

FORM 1: Eligibility and Enrollment

YES	NO	Inclusion Criteria:
<input type="checkbox"/>	<input type="checkbox"/>	Age ≥ 18 years
<input type="checkbox"/>	<input type="checkbox"/>	Weight ≥ 55 kg
<input type="checkbox"/>	<input type="checkbox"/>	Plan to initiate CRRT or within 24 hours of having started CRRT for AKI
<input type="checkbox"/>	<input type="checkbox"/>	Expected to survive and receive CRRT for a duration of ≥ 48 hours.
<input type="checkbox"/>	<input type="checkbox"/>	Able to provide informed consent or have an authorized representative provide consent after being informed on the details and risks of the trial unless a deferred consent process is approved by the local REB
YES	NO	Exclusion Criteria:
<input type="checkbox"/>	<input type="checkbox"/>	Indication for sustained higher dose-intensity CRRT
<input type="checkbox"/>	<input type="checkbox"/>	End-stage kidney disease receiving maintenance dialysis
<input type="checkbox"/>	<input type="checkbox"/>	Receipt of any RRT for AKI during the current hospitalization
<input type="checkbox"/>	<input type="checkbox"/>	Inability to comply with the requirements of the study protocol
YES	NO	Eligibility:
<input type="checkbox"/>	<input type="checkbox"/>	Was “YES” answered for all inclusion criteria?
<input type="checkbox"/>	<input type="checkbox"/>	Was “NO” answered for all exclusion criteria?
If YES for both, enter date and time		Date (dd/mmm/yyyy) of full eligibility: □□/□□□/□□□□ Time (24 hr clock) of full eligibility: □□:□□
YES	NO	Attestation:
<input type="checkbox"/>	<input type="checkbox"/>	I attest that I have reviewed the eligibility criteria, and this patient has fulfilled all the inclusion criteria and none of the exclusion criteria.
Principal Investigator or Co-Investigator		Name: _____ Date: □□/□□□/20□□ Time: □□:□□ Signature:

PI/Co-I or Coordinator Signature: _____ Date (dd/mmm/yyyy): _____

FORM 1: Eligibility and Enrollment

YES	NO	Initial Consent Prior to Randomization:
<input type="checkbox"/>	<input type="checkbox"/>	Was consent/deferred consent obtained <u>prior to randomization</u> ?
Type of Consent obtained:		
<input type="checkbox"/>	Participant consent	
<input type="checkbox"/>	Substitute Decision Maker (SDM) or Legally Authorized Representative (LAR) consent	
<input type="checkbox"/>	Deferred consent with assent of the clinical team	
If YES	Date (dd/mmm/yyyy) of consent/deferred consent signatures: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / 20 <input type="text"/> <input type="text"/> Time (24 hr clock) of consent/deferred consent signatures: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	
YES	NO	Registration in REDCap:
<input type="checkbox"/>	<input type="checkbox"/>	Was the participant entered into REDCap?
Participant ID*: (Created when eligibility entered in REDCap)		_____ - _____ 3-letter site code – 3-digit number See MOP for details on Participant ID creation *The Participant ID # should be used on all other CRFs.
YES	NO	Enrollment in the study:
<input type="checkbox"/>	<input type="checkbox"/>	Was the participant enrolled on the study in REDCap?
If YES		Complete Randomization in REDCap and enter the information below.
YES	NO	Randomization:
<input type="checkbox"/>	<input type="checkbox"/>	Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / 20 <input type="text"/> <input type="text"/> Time: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>
Allocated Study Arm:	<input type="checkbox"/> Low Dose-Intensity Arm <input type="checkbox"/> Standard Dose-Intensity Arm	
If NO	Complete the <u>Eligible But Not Enrolled</u> CRF (Form 2 in this package and in REDCap).	

PI/Co-I or Coordinator Signature: _____ Date (dd/mmm/yyyy): _____

FORM 1: Eligibility and Enrollment

<input type="checkbox"/> This section is Not Applicable if Deferred Consent was <u>not</u> selected above.		
YES	NO	Consent Post-Randomization following Deferred Consent:
<input type="checkbox"/>	<input type="checkbox"/>	If a Deferred Consent process was used prior to randomization, was consent (Participant/SDM) obtained to continue participation post-randomization?
If YES, Type of Consent obtained:		
<input type="checkbox"/>	Participant consent	
<input type="checkbox"/>	Substitute Decision Maker (SDM) or Legally Authorized Representative (LAR) consent	
If YES	Date (dd/mmm/yyyy) of consent: <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> /20 <input type="text"/> <input type="text"/> Time (24 hr clock) of consent: <input type="text"/> : <input type="text"/> <input type="text"/>	
If NO	Please specify why SDM or Participant consent was not obtained post-randomization.	
YES	NO	If NO above , was the local REB notified and permission given by REB to keep the data for this participant?
<input type="checkbox"/>	<input type="checkbox"/>	

<input type="checkbox"/> This section is Not Applicable if participant consent or regained capacity consent was already obtained either prior to randomization or post-randomization.		
YES	NO	Consent Post-Randomization following SDM consent:
<input type="checkbox"/>	<input type="checkbox"/>	If SDM consent was obtained either <u>prior to randomization or post-randomization</u> , was regained capacity consent obtained from the participant?
If YES	Date (dd/mmm/yyyy) of consent: <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> /20 <input type="text"/> <input type="text"/> Time (24 hr clock) of consent: <input type="text"/> : <input type="text"/> <input type="text"/>	
If NO	Please specify why participant regained capacity consent was not obtained post-randomization.	

