

Midodrine for the early liberation from vasopressor support LIBERATE Study

Case Report Form

REDCap record ID #: _____

Randomization #: _____

Patient initials: _____

SCREENING FOR ELIGIBILITY	
Date of screening (dd/mm/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 (i.e., any of norepinephrine ≥ 0.05 mcg/kg/min, epinephrine ≥ 0.05 mcg/kg/min, vasopressin ≥ 0.04 u/min or phenylephrine ≥ 0.1 mcg/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
<i>If NO $\rightarrow$ PATIENT IS EXCLUDED $\rightarrow$ skip to signature block</i>	
Date and time of peak vasopressor dose ____/____/____; ____/____ dd mmm yyyy 24 hh:mm	

Form completed by: _____ (please print name)	Signature: _____	Date: ____/____/____ (dd mmm yyyy)
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REDCap record ID #:	Randomization #:	Patient initials:
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CONSENT

Was consent of ANY approved type (from participant or 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

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RANDOMIZATION

Date and time randomized (time IP order submitted to pharmacy)	____/____/____; ____/____ dd mmm yyyy 24 hh:mm
Randomization code assigned to patient (number assigned by the research pharmacy from the randomization table (scenario 1) or the kit# on the pre dispensed IP container (scenario 2))	_____

REDCap record ID #:	Randomization #:	Patient initials:
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DEMOGRAPHICS

Date of birth (dd/mmm/yyyy)	____/____/____
Age (yrs)	
Sex:	☐ Male ☐ Female
Weight:	_____ kg
Height:	_____ cm
Ethnicity	☐ Black ☐ East/Southeast Asian (Chinese, Korean, Japanese Filipino, Vietnamese, Cambodian, Laotian, Thai) ☐ Indigenous (First Nations, Inuk/Inuit, Metis) ☐ Latino ☐ Middle Eastern (Arab, West Asian (e.g., Iranian, Afghan) ☐ South Asian (East Indian, Pakistani, Sri Lankan) ☐ White ☐ Other, not specified above: ☐ Do not know/prefer not to answer

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 (derive from the worst values in the first 24 hours after ICU admission)	_____
SOFA score at time of first IP administration (derive from the worst values in the 24 hour period prior to the 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

REDCap record ID #:	Randomization #:	Patient initials:
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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

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VASOPRESSOR/INOTROPIC THERAPY:

Date/time of 1st dose study medication/IP administration:
dd/mm/yyyy 24hh:mm

Day	Vasopressor /Inotrope Date (dd/mm/yyyy)	Vasopressor /Inotrope 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		
2		1.	☐ Yes ☐ No	☐ Yes ☐ No		
		2.	☐ Yes ☐ No	☐ Yes ☐ No		
		3.	☐ Yes ☐ No	☐ Yes ☐ No		
		4.	☐ 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		
4		1.	☐ Yes ☐ No	☐ Yes ☐ No		
		2.	☐ Yes ☐ No	☐ Yes ☐ No		
		3.	☐ Yes ☐ No	☐ Yes ☐ No		
		4.	☐ 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		

*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

**lowest daily dose on day of IV vasopressor discontinuation should be recorded as 0.00. If the IV vasopressor is paused and then restarted within 24 hours the lowest dose should be the lowest dose administered that day not 0.00.

REDCap record ID #:	Randomization #:	Patient initials:
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Day	Vasopressor /Inotrope Date (dd/mmm/yyyy)	Vasopressor /Inotrope 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		
		1.	☐ Yes ☐ No	☐ Yes ☐ No		
		2.	☐ Yes ☐ No	☐ Yes ☐ No		
		3.	☐ Yes ☐ No	☐ Yes ☐ No		
		4.	☐ Yes ☐ No	☐ Yes ☐ No		
		1.	☐ Yes ☐ No	☐ Yes ☐ No		
		2.	☐ Yes ☐ No	☐ Yes ☐ No		
		3.	☐ Yes ☐ No	☐ Yes ☐ No		
		4.	☐ Yes ☐ No	☐ Yes ☐ No		
		1.	☐ Yes ☐ No	☐ Yes ☐ No		
		2.	☐ Yes ☐ No	☐ Yes ☐ No		
		3.	☐ Yes ☐ No	☐ Yes ☐ No		
		4.	☐ Yes ☐ No	☐ Yes ☐ No		
		1.	☐ Yes ☐ No	☐ Yes ☐ No		
		2.	☐ Yes ☐ No	☐ Yes ☐ No		
		3.	☐ Yes ☐ No	☐ Yes ☐ No		
		4.	☐ Yes ☐ No	☐ Yes ☐ No		

Add additional Vasopressor Therapy sheets as needed.

**lowest daily dose on day of IV vasopressor discontinuation should be recorded as 0.00. If the IV vasopressor is paused and then restarted within 24 hours the lowest dose should be the lowest dose administered that day not 0.00.

REDCap record ID #:	Randomization #:	Patient initials:
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SEDATION: Continuous IV infusions only (do not record prn 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/mm/yyyy)	Sedation Type (Hydromorphone, Morphine, Fentanyl, Midazolam, Propofol, Ketamine, other/specify)	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		
2		1.	☐ Yes ☐ No	☐ Yes ☐ No		
		2.	☐ Yes ☐ No	☐ Yes ☐ No		
		3.	☐ Yes ☐ No	☐ Yes ☐ No		
		4.	☐ 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		
4		1.	☐ Yes ☐ No	☐ Yes ☐ No		
		2.	☐ Yes ☐ No	☐ Yes ☐ No		
		3.	☐ Yes ☐ No	☐ Yes ☐ No		
		4.	☐ 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		

*lowest daily dose on day of sedation discontinuation should be recorded as 0.00. If the sedation is paused and then restarted within 24 hours the lowest dose should be the lowest dose administered that day not 0.00.

