain (5) ☐ Obeys commands (6)	motor
4. Verbal response score:	☐ None, or generally unresponsive on ventilator (1) ☐ Incomprehensible (2) ☐ Inappropriate, or questionable oriented if on ventilator(3) ☐ Confused (4) ☐ Oriented, or appears oriented on ventilator (5)	verbal

Day 7

1. Is patient on a sedative or neuromuscular blocker?	☐ Yes ☐ No	sedate
2. Eye opening score:	☐ None (1) ☐ To pain (2) ☐ To voice (3) ☐ Spontaneous (4)	eye
3. Motor response score:	☐ Flaccid (1) ☐ Abnormal Extension (2) ☐ Abnormal flexion (3) ☐ Flexion withdrawal (4) ☐ Localizes to pain (5) ☐ Obeys commands (6)	motor
4. Verbal response score:	☐ None, or generally unresponsive on ventilator (1) ☐ Incomprehensible (2) ☐ Inappropriate, or questionable oriented if on ventilator(3) ☐ Confused (4) ☐ Oriented, or appears oriented on ventilator (5)	verbal

Unscheduled

1. Is patient on a sedative or neuromuscular blocker?	☐ Yes ☐ No	sedate
2. Eye opening score:	☐ None (1) ☐ To pain (2) ☐ To voice (3) ☐ Spontaneous (4)	eye
3. Motor response score:	☐ Flaccid (1) ☐ Abnormal Extension (2) ☐ Abnormal flexion (3) ☐ Flexion withdrawal (4) ☐ Localizes to pain (5) ☐ Obeys commands (6)	motor
4. Verbal response score:	☐ None, or generally unresponsive on ventilator (1) ☐ Incomprehensible (2) ☐ Inappropriate, or questionable oriented if on ventilator(3) ☐ Confused (4) ☐ Oriented, or appears oriented on ventilator (5)	verbal
Date of score for day of discharge or day 14:		gcsdt

Secondary Outcomes-SAILS

Complete one time at hospital discharge

1. Clinical evidence of VTE while on study drug? (Includes documentation by venous ultrasound, impedance plethysmography, contrast venography, ventilation-perfusion lung scan, CTPA/V, or pulmonary angiography)	☐Yes ☐No	vte
2. Clinical evidence of MI while on study drug?	☐Yes ☐No	mi
3. Clinical evidence of bowel ischemia while on study drug?	☐Yes ☐No	bowel
4. Clinical evidence of ischemic stroke while on study drug?	☐Yes ☐No	stroke
5. Arrhythmias requiring treatment while on study drug?	☐Yes ☐No	arryth
6. Evidence in the medical record of myopathy? (includes diagnosis or mention of the following: Myopathy, myositis, neuropathy, muscle weakness, paralysis)	☐Yes ☐No	myo
7. Enter the date and value of the creatinine from day 15 through day 28. **If highest value occurs more than once in that time, enter first date.**	Date: ________ Value: ________ mg/dL	hightcreatdt highcreat

AE Follow-up Call (SAILS)

All subjects must be followed for adverse events for 7 days after the last dose of study drug. This form should be completed for all SAILS subjects who were discharged or transferred prior to 7 days after the last dose of study drug. You should use this form as your source document when you make the follow up phone call.

Phone call script:

I am a researcher from _______________ (hospital name or University name). You participated in a trial of rosuvastatin or placebo for acute lung injury. I am calling to ask you a few questions about your health since you left the hospital.

1. Did you have any **NEW** medical problems since _________________ (give date of last dose of study drug) that caused you to seek medical attention?

   Yes / No

a. If yes, please describe the problem:

2. Have you been readmitted to the hospital for any reason since _________________ (give date of last dose of study drug)?

   Yes / No

a. If yes, please describe the problem:

AE Follow up CRF

1. Was follow up call completed?	☐ Yes ☐ No **If no, please indicate why not completed:** • Patient still in study hospital 7 days after last dose • Other: ____________________	callcomp
2. Has subject developed a new medical problem or sought medical attention for new medical problem in the week following last dose?	☐ Yes ☐ No	funewcond
3. Has patient been readmitted to the hospital for any reason in the 7 days after the last dose?	☐ Yes ☐ No	fureadmit
If either #2 or #3 = YES, complete adverse event CRF.		