PI/Co-I or Coordinator Signature: _____ Date (dd/mmm/yyyy): _____

FORM 2: Eligible But Not Enrolled

YES	NO						
<input type="checkbox"/>	<input type="checkbox"/>	Did your REB approve collection of the minimal dataset for patients that are eligible but not enrolled?					
If YES		Complete the CRF below and in REDcap					
If NO		Complete the initial question in the eCRF in REDCap to record that this data cannot be provided.					
Demographics and Medical Details (Minimal Data)							
Age (on day of screening) (years)				_____			
Sex				<input type="checkbox"/> Male <input type="checkbox"/> Female			
Receiving invasive mechanical ventilation				<input type="checkbox"/> YES <input type="checkbox"/> NO			
Receiving any vasoactive therapy				<input type="checkbox"/> YES <input type="checkbox"/> NO			
SOFA score (most extreme parameter in the 24 hours preceding screening)							
Enter Score for each category in the box below			0	1	2	3	4
Respiratory	PaO ₂ /FiO ₂ ratio	<input type="checkbox"/>	> 400	≤ 400 ± respiratory support	≤ 300 ± respiratory support	≤ 200 + respiratory support	< 100 + respiratory support
Coagulation	Platelets	<input type="checkbox"/>	>150	101-150	50-100	20-49	<20
Hepatic	Bilirubin	<input type="checkbox"/>	< 20 µmol/L	20-32 µmol/L	33-101 µmol/L	102-204 µmol/L	>204 µmol/L
CNS	GCS	<input type="checkbox"/>	15	13-14	10-12	6-9	<6
Cardiovascular	MAP + support	<input type="checkbox"/>	MAP ≥ 70 mmHg	MAP < 70 mmHg	DA ≤ 5 µg/kg/min or DOB (any) or MILR (any)	DA > 5 µg/kg/min or EPI ≤ 0.1 µg/kg/min or NE ≤ 0.1 µg/kg/min or AVP <0.03 units/min or Phenyl (any)	DA > 15 µg/kg/min or EPI > 0.1 µg/kg/min or NE > 0.1 µg/kg/min or AVP >0.03 units/min
Renal	Creatinine and urine output	<input type="checkbox"/>	≤ 97 µmol/L	98-168 µmol/L	169-299 µmol/L	300-433 µmol/L or urine output ≤ 500 mL/day	≥ 433 µmol/L or urine output ≤ 200 mL/day or receiving RRT
Total Score	<input type="checkbox"/> <input type="checkbox"/> (max 24; range 0-24)						
Death in ICU				<input type="checkbox"/> YES <input type="checkbox"/> NO			
Death in hospital				<input type="checkbox"/> YES <input type="checkbox"/> NO			
Receiving RRT at ICU discharge				<input type="checkbox"/> YES <input type="checkbox"/> NO			
Receiving RRT at hospital discharge				<input type="checkbox"/> YES <input type="checkbox"/> NO			

PI/Co-I or Coordinator Signature: _____ Date (dd/mmm/yyyy): _____

FORM 2: Eligible But Not Enrolled

Reason for exclusion:	<input type="checkbox"/> Clinician refusal <input type="checkbox"/> SDM or participant refused consent
If Clinician refusal, provide reason(s) given:	

PI/Co-I or Coordinator Signature: _____ Date (dd/mmm/yyyy): _____

FORM 3: BASELINE

Demographics	
Year of Birth (yyyy)	□□□□
Sex	<input type="checkbox"/> Male <input type="checkbox"/> Female
Weight (earliest available upon admission, estimated or actual)	____.____ kg
Hospitalization	
Hospital admission	<u>Date:</u> □□/□□□/20□□ <u>Time (24 hr clock):</u> □□:□□
ICU admission	<u>Date:</u> □□/□□□/20□□ <u>Time (24 hr clock):</u> □□:□□
Location prior to ICU admission	<input type="checkbox"/> Emergency Department <input type="checkbox"/> Hospital Ward <input type="checkbox"/> Operating Theatre <input type="checkbox"/> Direct transfer (other ICU) <input type="checkbox"/> Other, Specify: _____
Surgical (surgical procedure within 7 days)	<input type="checkbox"/> YES <input type="checkbox"/> NO
If YES, unplanned (emergency) procedure	<input type="checkbox"/> YES <input type="checkbox"/> NO
Primary Diagnostic Category (Select one)	
<input type="checkbox"/>	Cardiovascular
<input type="checkbox"/>	Respiratory
<input type="checkbox"/>	Gastrointestinal/hepatic
<input type="checkbox"/>	Neurological
<input type="checkbox"/>	Hematologic/Oncologic
<input type="checkbox"/>	Kidney/Urologic

PI/Co-I or Coordinator Signature: _____ Date (dd/mmm/yyyy): _____

FORM 3: BASELINE

<input type="checkbox"/>	Metabolic/Endocrinologic/Toxic	
<input type="checkbox"/>	Sepsis	
<input type="checkbox"/>	Trauma	
<input type="checkbox"/>	Other, Specify: _____	
Kidney Function		
Baseline serum creatinine <small>(closest outpatient value prior to the present hospitalization that is obtained no more than 365 days before the admission date for the current hospitalization; if such a value is not available, the lowest serum creatinine obtained on the present hospitalization is the baseline)</small>		□□□□ μmol/L
Baseline estimated GFR (CKD-EPI formula – available at: https://qxmd.com/calculate/calculator_251/egfr-using-ckd-epi-2021-update)		□□□.□ mL/min/1.73m ²
Chronic Disease		
YES	NO	
<input type="checkbox"/>	<input type="checkbox"/>	Hypertension
<input type="checkbox"/>	<input type="checkbox"/>	Diabetes mellitus
<input type="checkbox"/>	<input type="checkbox"/>	Heart failure
<input type="checkbox"/>	<input type="checkbox"/>	Coronary artery disease
<input type="checkbox"/>	<input type="checkbox"/>	Peripheral vascular disease
<input type="checkbox"/>	<input type="checkbox"/>	Cerebrovascular disease
<input type="checkbox"/>	<input type="checkbox"/>	Liver disease
<input type="checkbox"/>	<input type="checkbox"/>	Chronic lung disease
<input type="checkbox"/>	<input type="checkbox"/>	Immunosuppression
<input type="checkbox"/>	<input type="checkbox"/>	Leukemia/lymphoma
<input type="checkbox"/>	<input type="checkbox"/>	Solid organ tumor or metastatic disease

