Midodrine for the early liberation from vasopressor support
LIBERATE Study

Case Report Form

Site #: | | | |

Enrollment #: | | | |

Patient initials: | | | |

SCREENING FOR ELIGIBILITY	
Date of screening (dd/mmm/yyyy)	___/_____/____
INCLUSION CRITERIA (Each of criteria 1 through 3 must be fulfilled)	
1. Age ≥18 years (on the day of assessment)	[ ] Y [ ] N
2. Ongoing vasopressor support (any of norepinephrine ≥0.05mcg/kg/min, epinephrine ≥0.05mcg/kg/min, vasopressin ≥0.04u/min or phenylephrine ≥0.1mcg/kg/min)	[ ] Y [ ] N
3. Decreasing vasopressor dose(s) (i.e., current dose less than peak dose(s))	[ ] Y [ ] N
EXCLUSION CRITERIA (Any one criterion fulfilled and the patient is ineligible)	
1. Greater than 24 hours from peak vasopressor dose	[ ] Y [ ] N
2. Contraindications to enteral medications	[ ] Y [ ] N
3. Previous midodrine usage in last 7 days	[ ] Y [ ] N
4. Known or presumed pregnancy	[ ] Y [ ] N
5. Contraindication to midodrine	[ ] Y [ ] N
6. Known allergy to midodrine	[ ] Y [ ] N
7. High probability of death within 24 hours or compassionate care	[ ] Y [ ] N
8. Treating clinician does not believe enrolment would be in the best interest of the patient	[ ] Y [ ] N
ELIGIBILITY	
According to the screening criteria above, is the patient eligible for the study?	[ ] Y [ ] N
If NO → PATIENT IS EXCLUDED → skip to signature block	
INFORMED CONSENT	
Was Informed Consent obtained?	[ ] Y [ ] N
Was Deferred Consent obtained?	[ ] Y [ ] N
If YES → Proceed to Randomization	

Form completed by: ____________________ (please print name) Signature: ______________ Date: ____/_____/____ (dd mmm yyyy)

Site #:	Enrollment #:	Patient initials:

CONSENT

Was consent of ANY approved type (from participant of substitute decision maker) OR was a decision taken to randomize the participant using a deferred/delayed) consent mechanism (at sites where permitted)?	[ ] Y [ ] N
Date and time of initial consent (from participant or SDM) or documentation for sure of deferred/delayed consent.	____/______/____; ___/___ dd mmm yyyy 24 hh:mm
What type of consent model was used for study entry?	☐ Participant consent ☐ SDM consent ☐ Deferred/delayed consent ☐ Other; Specify
If SDM consent (in person or via telephone) was obtained for the study, was consent ultimately obtained from the participant to continue participation in LIBERATE post-randomization?	[ ] Y [ ] N
By what method(s) was consent to continue participation in LIBERATE post-randomization obtained?	☐ Participant consent ☐ SDM consent ☐ Other; Specify
Participant randomized?	[ ] Y [ ] N

Site #:	Enrollment #:	Patient initials:

DEMOGRAPHICS

Date of birth (dd/mmm/yyyy)	____/______/________
Age (yrs)	
Sex:	[ ] Male [ ] Female
Weight:	___________._____ kg
Height:	___________._____ cm

ICU INFORMATION

Date of Study Eligibility (dd/mmm/yyyy; 24hh:mm):	____/______/________; ____/____
Date of Hospital Admission (dd/mmm/yyyy):	____/______/________
Date of ICU Admission (dd/mmm/yyyy):	____/______/________
APACHE II Score at ICU admission	___________
SOFA score at time of first IP administration	___________
to calculate APACHE II and SOFA scores see Appendix 2 and 3 worksheets	
Clinical Frailty Scale Score	
Etiology of Shock: Sepsis	[ ] Y [ ] N
Hypovolemia	[ ] Y [ ] N
Cardiogenic	[ ] Y [ ] N
Neurogenic	[ ] Y [ ] N
Anaphylactic	[ ] Y [ ] N
Unknown	[ ] Y [ ] N
Type of ICU Admission	[ ] Medical [ ] Surgical
If Surgical Admission - Reason:	[ ] Elective surgery [ ] Emergency Surgery
ICU admission diagnosis code (see attached Appendix 1 guide sheet)	______ # ____________________________________ diagnosis