Date of phone call: ______________________

Study staff member conducting phone call: ____________________________________

Name of patient or surrogate called/spoken with: ________________________________

Adverse Event Form-BOTH

- ❑ **Call CCC immediately for serious, unexpected, study related adverse events**

1. Date of event:	______/_____/_____ aedt
2. Time of event:	_____:_____ (24 hr clock) aetm
3. Protocol Specified SAILS AE? protsails	☐ No ☐ Yes, pick one ○ CK> 10 x ULN ○ ALT> 8 x ULN ○ Intraparenchymal CNS Bleed
4. If #3=yes, has patient received any of these medications while on study?	☐ None medaenone ☐ Niacin medaenaicin ☐ Fenofibrate medaefenofib ☐ Cyclosporin medaecyclo ☐ Gemfibrozil medaegem ☐ Lopinavir medaelop ☐ Ritonavir medaerit ☐ Daptomycin medaedapt ☐ Atazanavir medaeata ☐ non-study statins medaensstat
5. Name of event if not a protocol specified event (COSTART term):	costart ______________________________
6. Describe events leading to and following the event:	aedesc
7. Severity of event:	☐Mild ☐Moderate ☐Severe aesever
8. Was the event unexpected or more severe than expected for ALI patients receiving statin therapy?	☐Yes ☐No ☐Unknown expectsails
9. Causal relationship to SAILS study drug?	☐Definitely associated ☐Probably associated ☐Possible association ☐Probably not associated ☐Definitely not associated ☐Uncertain association causesails
10. Causal relationship to other study procedures? (fluid protocol, etc.)	☐Definitely associated ☐Probably associated ☐Possible association ☐Probably not associated ☐Definitely not associated ☐Uncertain association causestud
11. Was SAILS study drug permanently discontinued because of this event?	☐Yes, Date ______/______/______ ☐No wdrawsails
	☐Recovered, date ______/______/______

12. Status of this adverse event at the time of initial AE report:	☐AE present, no treatment ☐AE present, being treated ☐Residual effect/no treatment ☐Residual effect/being treated ☐Deceased as a result of this AE aestatus
13. Final outcome of this adverse event (until resolution of 48 hr of UAB):	☐Recovered, date ______/______/______ ☐AE present, no treatment ☐AE present, being treated ☐Residual effect/no treatment ☐Residual effect/being treated ☐Deceased as a result of this AE aeoutcome
14. Has a site investigator reviewed this adverse event?	☐Yes ☐No

Study Termination-BOTH

Begin completion of this form by day 28. Patients not home yet with unassisted breathing (UAB) should be followed through day 90

Question	Response
1. Pt status (through day 90) status	☐Home w/ UAB Date ______/______/______ ☐Dead prior to home w/ UAB Date ______/______/___ ☐Other, date of last know pt status if not home w/ U/ dead ______/______/______ Homedt Deathdt othstatdt
2. Was this patient permanently withdrawn from the trial (through day 28)? sailspt **Study completion does not qualify as withdrawn from study.**	☐SAILS patient sailswdraw ○ Not withdrawn ○ Withdrawn date ______/____ sailswdrawreas Reason for withdrawal sailswdrawdt __________
hospdc 3. Was patient discharged alive from study hospital (through day 90)?	☐Yes, date: ______/______/_ hospdcdt ☐No
sbtcrit 4. Did patient meet criteria for spontaneous breathing trial prior to day 29? If yes, enter 1st date pt met criteria for SBT.	☐Yes, date: ______/______/_ ☐No sbtcritdt
sbttol Did patient tolerate a SBT before day 29? If yes, enter date 1st tolerated:	☐Yes, date ______/______/______ sbttoldt ☐No
uab Did patient reach 48hrs of UAB prior to day 29? If yes, enter date 1st reached 48hr UAB	☐Yes, date ______/______/______ uabdt ☐No
extub Was patient extubated before day 29? If yes, enter date 1st extubated:	☐Yes, date ______/______/______ extubdt ☐No
8. Did subject undergo tracheostomy prior to day 29? 9. If yes, enter date: trach	☐Yes, date ______/______/______ ☐No trachdt

ICU History

ICU days during study hospitalization to day 90 (days in which patient spent any time in an ICU during study hospitalization) Please capture all ICU readmissions during study hospitalization thru day 90