PI/Co-I or Coordinator Signature: _____ Date (dd/mmm/yyyy): _____

FORM 3: BASELINE

Clinical Frailty Scale (CFS) score	<ul style="list-style-type: none"><input type="checkbox"/> 1 – <u>Very Fit</u> – robust, active, energetic, and motivated.<input type="checkbox"/> 2 – <u>Fit</u> – no active disease symptoms but are less fit, active occasionally.<input type="checkbox"/> 3 – <u>Managing Well</u> – well controlled medical problems, not regularly active.<input type="checkbox"/> 4 – <u>Living With Very Mild Frailty</u> – not dependent, symptoms limit activities.<input type="checkbox"/> 5 – <u>Living With Mild Frailty</u> – more evident slowing, needs help with high order instrumental activities of daily living.<input type="checkbox"/> 6 – <u>Living With Moderate Frailty</u> – needs help with all outside activities, keeping house, bathing, and often have problems with stairs.<input type="checkbox"/> 7 – <u>Living With Severe Frailty</u> – complete dependence for personal care (physical or cognitive), stable not at risk of dying.<input type="checkbox"/> 8 – <u>Living With Very Severe Frailty</u> – approaching end of life, unlikely to recover from minor illness.<input type="checkbox"/> 9 – <u>Terminally Ill</u> – life expectancy <6 months who are not otherwise living with severe frailty.
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PI/Co-I or Coordinator Signature: _____ Date (dd/mmm/yyyy): _____

FORM 4: PRE-RANDOMIZED ACUITY/ORGAN DYSFUNCTION

Acuity and Organ Dysfunction Scores		
APACHE II score at ICU admission* (if auto-calculated in EMR)	□□□	<input type="checkbox"/> Not Available
SAPS III score at ICU admission* (if auto-calculated in EMR)	□□□	<input type="checkbox"/> Not Available
Parameters Common to Both APACHE II and SAPS III (where applicable, worst value within 24 hours prior to randomization)		
Age	□□□ years	
Temperature	□□.□ degrees C	<input type="checkbox"/> Not Available
Heart rate	□□□ beats/min	<input type="checkbox"/> Not Available
GCS	□□	<input type="checkbox"/> Not Available
WBC count	□□□.□ x 10 ⁹ /L	<input type="checkbox"/> Not Available
Blood pH <small>(arterial pH preferred, serum pH acceptable)</small>	□□.□□	<input type="checkbox"/> Not Available
If no pH, Serum HCO ₃	□□.□ mmol/L	<input type="checkbox"/> Not Available
Serum Creatinine	□□ μmol/L	<input type="checkbox"/> Not Available
APACHE II Parameters (worst value during 24 hr prior to randomization)		
Mean Arterial Pressure (MAP)	□□□ mmHg	<input type="checkbox"/> Not Available
Respiratory Rate <small>(non-ventilated or ventilated)</small>	□□ breaths/min	<input type="checkbox"/> Not Available
Oxygenation:		
FiO ₂ <small>(fraction of inspired oxygen)</small>	□.□	<input type="checkbox"/> Not Available
PCO ₂ <small>(partial pressure of CO₂)</small>	□□□ mmHg	<input type="checkbox"/> Not Available
PO ₂ <small>(partial pressure of oxygen)</small>	□□□ mmHg	<input type="checkbox"/> Not Available
PaO ₂ <small>(partial pressure of oxygen in arterial blood)</small>	□□□ mmHg	<input type="checkbox"/> Not Available
Serum Sodium	□□□ mmol/L	<input type="checkbox"/> Not Available
Serum Potassium	□□.□ mmol/L	<input type="checkbox"/> Not Available
Hematocrit	□□.□ %	<input type="checkbox"/> Not Available

PI/Co-I or Coordinator Signature: _____ Date (dd/mmm/yyyy): _____

FORM 4: PRE-RANDOMIZED ACUITY/ORGAN DYSFUNCTION

Acute Renal Failure	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not Available	
History of severe organ system insufficiency or immunocompromise?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not Available	
If YES: Participant Surgical Status	<input type="checkbox"/> Non-operative or emergency post-operative <input type="checkbox"/> Elective post-operative	
SAPS III Parameters (worst value during 24 hr prior to randomization)		
Length of stay before ICU Admission	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/> days	<input type="checkbox"/> Not Available
Intrahospital Location before ICU Admission	<input type="checkbox"/> Operative Room <input type="checkbox"/> Emergency Room <input type="checkbox"/> Other ICU <input type="checkbox"/> Other, specify: _____	
Comorbidities (specify all that apply)	<input type="checkbox"/> Cancer Therapy <input type="checkbox"/> Cancer <input type="checkbox"/> Hematological cancer <input type="checkbox"/> Chronic Heart Failure (NYHA IV) <input type="checkbox"/> Cirrhosis <input type="checkbox"/> AIDS <input type="checkbox"/> No applicable comorbidities	
Use of major therapeutic options before ICU admission: vasoactive drugs?	<input type="checkbox"/> YES <input type="checkbox"/> NO	
Type of ICU Admission	<input type="checkbox"/> Planned <input type="checkbox"/> Unplanned	
Reason(s) for ICU Admission <small>(select all that apply)</small>	<input type="checkbox"/> Cardiovascular <input type="checkbox"/> Hepatic <input type="checkbox"/> Digestive	