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SEDATION: Continuous IV infusions only (do not record prn 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/mm/yyyy)	Sedation Type (Hydromorphone, Morphine, Fentanyl, Midazolam, Propofol, Ketamine, other/specify)	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		
2		1.	☐ Yes ☐ No	☐ Yes ☐ No		
		2.	☐ Yes ☐ No	☐ Yes ☐ No		
		3.	☐ Yes ☐ No	☐ Yes ☐ No		
		4.	☐ 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		
4		1.	☐ Yes ☐ No	☐ Yes ☐ No		
		2.	☐ Yes ☐ No	☐ Yes ☐ No		
		3.	☐ Yes ☐ No	☐ Yes ☐ No		
		4.	☐ 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		

*lowest daily dose on day of sedation discontinuation should be recorded as 0.00. If the sedation is paused and then restarted within 24 hours the lowest dose should be the lowest dose administered that day not 0.00.

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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	_____ mls round up to next hour if required	+ / - _____ mls to 2 decimal places
				albumin ☐ 25% or ☐ 5% _____ mls		
				fresh frozen plasma _____ mls		
				platelets _____ mls		
				cryoprecipitate _____ mls		
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	_____ mls round up to next hour if required	+ / - _____ mls to 2 decimal places
				albumin ☐ 25% or ☐ 5% _____ mls		
				fresh frozen plasma _____ mls		
				platelets _____ mls		
				cryoprecipitate _____ mls		
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	_____ mls round up to next hour if required	+ / - _____ mls to 2 decimal places
				albumin ☐ 25% or ☐ 5% _____ mls		
				fresh frozen plasma _____ mls		
				platelets _____ mls		
				cryoprecipitate _____ mls		
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	_____ mls round up to next hour if required	+ / - _____ mls to 2 decimal places
				albumin ☐ 25% or ☐ 5% _____ mls		
				fresh frozen plasma _____ mls		
				platelets _____ mls		
				cryoprecipitate _____ mls		

REDCap record ID #:	Randomization #:	Patient initials:
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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 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.

REDCap record ID #:	Randomization #:	Patient initials:
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OUTCOMES

ICU Stay	
Date and time IV vasopressor stopped: dd/mm/yyyy 24hh:mm <u>Important note: this does not include inotropic support</u>	____/____/____ ____/____
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/time of ICU Death or discharge: dd/mmm/yyyy 24hh:mm	[] Y [] N ____/____/____ ____:____
Date/Time of <u>decision to discharge from ICU</u> : <u>Note: The time the order is written to transfer out of ICU</u> dd/mmm/yyyy 24hh:mm	[] data not available ____/____/____ ____:____
ICU re-admission less than 48 hours after ICU discharge	[] Y [] N
Death in Hospital Date/time of hospital death or hospital discharge dd/mmm/yyyy 24hh:mm	[] Y [] N ____/____/____ ____:____
Discharge location: n/a Home Another hospital Long-term care Facility Other (please specify)	[] [] [] [] [] _____

REDCap record ID #:	Randomization #:	Patient initials:
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Was the subject co-enrolled in other studies during their participation in the LIBERATE study? If yes, please list the study names:	☐ Y ☐ N
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REDCap record ID #:	Randomization #:	Patient initials:
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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

REDCap record ID #:	Randomization #:	Patient initials:
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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 that jeopardizes the study participant and requires intervention to prevent one of the other criteria listed above. ☐ Y ☐ N	
If YES to any of the above, please complete a <u>Serious Adverse Event form</u> for each event.	
If NO, please complete an <u>Adverse Event Form</u> for each event.	

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PROTOCOL VIOLATIONS

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

Randomized but did not meet all inclusion/exclusion criteria	☐ Y ☐ N
Study medication dose missed	☐ Y ☐ N
Participant accidentally unblinded	☐ Y ☐ N
Other, specify:	☐ Y ☐ N
If yes:	
Date of violation/deviation (dd/mmm/yyyy)	___/___/___
Did the deviation result in a:	☐ Y ☐ N
Adverse event	☐ Y ☐ N
Serious Adverse Drug Reaction	☐ 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 details:	

Print additional sheets as needed for each protocol violation

Principal Investigator: _____ (please print name)	Signature of PI: _____	Date: ___/___/___ (dd mm yyyy)
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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: _____
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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 (°C)	≥ 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: $[A-aDO_2 = (FiO_2 \times 710) - (PCO_2 \times 1.25) - PO_2]$						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	ACUTE PHYSIOLOGY SCORE (APS): Sum of the 12 individual variable points =									
double points for ACUTE Renal Failure										

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:

- For nonoperative or emergency postoperative pt -- 5 points
- 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
	<i>To painful stimulus:</i>	
	Localized pain	5
	Flexion withdrawal	4
	Flexion abnormal	3
	Extension	2
	No response	1
Best Verbal Response	<i>(Not on ventilator)</i>	
	Oriented & converses	5
	Disoriented & converses	4
	Inappropriate words	3
	Incomprehensible sounds	2
	No response	1
	<i>(On ventilator)</i>	
	Appears oriented	5
	Questionably oriented	3
	Generally unresponsive	1
TOTAL GCS =		

Appendix 3: SOFA Score Worksheet

	0	1	2	3	4	Score
Respiration PaO₂/FiO₂	> 400	≤ 400 ≤ 300 (± resp. support)		≤ 200 ≤ 100 (+ resp. support)		
Coagulation Platelets(x 10⁹/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	