Site #:	Enrollment #:	Patient initials:

COMORBID ILLNESSES

Co-morbid disease	
AIDS	[ ] Y [ ] N
Chronic Dialysis	[ ] Y [ ] N
Congestive Heart Failure	[ ] Y [ ] N
Respiratory Insufficiency	[ ] Y [ ] N
Chronic Liver Failure (e.g., cirrhosis, hepatitis, etc.)	[ ] Y [ ] N
Diabetes Mellitus	[ ] Y [ ] N
Acute Liver Failure (e.g., Tylenol overdose, alcoholic hepatitis, etc)	[ ] Y [ ] N
Immune Suppression	[ ] Y [ ] N
Leukemia	[ ] Y [ ] N
Lymphoma	[ ] Y [ ] N
Metastatic Cancer	[ ] Y [ ] N
Coronary Artery Disease	[ ] Y [ ] N

Site #:	Enrollment #:	Patient initials:

VASOPRESSOR THERAPY:

1st dose study medication/IP administration: ___________

Study Day 1 starts at time of first IP administration and ends at 0659hrs the following morning. All following study days are from 0700hrs – 0659hrs

Day	Vasopressor Date (dd/mmm/yyyy)	Vasopressor Type	Started today?	Stopped today?	Highest Daily dose (include units)	Lowest Daily dose (include units)
1		1.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		2.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		3.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		4.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		5.	[ ] Yes [ ] No	[ ] Yes [ ] No		
2		1.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		2.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		3.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		4.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		5.	[ ] Yes [ ] No	[ ] Yes [ ] No		
3		1.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		2.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		3.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		4.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		5.	[ ] Yes [ ] No	[ ] Yes [ ] No		
4		1.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		2.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		3.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		4.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		5.	[ ] Yes [ ] No	[ ] Yes [ ] No		
5		1.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		2.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		3.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		4.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		5.	[ ] Yes [ ] No	[ ] Yes [ ] No		

Site #:	Enrollment #:	Patient initials:

Day	Vasopressor Date (dd/mmm/yyyy)	Vasopressor Type	Started today?	Stopped today?	Highest Daily dose (include units)	Lowest Daily dose (include units)
		1.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		2.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		3.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		4.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		5.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		1.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		2.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		3.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		4.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		5.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		1.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		2.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		3.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		4.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		5.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		1.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		2.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		3.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		4.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		5.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		1.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		2.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		3.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		4.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		5.	[ ] Yes [ ] No	[ ] Yes [ ] No		

Add additional Vasopressor Therapy sheets as needed.

Site #:	**Enrollment #:**	**Patient initials:**

SEDATION: **Study Day 1 starts at time of first IP administration and ends at 0659hrs. All following study days are from 0700 - 0659**

Day	**Sedation Date (dd/mmm/yyyy)**	**Sedation Type** (Hydromorphone, Morphine, Fentanyl, Midazolam, Propofol, Ketamine)	**Started today?**	**Stopped today?**	**Highest Daily dose (include units)**	**Lowest Daily dose (include units)**
1		1.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		2.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		3.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		4.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		5.	[ ] Yes [ ] No	[ ] Yes [ ] No		
2		1.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		2.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		3.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		4.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		5.	[ ] Yes [ ] No	[ ] Yes [ ] No		
3		1.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		2.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		3.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		4.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		5.	[ ] Yes [ ] No	[ ] Yes [ ] No		
4		1.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		2.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		3.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		4.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		5.	[ ] Yes [ ] No	[ ] Yes [ ] No		
5		1.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		2.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		3.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		4.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		5.	[ ] Yes [ ] No	[ ] Yes [ ] No		

Site #:	Enrollment #:	Patient initials:

Day	Sedation Date (dd/mmm/yyyy)	Sedation Type (Hydromorphone, Morphine, Fentanyl, Midazolam, Propofol, Ketamine)	Started today?	Stopped today?	Highest Daily dose (include units)	Lowest Daily dose (include units)
		1.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		2.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		3.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		4.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		5.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		1.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		2.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		3.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		4.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		5.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		1.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		2.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		3.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		4.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		5.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		1.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		2.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		3.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		4.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		5.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		1.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		2.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		3.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		4.	[ ] Yes [ ] No	[ ] Yes [ ] No		
		5.	[ ] Yes [ ] No	[ ] Yes [ ] No		

Add additional Sedation sheets as needed.

Site #:	Enrollment #:	Patient initials:

CO-INTERVENTIONS

Study Day 1 starts at time of first IP administration and ends at 0659 the following morning. All following study days are from 0700 - 0659

Day	Ventilation	Renal Replacement Therapy	Corticosteroids (include units)	Blood Products	Total Daily Urine Output	Net Daily Fluid Balance
1	[ ] Yes [ ] No If Yes, Type: [ ] invasive [ ] non-invasive [ ] high-flow [ ] nasal cannula	[ ] Yes [ ] No If Yes, Type: [ ] CRRT [ ] SLED [ ] IHD [ ] PD	[ ] Yes [ ] No If Yes: Type/Dose: Type/Dose	packed red blood cells ______ units albumin [ ] 25% or [ ] 5% _______ mls fresh frozen plasma _______ mls platelets _______ mls cryoprecipitate _______ mls	_______ mls round up to next hour if required	+ / - _____ mls to 2 decimal places
2	[ ] Yes [ ] No If Yes, Type: [ ] invasive [ ] non-invasive [ ] high-flow [ ] nasal cannula	[ ] Yes [ ] No If Yes, Type: [ ] CRRT [ ] SLED [ ] IHD [ ] PD	[ ] Yes [ ] No If Yes: Type/Dose: Type/Dose	packed red blood cells ______ units albumin [ ] 25% or [ ] 5% _______ mls fresh frozen plasma _______ mls platelets _______ mls cryoprecipitate _______ mls	_______ mls round up to next hour if required	+ / - _____ mls to 2 decimal places
3	[ ] Yes [ ] No If Yes, Type: [ ] invasive [ ] non-invasive [ ] high-flow [ ] nasal cannula	[ ] Yes [ ] No If Yes, Type: [ ] CRRT [ ] SLED [ ] IHD [ ] PD	[ ] Yes [ ] No If Yes: Type/Dose: Type/Dose	packed red blood cells ______ units albumin [ ] 25% or [ ] 5% _______ mls fresh frozen plasma _______ mls platelets _______ mls cryoprecipitate _______ mls	_______ mls round up to next hour if required	+ / - _____ mls to 2 decimal places
4	[ ] Yes [ ] No If Yes, Type: [ ] invasive [ ] non-invasive [ ] high-flow [ ] nasal cannula	[ ] Yes [ ] No If Yes, Type: [ ] CRRT [ ] SLED [ ] IHD [ ] PD	[ ] Yes [ ] No If Yes: Type/Dose: Type/Dose	packed red blood cells ______ units albumin [ ] 25% or [ ] 5% _______ mls fresh frozen plasma _______ mls platelets _______ mls cryoprecipitate _______ mls	_______ mls round up to next hour if required	+ / - _____ mls to 2 decimal places

Site #:	Enrollment #:	Patient initials:

Day	Ventilation	Renal Replacement Therapy	Corticosteroids	Blood Products	Total Daily Urine Output	Net Daily Fluid Balance
	[ ] Yes [ ] No If Yes, Type: [ ] invasive [ ] non-invasive [ ] high-flow [ ] nasal cannula	[ ] Yes [ ] No If Yes, Type: [ ] CRRT [ ] SLED [ ] IHD [ ] PD	[ ] Yes [ ] No If Yes: Type/Dose: Type/Dose	packed red blood cells ______ units albumin [ ] 25% or [ ] 5% _______ mls fresh frozen plasma _______ mls platelets _______ mls cryoprecipitate _______ mls	_______ mls round up to next hour if required	+ / - _____ mls to 2 decimal places
	[ ] Yes [ ] No If Yes, Type: [ ] invasive [ ] non-invasive [ ] high-flow [ ] nasal cannula	[ ] Yes [ ] No If Yes, Type: [ ] CRRT [ ] SLED [ ] IHD [ ] PD	[ ] Yes [ ] No If Yes: Type/Dose: Type/Dose	packed red blood cells ______ units albumin [ ] 25% or [ ] 5% _______ mls fresh frozen plasma _______ mls platelets _______ mls cryoprecipitate _______ mls	_______ mls round up to next hour if required	+ / - _____ mls to 2 decimal places
	[ ] Yes [ ] No If Yes, Type: [ ] invasive [ ] non-invasive [ ] high-flow [ ] nasal cannula	[ ] Yes [ ] No If Yes, Type: [ ] CRRT [ ] SLED [ ] IHD [ ] PD	[ ] Yes [ ] No If Yes: Type/Dose: Type/Dose	packed red blood cells ______ units albumin [ ] 25% or [ ] 5% _______ mls fresh frozen plasma _______ mls platelets _______ mls cryoprecipitate _______ mls	_______ mls round up to next hour if required	+ / - _____ mls to 2 decimal places
	[ ] Yes [ ] No T If Yes, Type: [ ] invasive [ ] non-invasive [ ] high-flow [ ] nasal cannula	[ ] Yes [ ] No If Yes, Type: [ ] CRRT [ ] SLED [ ] IHD [ ] PD	[ ] Yes [ ] No If Yes: Type/Dose: Type/Dose	packed red blood cells ______ units albumin [ ] 25% or [ ] 5% _______ mls fresh frozen plasma _______ mls platelets _______ mls cryoprecipitate _______ mls	_______ mls round up to next hour if required	+ / - _____ mls to 2 decimal places

Add additional Co-Intervention sheets as needed.

Site #:	Enrollment #:	Patient initials:

OUTCOMES

ICU Stay	
Total duration of IV vasopressor support (hours) (from time of first study medication/IP administration to discontinuation of IV vasopressors for a continuous 24 hour period)	
Vasopressors re-initiated over 24 hours after cessation If Yes: Vasopressor restart date/time: (dd/mmm/yyyy 24hh:mm)	[ ] Y [ ] N _____/_____/______; _____ :_____
Echocardiogram (number performed between study start and ICU discharge. Does not include bedside tests)	# of tests : ______
Death in ICU Date of ICU Death/Discharge (dd/mmm/yyyy):	[ ] Y [ ] N ____/____/____
ICU re-admission less than 48 hours after ICU discharge	[ ] Y [ ] N
Death in Hospital Date hospital death/discharge (dd/mmm/yyyy):	[ ] Y [ ] N ____/____/____
Discharge location: n/a Home Another hospital Long-term care Facility Other (please specify)	[ ] [ ] [ ] [ ] [ ] ________________________

Site #:	Enrollment #:	Patient initials:

90 DAY FOLLOW UP ASSESSMENT

What is the patient's mortality status?	[ ] Alive [ ] Dead
Persistent Organ Dysfunction at 90 days	[ ] Y [ ] N [ ] NA
If yes, type :	[ ] mechanical ventilation [ ] renal replacement therapy [ ] ongoing vasopressor use

Site #:	Enrollment #:	Patient initials:

ADVERSE EVENTS/SAFETY ENDPOINTS

Were there any **adverse events** attributed to the study intervention? [ ] Y [ ] N

If YES, did they include any of the following?:

Clinically significant bradycardia (as per the judgement of the treating team)	[ ] Y [ ] N
Acute coronary syndrome (unstable angina, non-/STEMI or STEMI	[ ] Y [ ] N
Allergic event(s) (paraesthesia, piloerection, dysuria, pruritis, chills, pain or rash)	[ ] Y [ ] N
Hypertension (sustained systolic measurement over 180mm Hg)	[ ] Y [ ] N
Bowel Ischemia – clinically significant as per the judgement of the treating team	[ ] Y [ ] N
Limb Ischemia - clinically significant as per the judgement of the treating team	[ ] Y [ ] N
Stroke – radiographical diagnosis	[ ] Y [ ] N
Other event considered to be related to study treatment or in the PI's clinical judgement is not recognised as consistent with the subjects underlying critical illness and/or chronic disease and expected clinical course	[ ] Y [ ] N

.