PI/Co-I or Coordinator Signature: _____ Date (dd/mmm/yyyy): _____

FORM 4: PRE-RANDOMIZED ACUITY/ORGAN DYSFUNCTION

	<input type="checkbox"/> Neurologic <input type="checkbox"/> None of the above
If Cardiovascular:	<input type="checkbox"/> Rhythm disturbances <input type="checkbox"/> Hypovolemic hemorrhagic shock, hypovolemic non-hemorrhagic shock <input type="checkbox"/> Septic Shock <input type="checkbox"/> Anaphylactic shock, mixed and undefined shock <input type="checkbox"/> Other, specify: _____
If Hepatic:	<input type="checkbox"/> Liver failure <input type="checkbox"/> Other, specify: _____
If Digestive:	<input type="checkbox"/> Severe pancreatitis <input type="checkbox"/> Other, acute abdomen <input type="checkbox"/> Other, specify: _____
If Neurologic:	<input type="checkbox"/> Intracranial mass effect <input type="checkbox"/> Focal neurological deficit <input type="checkbox"/> Seizures <input type="checkbox"/> Coma, Stupor, Obtunded, Agitation, Vigilance disturbances, Confusion, Delirium <input type="checkbox"/> Other, specify: _____
Surgical Status at ICU Admission	<input type="checkbox"/> Scheduled surgery <input type="checkbox"/> Emergency surgery <input type="checkbox"/> No surgery
Anatomical Site of Surgery	<input type="checkbox"/> Transplantation surgery: Liver, Kidney, Pancreas, Kidney and Pancreas, transplantation other <input type="checkbox"/> Trauma – other isolated: (includes thorax, abdomen, limb); Trauma – Multiple <input type="checkbox"/> Cardiac surgery: CABG without valvular repair

PI/Co-I or Coordinator Signature: _____ Date (dd/mmm/yyyy): _____

FORM 4: PRE-RANDOMIZED ACUITY/ORGAN DYSFUNCTION

	<input type="checkbox"/> Neurosurgery: Cerebrovascular accident <input type="checkbox"/> All others (default)	
Acute Infection at ICU Admission	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> Not Available
If Yes, Type of infection	<input type="checkbox"/> Nosocomial <input type="checkbox"/> Respiratory	
Total bilirubin	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> μmol/L	<input type="checkbox"/> Not Available
Platelet Count	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> x 10 ⁹ /L	<input type="checkbox"/> Not Available
Systolic Blood Pressure	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> mmHg	<input type="checkbox"/> Not Available
Oxygenation	<input type="checkbox"/> Mechanical ventilation <input type="checkbox"/> No mechanical ventilation	<input type="checkbox"/> Not Available

SOFA score (most extreme parameter in the 24 hours preceding randomization)							
Enter Score for each category in the box below			0	1	2	3	4
Respiratory	PaO ₂ /FiO ₂ ratio	<input type="checkbox"/>	> 400	≤ 400 ± respiratory support	≤ 300 ± respiratory support	≤ 200 + respiratory support	< 100 + respiratory support
Coagulation	Platelets	<input type="checkbox"/>	>150	101-150	50-100	20-49	<20
Hepatic	Bilirubin	<input type="checkbox"/>	< 20 μmol/L	20-32 μmol/L	33-101 μmol/L	102-204 μmol/L	>204 μmol/L
CNS	GCS	<input type="checkbox"/>	15	13-14	10-12	6-9	<6
Cardiovascular	MAP + support	<input type="checkbox"/>	MAP ≥ 70 mmHg	MAP < 70 mmHg	DA ≤ 5 μg/kg/min or DOB (any) or MILR (any)	DA > 5 μg/kg/min or EPI ≤ 0.1 μg/kg/min or NE ≤ 0.1 μg/kg/min or AVP <0.03 units/min or Phenyl (any)	DA > 15 μg/kg/min or EPI > 0.1 μg/kg/min or NE > 0.1 μg/kg/min or AVP >0.03 units/min
Renal	Creatinine and urine output	<input type="checkbox"/>	≤ 97 μmol/L	98-168 μmol/L	169-299 μmol/L	300-433 μmol/L or urine output ≤ 500 mL/day	≥ 433 μmol/L or urine output ≤ 200 mL/day or receiving RRT
Total Score	<input type="checkbox"/> <input type="checkbox"/> (max 24; range 0-24)						

PI/Co-I or Coordinator Signature: _____ Date (dd/mmm/yyyy): _____

FORM 4: PRE-RANDOMIZED ACUITY/ORGAN DYSFUNCTION

Physiologic Parameters (worst value during 24 hr prior to randomization)		
Hemoglobin	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> g/L	<input type="checkbox"/> Not Available
INR	<input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Not Available
Serum phosphate	<input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/> mmol/L	<input type="checkbox"/> Not Available
Serum ionized calcium	<input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/> mmol/L	<input type="checkbox"/> Not Available
Serum total calcium	<input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/> mmol/L	<input type="checkbox"/> Not Available

Interventions at the Time of Randomization		
Invasive mechanical ventilation (IMV)	<input type="checkbox"/> YES <input type="checkbox"/> NO	
If YES, to receiving IMV	PEEP _{MAX} <input type="checkbox"/> <input type="checkbox"/> cmH ₂ O MAP _{MAX} <input type="checkbox"/> <input type="checkbox"/> cmH ₂ O PPlat _{MAX} <input type="checkbox"/> <input type="checkbox"/> cmH ₂ O FiO _{2MAX} <input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Not Available <input type="checkbox"/> Not Available <input type="checkbox"/> Not Available <input type="checkbox"/> Not Available
Non-invasive ventilation (e.g., CPAP, BiPAP)	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> Not Available
If YES, to receiving NIV	FiO _{2MAX} <input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Not Available
High Flow oxygen (HFO ₂)	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> Not Available
If YES, to receiving HFO ₂	FiO _{2MAX} <input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Not Available
Norepinephrine infusion	<input type="checkbox"/> YES <input type="checkbox"/> NO Dose _{MAX} <input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/> µg/kg/min	<input type="checkbox"/> Not Available
Epinephrine infusion	<input type="checkbox"/> YES <input type="checkbox"/> NO Dose _{MAX} <input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/> µg/kg/min	<input type="checkbox"/> Not Available
Vasopressin infusion	<input type="checkbox"/> YES <input type="checkbox"/> NO Dose _{MAX} <input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/> units/min	<input type="checkbox"/> Not Available
Phenylephrine infusion	<input type="checkbox"/> YES <input type="checkbox"/> NO Dose _{MAX} <input type="checkbox"/> <input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/> µg/kg/min	<input type="checkbox"/> Not Available