Question	Response
10. Discharged from ICU? discharge1	☐Yes, date of ICU D/C: ______/__ dischargedt1 ☐No
11. Readmitted to ICU? readmit1	☐Yes, date of ICU readmission: ____ readmitdt1 ☐No
12. Discharged from ICU a 2nd tim discharge2	☐Yes, date of ICU D/C: ______/_____ dischargedt2 ☐No
13. Readmitted to ICU? readmit2	☐Yes, date of ICU readmission: __ readmitdt2 ☐No
14. Discharged from ICU a 3rd tim discharge3	☐Yes, date of ICU D/C: ______/_____ dischargedt3 ☐No
15. Readmitted to ICU? readmit3	☐Yes, date of ICU readmission: __ readmitdt3 ☐No
16. Discharged from ICU a 4th tim discharge4	☐Yes, date of ICU D/C: ______/______ dischargedt4 ☐No
17. Readmitted to ICU? readmit4	☐Yes, date of ICU readmission: __ readmitdt4 ☐No
18. Discharged from ICU a 5th time?	☐Yes, date of ICU D/C: ______/______/______ ☐No

Ventilator History

Ventilator days until unassisted breathing (UAB) at home, death, or day 90 (a ventilator day is any day in which the patient received assisted breathing (AB), except for assisted breathing for < 24hrs for a procedure or surgery)

Question	Response
19. Patient achieved unassisted breathing? uab1	☐Yes, date of 1st UAB(first date w/o AB midnight to midnight) ______/______/______ uabdt1 ☐No
20. Patient returned to assisted breathing? retab1	☐Yes, date of return to AB: ______/ retabdt1

	☐No
21. Patient achieved unassisted breathing again? uab2	☐Yes, date of 2nd UAB(first date w/o AB midnight to midnight) _____/_____/_____ uabdt2 ☐No
22. Patient returned to assisted breathing? retab2	☐Yes, date of return to AB: retabdt2 ____ ☐No
23. Patient achieved unassisted breathing again? uab3	☐Yes, date of 3rd UAB(first date w/o AB midnight to midnight) _____/_____/_____ uabdt3 ☐No
24. Patient returned to assisted breathing? retab3	☐Yes, date of return to AB: __ retabdt3 ___ ☐No
25. Patient achieved unassisted breathing again? uab4	☐Yes, date of 4th UAB(first date w/o AB midnight to midnight) _____/_____/_____ uabdt4 ☐No
26. End of life decision making (for all patients, alive or dead) dnr	☐No DNR decision made ☐DNR decision made-withhold only CPR (CR or PR) ☐DNR decision made-withhold life support in addition to CPR ☐DNR decision made-withdraw life support ☐Diagnosis of brain death ☐Unknown/can't tell
27. Was written consent obtained **from subject** during study hospitalization? wconsent	☐Yes ☐No, reason wconsentreas o Patient died o Patient never regained decision making capacity o Patient declined further participation in study o Other: wconsentreasoth __________________________________
28. Did patient require dialysis during study hospitalization? dialysis	☐Yes If yes, enter first and last date of dialysis during study hospitalization: dialfirstdt diallastdt First:_________________ Last:_________________ ☐No

Delirium and Sedation CRF

	Collect the first CAM-ICU assessment recorded after 7am daily and the RASS/RIKER score done closest in time to the CAM-ICU.		
	CAM-ICU Delirium?	**RASS/RIKER** (if not done, code as "9")	
Study day 0	Yes / No / Not Done	rassriker0-rassriker28	☐$_1$ RASS (-5 to 4) ☐$_2$ RIKER (1 to 7)
Study day 1	camicu0-camicu28 Done	___	☐$_1$ RASS (-5 to 4) ☐$_2$ RIKER (1 to 7)
Study day 2	Yes / No / Not Done	___	☐ RASS (-5 to 4) ☐ rass0-rass28)
Study day 3	Yes / No / Not Done	___	☐$_1$ RASS (-5 to 4) ☐ RIKER (1 to 7)
Study day 4	Yes / No / Not Done	___	☐ riker0-riker28 ☐$_2$ RIKER (1 to 7)
Study day 5	Yes / No / Not Done	___	☐$_1$ RASS (-5 to 4) ☐$_2$ RIKER (1 to 7)
Study day 6	Yes / No / Not Done		☐$_1$ RASS (-5 to 4)