If YES for any of the above, Does the event meet any criteria for a Serious Adverse Event :	
Death	[ ] Y [ ] N
Life Threatening	[ ] Y [ ] N
Requires or prolongs hospital stay	[ ] Y [ ] N
Results in persistent or significant disability	[ ] Y [ ] N
Constitutes an important medical event as per local Principal Investigator	[ ] Y [ ] N
If YES to any of the above, please complete a Serious Adverse Event form for each event.	
If NO, please complete an Adverse Event Form for each event.	

Site #:	**Enrollment #:**	**Patient initials:**

PROTOCOL VIOLATIONS

Were there any **protocol violations AND/OR deviations**? [ ] Y [ ] N

Randomized but did not meet all inclusion/exclusion criteria Study medication dose missed Participant accidently unblinded Other, specify:	[ ] Y [ ] N [ ] Y [ ] N [ ] Y [ ] N [ ] Y [ ] N
If yes:	
Date of violation/deviation (dd/mmm/yyyy)	___/_____/____
Did the deviation result in a: Adverse event Serious Adverse Drug Reaction	[ ] Y [ ] N [ ] Y [ ] N [ ] Y [ ] N
Did the subject continue in the study?	[ ] Y [ ] N
Was it determined the protocol deviation required REB notification?	[ ] Y [ ] N
If yes: date of REB notification (dd/mmm/yyyy) Date of REB acknowledgment	___/_____/____ ___/_____/____
If the subject was withdrawn from the study please complete the Completion Form in the REDCap system	
Additional comments:	

Print additional sheets as needed for each protocol violation

Principal Investigator: _____________ (please print name)	Signature of PI: __________	Date: ____/____/____ (dd mm yyyy)

Appendix 1: ICU Admitting Diagnosis

MEDICAL (NON OPERATIVE CONDITIONS)

Cardiovascular / vascular:

1. Cardiogenic shock
2. Cardiac arrest
3. Aortic aneurysm
4. Congestive heart failure
5. Peripheral vascular disease
6. Rhythm disturbance
7. Acute myocardial infarction
8. Hypertension
9. Other cardiovascular/vascular disease: __________

Respiratory:

10. Parasitic pneumonia (ie.pneumocystis carinii)
11. Aspiration pneumonia
12. Respiratory neoplasm (include larynx, trachea)
13. Respiratory arrest
14. Pulmonary edema (non-cardiogenic)
15. Bacterial / Viral pneumonia
16. Chronic obstructive pulmonary disease
17. Pulmonary embolism
18. Mechanical airway obstruction
19. Asthma
20. Other respiratory disease: ___________

Gastrointestinal:

21. Hepatic failure
22. GI perforation/obstruction
23. GI bleeding due to varices
24. GI inflammatory disease (ulcerative colitis, crohn's disease)
25. GI bleeding due to ulcer/laceration
26. GI bleeding due to diverticulosis
27. Other GI disease: __________

Neurologic:

28. Intracerebral hemorrhage
29. Subarachnoid hemorrhage
30. Stroke
31. Neurologic infection
32. Neurologic neoplasm
33. Neuromuscular disease
34. Seizure
35. Other neurologic disease: _________

Sepsis:

36. Sepsis (other than urinary tract)
37. Sepsis of urinary tract origin

Trauma:

38. Head trauma (with/without multiple trauma)
39. Multiple trauma (excluding head trauma)

Metabolic:

40. Metabolic coma
41. Diabetic ketoacidosis
42. Drug overdose
43. Other metabolic disease:_____________

Hematologic:

44. Coagulopathy //neutropeniathrombocytopenia
45. Other hematologic condition: __________

Renal:

46: Renal diseases

Other:

47. Other medical diseases:_____________________

SURGICAL (POST OPERATIVE CONDITIONS)

Vascular / cardiovascular:

48. Dissecting/ruptured aorta
49. Peripheral vascular surgery (no bypass graft)
50. Valvular heart surgery
51. Elective abdominal aneurysm repair
52. Peripheral artery bypass graft
53. Carotid endarterectomy
54. Other cardiovascular disease: _____________

Respiratory:

55. Respiratory infection
56. Lung neoplasm
57. Respiratory neoplasm (mouth, sinus, larynx, trachea)
58. Other respiratory disease: __________

Gastrointestinal:

59. GI perforation/rupture
60. GI inflammatory disease
61. GI obstruction
62. GI bleeding
63. Liver transplant
64. GI neoplasm
65. GI cholecystitis / cholangitis
66. Other GI disease: _____________

Neurologic:

67. Intracerebral hemorrhage
68. Subdural/epidural hematoma
69. Subarachnoid hemorrhage
70. Laminectomy/other spinal cord surgery
71. Craniotomy for neoplasm
72. Other neurologic disease: ___________

Trauma:

73. Head trauma (with/without multiple trauma)
74. Multiple trauma (excluding head trauma)

Renal:

75. Renal neoplasm
76. Other renal disease: _____________

Gynecologic:

77. Hysterectomy

Orthopedic:

78. Hip or extremity fracture

Other:

79. Other surgical conditions:___________

Cardiovascular Surgery:

80. CABGx1
81. CABGx2
82. CABGx3
83. CABG>4
84. Valve Surgery
85. Other:___________

Appendix 2: APACHE II Calculation Worksheet

A. Physiologic Variables Points

PHYSIOLOGIC VARIABLE	HIGH ABNORMAL RANGE								LOW ABNORMAL RANGE	PT SCORE
	4	**3**	**2**	**1**	**0**	**1**	**2**	**3**	**4**	
Temperature - rectal (ºC)	≥ 41	39-40.9		38.5-38.9	36-38.4	34-35.9	32-33.9	30-31.9	≤ 29.9	
MAP (mmHg)	≥ 160	130-159	110-129		70-109		50-69		≤ 49	
Heart Rate	≥ 180	140-179	110-139		70-109		55-69	40-54	≤ 39	
Respiratory Rate (non-ventilated or ventilated)	≥ 50	35-49		25-34	12-24	10-11	6-9		≤ 5	
Oxygenation: [A-aDO_2 = (FiO_2 x 710) – (PCO_2 x 1.25) – PO_2]					FiO_2 =	PCO_2 =		PO_2 =		
a. FiO_2 ≥ 0.5 record A-aDO_2	≥ 500	350-499	200-349		< 200					
b. FiO_2 < 0.5 record only PaO_2					PO_2 > 70	PO_2 61-70		PO_2 55-60	PO_2 < 55	
Arterial pH	≥ 7.7	7.6-7.69		7.5-7.59	7.33-7.49		7.25-7.32	7.15-7.24	< 7.15	
Serum Na (mmol/L)	≥ 180	160-179	155-159	150-154	130-149		120-129	111-119	≤ 110	
Serum K (mmol/L)	≥ 7	6-6.9		5.5-5.9	3.5-5.4	3-3.4	2.5-2.9		< 2.5	
Serum Creatinine (umol/L)	> 305	170-304	130-169		53-129		<53			
Hematocrit (%)	≥ 60		50-59.9	46-49.9	30-45.9		20-29.9		< 20	
WBC (total/mm^3)	≥ 40		20-39.9	15-19.9	3-14.9		1-2.9		< 1	
Glasgow Coma Score (GCS)	Score = 15 minus actual GCS (see below)									
Serum HCO_3 (venous mmol/L) - not preferred, use if no ABG's	≥ 52	41-51.9		32-40.9	22-31.9		18-21.9	15-17.0	< 15	
Creatinine double points for ACUTE Renal Failure	**ACUTE PHYSIOLOGY SCORE (APS): Sum of the 12 individual variable points =**									