PI/Co-I or Coordinator Signature: _____ Date (dd/mmm/yyyy): _____

FORM 4: PRE-RANDOMIZED ACUITY/ORGAN DYSFUNCTION

Angiotensin II infusion	<input type="checkbox"/> YES <input type="checkbox"/> NO Dose _{MAX} <input type="checkbox"/> <input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/> µg/kg/min	<input type="checkbox"/> Not Available
Dopamine infusion	<input type="checkbox"/> YES <input type="checkbox"/> NO Dose _{MAX} <input type="checkbox"/> <input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/> µg/kg/min	<input type="checkbox"/> Not Available
Dobutamine infusion	<input type="checkbox"/> YES <input type="checkbox"/> NO Dose _{MAX} <input type="checkbox"/> <input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/> µg/kg/min	<input type="checkbox"/> Not Available
Milrinone infusion	<input type="checkbox"/> YES <input type="checkbox"/> NO Dose _{MAX} <input type="checkbox"/> <input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/> µg/kg/min	<input type="checkbox"/> Not Available
Levosimendan infusion	<input type="checkbox"/> YES <input type="checkbox"/> NO Dose _{MAX} <input type="checkbox"/> <input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/> µg/kg/min	<input type="checkbox"/> Not Available
Enteral nutrition	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> Not Available
Parenteral nutrition	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> Not Available

PI/Co-I or Coordinator Signature: _____ Date (dd/mmm/yyyy): _____

FORM 5: INTERVENTION (Daily)

Continuous Renal Replacement Therapy	
CRRT Initiation: (This may be before or after randomization)	Date (dd/mmm/yyyy): <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> / 20 <input type="text"/> <input type="text"/> Time (24 hr clock): <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>
Vascular access catheter	<input type="checkbox"/> Right internal jugular vein <input type="checkbox"/> Left internal jugular vein <input type="checkbox"/> Right femoral vein <input type="checkbox"/> Left femoral vein <input type="checkbox"/> Permanent catheter (tunneled) <input type="checkbox"/> Other, specify: _____
CRRT dose-intensity being received at time of randomization	
<input type="checkbox"/> CRRT not yet started at time of randomization (Additional fields below do not need to be completed if CRRT not yet started.)	
Dose (total effluent)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL/hr
Dose (hemofiltration)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL/hr
Hemofiltration – pre-filter	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL/hr
Hemofiltration – post-filter	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL/hr
Dose (dialysate)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL/hr
CRRT anticoagulation prescribed	<input type="checkbox"/> No anticoagulation given <input type="checkbox"/> Citrate (4% trisodium citrate) <input type="checkbox"/> Citrate (18/0 dilute solution) <input type="checkbox"/> Citrate (ACD-A) <input type="checkbox"/> Unfractionated heparin <input type="checkbox"/> LMWH <input type="checkbox"/> Other, specify: _____
Study Allocated CRRT Initiation:	Date (dd/mmm/yyyy): <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> / 20 <input type="text"/> <input type="text"/> Time (24 hr clock): <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>

PI/Co-I or Coordinator Signature: _____ Date (dd/mmm/yyyy): _____

FORM 5: INTERVENTION (Daily)

Daily Data Worksheet (Day 0 [randomization] to Day 6)							
Daily variable	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6
CRRT duration	<input type="text"/> hr : <input type="text"/> min	<input type="text"/> hr : <input type="text"/> min	<input type="text"/> hr : <input type="text"/> min	<input type="text"/> hr : <input type="text"/> min	<input type="text"/> hr : <input type="text"/> min	<input type="text"/> hr : <input type="text"/> min	<input type="text"/> hr : <input type="text"/> min
Time in allocated target range	<input type="text"/> hr : <input type="text"/> min	<input type="text"/> hr : <input type="text"/> min	<input type="text"/> hr : <input type="text"/> min	<input type="text"/> hr : <input type="text"/> min	<input type="text"/> hr : <input type="text"/> min	<input type="text"/> hr : <input type="text"/> min	<input type="text"/> hr : <input type="text"/> min
Mode	<input type="checkbox"/> CVVH <input type="checkbox"/> CVVHD <input type="checkbox"/> CVVHDF	<input type="checkbox"/> CVVH <input type="checkbox"/> CVVHD <input type="checkbox"/> CVVHDF	<input type="checkbox"/> CVVH <input type="checkbox"/> CVVHD <input type="checkbox"/> CVVHDF	<input type="checkbox"/> CVVH <input type="checkbox"/> CVVHD <input type="checkbox"/> CVVHDF	<input type="checkbox"/> CVVH <input type="checkbox"/> CVVHD <input type="checkbox"/> CVVHDF	<input type="checkbox"/> CVVH <input type="checkbox"/> CVVHD <input type="checkbox"/> CVVHDF	<input type="checkbox"/> CVVH <input type="checkbox"/> CVVHD <input type="checkbox"/> CVVHDF
Blood flow rate	<input type="text"/> <input type="text"/> <input type="text"/> mL/min	<input type="text"/> <input type="text"/> <input type="text"/> mL/min	<input type="text"/> <input type="text"/> <input type="text"/> mL/min	<input type="text"/> <input type="text"/> <input type="text"/> mL/min	<input type="text"/> <input type="text"/> <input type="text"/> mL/min	<input type="text"/> <input type="text"/> <input type="text"/> mL/min	<input type="text"/> <input type="text"/> <input type="text"/> mL/min
Dose (total effluent)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL
Dose (hemofiltration)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL
Hemofiltration – pre-filter	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL
Hemofiltration – post-filter	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL
Dose (dialysate)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mL
Dose (total mean)	<input type="text"/> <input type="text"/> . <input type="text"/> mL/kg/hr	<input type="text"/> <input type="text"/> . <input type="text"/> mL/kg/hr	<input type="text"/> <input type="text"/> . <input type="text"/> mL/kg/hr	<input type="text"/> <input type="text"/> . <input type="text"/> mL/kg/hr	<input type="text"/> <input type="text"/> . <input type="text"/> mL/kg/hr	<input type="text"/> <input type="text"/> . <input type="text"/> mL/kg/hr	<input type="text"/> <input type="text"/> . <input type="text"/> mL/kg/hr
Dose (highest hourly)	<input type="text"/> <input type="text"/> . <input type="text"/> mL/kg/hr	<input type="text"/> <input type="text"/> . <input type="text"/> mL/kg/hr	<input type="text"/> <input type="text"/> . <input type="text"/> mL/kg/hr	<input type="text"/> <input type="text"/> . <input type="text"/> mL/kg/hr	<input type="text"/> <input type="text"/> . <input type="text"/> mL/kg/hr	<input type="text"/> <input type="text"/> . <input type="text"/> mL/kg/hr	<input type="text"/> <input type="text"/> . <input type="text"/> mL/kg/hr
Dose (lowest hourly)	<input type="text"/> <input type="text"/> . <input type="text"/> mL/kg/hr	<input type="text"/> <input type="text"/> . <input type="text"/> mL/kg/hr	<input type="text"/> <input type="text"/> . <input type="text"/> mL/kg/hr	<input type="text"/> <input type="text"/> . <input type="text"/> mL/kg/hr	<input type="text"/> <input type="text"/> . <input type="text"/> mL/kg/hr	<input type="text"/> <input type="text"/> . <input type="text"/> mL/kg/hr	<input type="text"/> <input type="text"/> . <input type="text"/> mL/kg/hr
Number of Filter Changes	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
Ultrafiltration (total) (mL)	+ / - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	+ / - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	+ / - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	+ / - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	+ / - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	+ / - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	+ / - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Fluid balance (total) (mL)	+ / - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	+ / - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	+ / - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	+ / - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	+ / - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	+ / - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	+ / - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Urine output (mL)	+ / - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	+ / - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	+ / - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	+ / - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	+ / - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	+ / - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	+ / - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Serum Base Excess	+ / - <input type="text"/> <input type="text"/> . <input type="text"/>	+ / - <input type="text"/> <input type="text"/> . <input type="text"/>	+ / - <input type="text"/> <input type="text"/> . <input type="text"/>	+ / - <input type="text"/> <input type="text"/> . <input type="text"/>	+ / - <input type="text"/> <input type="text"/> . <input type="text"/>	+ / - <input type="text"/> <input type="text"/> . <input type="text"/>	+ / - <input type="text"/> <input type="text"/> . <input type="text"/>

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FORM 5: INTERVENTION (Daily)

Daily Data Worksheet (Day 0 [randomization] to Day 6)							
Daily variable	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6
Serum pH _{MIN}	□.□□	□.□□	□.□□	□.□□	□.□□	□.□□	□.□□
Serum pH _{MAX}	□.□□	□.□□	□.□□	□.□□	□.□□	□.□□	□.□□
Serum [HCO ₃] _{MIN} (mmol/L)	□□.□	□□.□	□□.□	□□.□	□□.□	□□.□	□□.□
Serum [HCO ₃] _{MAX} (mmol/L)	□□.□	□□.□	□□.□	□□.□	□□.□	□□.□	□□.□
Serum [Na ⁺] _{MIN} (mmol/L)	□□□	□□□	□□□	□□□	□□□	□□□	□□□
Serum [Na ⁺] _{MAX} (mmol/L)	□□□	□□□	□□□	□□□	□□□	□□□	□□□
Serum [Cl ⁻] _{MIN} (mmol/L)	□□□	□□□	□□□	□□□	□□□	□□□	□□□
Serum [Cl ⁻] _{MAX} (mmol/L)	□□□	□□□	□□□	□□□	□□□	□□□	□□□
Serum [K ⁺] _{MIN} (mmol/L)	□□.□	□□.□	□□.□	□□.□	□□.□	□□.□	□□.□
Serum [K ⁺] _{MAX} (mmol/L)	□□.□	□□.□	□□.□	□□.□	□□.□	□□.□	□□.□
Serum [Mg ⁺] _{MIN} (mmol/L)	□.□□	□.□□	□.□□	□.□□	□.□□	□.□□	□.□□
Serum [Mg ⁺] _{MAX} (mmol/L)	□.□□	□.□□	□.□□	□.□□	□.□□	□.□□	□.□□
Serum [PO ₄] _{MIN} (mmol/L)	□.□□	□.□□	□.□□	□.□□	□.□□	□.□□	□.□□
Serum [PO ₄] _{MAX} (mmol/L)	□.□□	□.□□	□.□□	□.□□	□.□□	□.□□	□.□□
Serum [urea] _{MIN} (mmol/L)	□□.□	□□.□	□□.□	□□.□	□□.□	□□.□	□□.□
Serum [urea] _{MAX} (mmol/L)	□□.□	□□.□	□□.□	□□.□	□□.□	□□.□	□□.□
CRRT interrupted	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO
If Yes, Duration CRRT interrupted	□□hr : □□min	□□hr : □□min	□□hr : □□min	□□hr : □□min	□□hr : □□min	□□hr : □□min	□□hr : □□min

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FORM 5: INTERVENTION (Daily)