B. Age Points - Assign points to age as follows:

AGE (yrs)	POINTS
≤ 44	0
45-54	2
55-64	3
65-74	5
≥ 75	6
AGE SCORE =	

C. Chronic Health Points

If the patient has a history of severe organ system insufficiency (see below) or is immunocompromised assign points as follows:

a. For nonoperative or emergency postoperative pt -- 5 points
b. For elective postoperative pt -- 2 points

CHRONIC HEALTH SCORE =

D. APACHE II SCORE - Sum of A + B + C

A. APS points	
B. Age points	
C. Chronic Health points	
APACHE II SCORE =	

CHRONIC HEALTH DEFINITIONS

Organ insufficiency or immuno-compromised state evident prior to this hospital admission and are consistent with the following criteria:

LIVER: Biospy-proven cirrhosis and documented portal hypertension; prior episodes of upper GI bleeding attributed to portal hypertension; or prior episodes of hepatic failure/encephalopathy/coma

CARDIOVASCULAR: New York Heart Association Class IV

RESPIRATORY: Chronic restrictive, obstructive, or vascular disease resulting in severe exercise restriction (i.e., unable to climb stairs or perform activities of daily living or household duties; or documented chronic hypoxia, hypercapnia, secondary polycythemia, severe pulmonary hypertension (>40 mmHg), or ventilator dependency

RENAL: Receiving chronic dialysis

IMMUNO-COMPROMISED: The patient has received therapy that suppresses resistance to infection (i.e., immunosuppressive treatment, chemotherapy, radiation, long term or recent high dose steroids, or has a disease that is sufficiently advanced to suppress resistance to infection (i.e., leukemia, lymphoma, AIDS)

GLASCOW COMA SCALE		
Parameter	**Response**	**Points Assigned (please circle)**
Eyes Open	Spontaneously	4
	On spoken command	3
	On pain	2
	No response	1
Best Motor Response	To spoken command	6
	To painful stimulus:	
	Localized pain	5
	Flexion withdrawal	4
	Flexion abnormal	3
	Extension	2
	No response	1
Best Verbal Response	*(Not on ventilator)*	
	Oriented & converses	5
	Disoriented & converses	4
	Inappropriate words	3
	Incomprehensible sounds	2
	No response	1
	(On ventilator)	
	Appears oriented	5
	Questionably oriented	3
	Generally unresponsive	1
	TOTAL GCS =	

Appendix 3: SOFA Score Worksheet

	0	**1**	**2**	**3**	**4**	**Score**
Respiration PaO_2/FiO_2	> 400	≤ 400 (± resp. support)	≤ 300	≤ 200 (+ resp. support)	≤ 100	
Coagulation Platelets(x 10^9/L)	>150	≤ 150	≤ 100	≤ 50	≤ 20	
Liver Bilirubin (µmol/L)	< 20	20-32	33-101	102-204	> 204	
Cardiovascular	MAP ≥ 70 mmHg	MAP < 70 mmHg	DA ≤ 5 µg/kg/min or dobutamine (any dose) or milrinone (any dose)	DA > 5 µg/kg/min or EPI ≤ 0.1 µg/kg/min or NE ≤ 0.1 µg/kg/min or VP ≤ 0.02 U/min or phenylephrine (any dose if given as infusion NOT bolus)	DA > 15 µg/kg/min or EPI > 0.1 µg/kg/min or NE > 0.1 µg/kg/min or VP >0.02 U/min	
CNS Glasgow Coma Scale	15	13-14	10-12	6-9	< 6	
Renal Creatinine (µmol /L)	≤ 106	107 – 176	177 – 308	309 – 441 or urine output ≤ 500 mL/d	≥ 442 or urine output < 200 mL/d or patient receiving RRT	
					TOTAL SCORE	