Daily Data Worksheet (Day 0 [randomization] to Day 6)							
Daily variable	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6
Reason CRRT interrupted							
CRRT transition to IRRT	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO
Receipt of IMV	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO
Receipt of NIV	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO
Receipt of HFO ₂	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO
Receipt of any vasoactive	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO
Transfused RBC	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO
Transfused FFP	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO
Transfused PLT	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO
Supplementation Given?	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO
If Yes, select those that apply:	<input type="checkbox"/> Mg+	<input type="checkbox"/> Mg+	<input type="checkbox"/> Mg+	<input type="checkbox"/> Mg+	<input type="checkbox"/> Mg+	<input type="checkbox"/> Mg+	<input type="checkbox"/> Mg+
	<input type="checkbox"/> K+	<input type="checkbox"/> K+	<input type="checkbox"/> K+	<input type="checkbox"/> K+	<input type="checkbox"/> K+	<input type="checkbox"/> K+	<input type="checkbox"/> K+
	<input type="checkbox"/> PO ₄ -	<input type="checkbox"/> PO ₄ -	<input type="checkbox"/> PO ₄ -	<input type="checkbox"/> PO ₄ -	<input type="checkbox"/> PO ₄ -	<input type="checkbox"/> PO ₄ -	<input type="checkbox"/> PO ₄ -
	<input type="checkbox"/> HCO ₃ -	<input type="checkbox"/> HCO ₃ -	<input type="checkbox"/> HCO ₃ -	<input type="checkbox"/> HCO ₃ -	<input type="checkbox"/> HCO ₃ -	<input type="checkbox"/> HCO ₃ -	<input type="checkbox"/> HCO ₃ -
	<input type="checkbox"/> Protein	<input type="checkbox"/> Protein	<input type="checkbox"/> Protein	<input type="checkbox"/> Protein	<input type="checkbox"/> Protein	<input type="checkbox"/> Protein	<input type="checkbox"/> Protein
	<input type="checkbox"/> Multivitamins	<input type="checkbox"/> Multivitamins	<input type="checkbox"/> Multivitamins	<input type="checkbox"/> Multivitamins	<input type="checkbox"/> Multivitamins	<input type="checkbox"/> Multivitamins	<input type="checkbox"/> Multivitamins
If Mg+ given, number of doses	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
If Mg+ given, cumulative dose	<input type="checkbox"/> <input type="checkbox"/> grams	<input type="checkbox"/> <input type="checkbox"/> grams	<input type="checkbox"/> <input type="checkbox"/> grams	<input type="checkbox"/> <input type="checkbox"/> grams	<input type="checkbox"/> <input type="checkbox"/> grams	<input type="checkbox"/> <input type="checkbox"/> grams	<input type="checkbox"/> <input type="checkbox"/> grams

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FORM 5: INTERVENTION (Daily)

Daily Data Worksheet (Day 0 [randomization] to Day 6)							
Daily variable	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6
If K+ given, number of doses	□□	□□	□□	□□	□□	□□	□□
If K+ given, cumulative dose	□□□□ mmol	□□□□ mmol	□□□□ mmol	□□□□ mmol	□□□□ mmol	□□□□ mmol	□□□□ mmol
If PO ₄ given, number of doses	□□	□□	□□	□□	□□	□□	□□
If PO ₄ given, cumulative dose	□□□□ mmol	□□□□ mmol	□□□□ mmol	□□□□ mmol	□□□□ mmol	□□□□ mmol	□□□□ mmol
If HCO ₃ ⁻ given, number of doses	□□	□□	□□	□□	□□	□□	□□
If HCO ₃ ⁻ given, cumulative dose	□□□□ mmol	□□□□ mmol	□□□□ mmol	□□□□ mmol	□□□□ mmol	□□□□ mmol	□□□□ mmol
If Protein given, number of doses	□□	□□	□□	□□	□□	□□	□□
If Protein given, cumulative dose	□□ grams	□□ grams	□□ grams	□□ grams	□□ grams	□□ grams	□□ grams
If multivitamins given, number of doses	□□	□□	□□	□□	□□	□□	□□
Data Entered By: Initials/Date							

PI/Co-I or Coordinator Signature: _____ Date (dd/mmm/yyyy): _____

FORM 5: INTERVENTION (Daily)

Daily Data Worksheet (Day ____ to Day ____) – Copy this page as needed for recording data for additional days

Daily variable	Day ____	Day ____	Day ____	Day ____	Day ____	Day ____	Day ____
CRRT duration	<input type="text"/> hr : <input type="text"/> min	<input type="text"/> hr : <input type="text"/> min	<input type="text"/> hr : <input type="text"/> min	<input type="text"/> hr : <input type="text"/> min	<input type="text"/> hr : <input type="text"/> min	<input type="text"/> hr : <input type="text"/> min	<input type="text"/> hr : <input type="text"/> min
Time in allocated target range	<input type="text"/> hr : <input type="text"/> min	<input type="text"/> hr : <input type="text"/> min	<input type="text"/> hr : <input type="text"/> min	<input type="text"/> hr : <input type="text"/> min	<input type="text"/> hr : <input type="text"/> min	<input type="text"/> hr : <input type="text"/> min	<input type="text"/> hr : <input type="text"/> min
Mode	<input type="checkbox"/> CVVH <input type="checkbox"/> CVVHD <input type="checkbox"/> CVVHDF	<input type="checkbox"/> CVVH <input type="checkbox"/> CVVHD <input type="checkbox"/> CVVHDF	<input type="checkbox"/> CVVH <input type="checkbox"/> CVVHD <input type="checkbox"/> CVVHDF	<input type="checkbox"/> CVVH <input type="checkbox"/> CVVHD <input type="checkbox"/> CVVHDF	<input type="checkbox"/> CVVH <input type="checkbox"/> CVVHD <input type="checkbox"/> CVVHDF	<input type="checkbox"/> CVVH <input type="checkbox"/> CVVHD <input type="checkbox"/> CVVHDF	<input type="checkbox"/> CVVH <input type="checkbox"/> CVVHD <input type="checkbox"/> CVVHDF
Blood flow rate	<input type="text"/> mL/min	<input type="text"/> mL/min	<input type="text"/> mL/min	<input type="text"/> mL/min	<input type="text"/> mL/min	<input type="text"/> mL/min	<input type="text"/> mL/min
Dose (total effluent)	<input type="text"/> mL	<input type="text"/> mL	<input type="text"/> mL	<input type="text"/> mL	<input type="text"/> mL	<input type="text"/> mL	<input type="text"/> mL
Dose (hemofiltration)	<input type="text"/> mL	<input type="text"/> mL	<input type="text"/> mL	<input type="text"/> mL	<input type="text"/> mL	<input type="text"/> mL	<input type="text"/> mL
Hemofiltration – pre-filter	<input type="text"/> mL	<input type="text"/> mL	<input type="text"/> mL	<input type="text"/> mL	<input type="text"/> mL	<input type="text"/> mL	<input type="text"/> mL
Hemofiltration – post-filter	<input type="text"/> mL	<input type="text"/> mL	<input type="text"/> mL	<input type="text"/> mL	<input type="text"/> mL	<input type="text"/> mL	<input type="text"/> mL
Dose (dialysate)	<input type="text"/> mL	<input type="text"/> mL	<input type="text"/> mL	<input type="text"/> mL	<input type="text"/> mL	<input type="text"/> mL	<input type="text"/> mL
Dose (total mean)	<input type="text"/> mL/kg/hr	<input type="text"/> mL/kg/hr	<input type="text"/> mL/kg/hr	<input type="text"/> mL/kg/hr	<input type="text"/> mL/kg/hr	<input type="text"/> mL/kg/hr	<input type="text"/> mL/kg/hr
Dose (highest hourly)	<input type="text"/> mL/kg/hr	<input type="text"/> mL/kg/hr	<input type="text"/> mL/kg/hr	<input type="text"/> mL/kg/hr	<input type="text"/> mL/kg/hr	<input type="text"/> mL/kg/hr	<input type="text"/> mL/kg/hr
Dose (lowest hourly)	<input type="text"/> mL/kg/hr	<input type="text"/> mL/kg/hr	<input type="text"/> mL/kg/hr	<input type="text"/> mL/kg/hr	<input type="text"/> mL/kg/hr	<input type="text"/> mL/kg/hr	<input type="text"/> mL/kg/hr
Number of Filter Changes	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Ultrafiltration (total) (mL)	+/- <input type="text"/>	+/- <input type="text"/>	+/- <input type="text"/>	+/- <input type="text"/>	+/- <input type="text"/>	+/- <input type="text"/>	+/- <input type="text"/>
Fluid balance (total) (mL)	+/- <input type="text"/>	+/- <input type="text"/>	+/- <input type="text"/>	+/- <input type="text"/>	+/- <input type="text"/>	+/- <input type="text"/>	+/- <input type="text"/>
Urine output (mL)	+/- <input type="text"/>	+/- <input type="text"/>	+/- <input type="text"/>	+/- <input type="text"/>	+/- <input type="text"/>	+/- <input type="text"/>	+/- <input type="text"/>
Serum Base Excess	+/- <input type="text"/>	+/- <input type="text"/>	+/- <input type="text"/>	+/- <input type="text"/>	+/- <input type="text"/>	+/- <input type="text"/>	+/- <input type="text"/>

PI/Co-I or Coordinator Signature: _____ Date (dd/mmm/yyyy): _____

FORM 5: INTERVENTION (Daily)

Daily Data Worksheet (Day ____ to Day ____) – Copy this page as needed for recording data for additional days

Daily variable	Day ____	Day ____	Day ____	Day ____	Day ____	Day ____	Day ____
Serum pH _{MIN}	□.□□	□.□□	□.□□	□.□□	□.□□	□.□□	□.□□
Serum pH _{MAX}	□.□□	□.□□	□.□□	□.□□	□.□□	□.□□	□.□□
Serum [HCO ₃] _{MIN} (mmol/L)	□□.□	□□.□	□□.□	□□.□	□□.□	□□.□	□□.□
Serum [HCO ₃] _{MAX} (mmol/L)	□□.□	□□.□	□□.□	□□.□	□□.□	□□.□	□□.□
Serum [Na ⁺] _{MIN} (mmol/L)	□□□	□□□	□□□	□□□	□□□	□□□	□□□
Serum [Na ⁺] _{MAX} (mmol/L)	□□□	□□□	□□□	□□□	□□□	□□□	□□□
Serum [Cl ⁻] _{MIN} (mmol/L)	□□□	□□□	□□□	□□□	□□□	□□□	□□□
Serum [Cl ⁻] _{MAX} (mmol/L)	□□□	□□□	□□□	□□□	□□□	□□□	□□□
Serum [K ⁺] _{MIN} (mmol/L)	□□.□	□□.□	□□.□	□□.□	□□.□	□□.□	□□.□
Serum [K ⁺] _{MAX} (mmol/L)	□□.□	□□.□	□□.□	□□.□	□□.□	□□.□	□□.□
Serum [Mg ⁺] _{MIN} (mmol/L)	□.□□	□.□□	□.□□	□.□□	□.□□	□.□□	□.□□
Serum [Mg ⁺] _{MAX} (mmol/L)	□.□□	□.□□	□.□□	□.□□	□.□□	□.□□	□.□□
Serum [PO ₄] _{MIN} (mmol/L)	□.□□	□.□□	□.□□	□.□□	□.□□	□.□□	□.□□
Serum [PO ₄] _{MAX} (mmol/L)	□.□□	□.□□	□.□□	□.□□	□.□□	□.□□	□.□□
Serum [urea] _{MIN} (mmol/L)	□□.□	□□.□	□□.□	□□.□	□□.□	□□.□	□□.□
Serum [urea] _{MAX} (mmol/L)	□□.□	□□.□	□□.□	□□.□	□□.□	□□.□	□□.□
CRRT interrupted	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO
If Yes, Duration CRRT interrupted	□□hr : □□min	□□hr : □□min	□□hr : □□min	□□hr : □□min	□□hr : □□min	□□hr : □□min	□□hr : □□min

PI/Co-I or Coordinator Signature: _____ Date (dd/mmm/yyyy): _____

FORM 5: INTERVENTION (Daily)

Daily Data Worksheet (Day ___ to Day ___) – Copy this page as needed for recording data for additional days

Daily variable	Day _____	Day _____	Day _____	Day _____	Day _____	Day _____	Day _____
Reason CRRT interrupted							
CRRT transition to IRR	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO
Receipt of IMV	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO
Receipt of NIV	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO
Receipt of HFO ₂	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO
Receipt of any vasoactive	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO
Transfused RBC	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO
Transfused FFP	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO
Transfused PLT	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO
Supplementation Given?	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO	<input type="checkbox"/> YES : <input type="checkbox"/> NO
If Yes, select those that apply:	<input type="checkbox"/> Mg+ <input type="checkbox"/> K+ <input type="checkbox"/> PO4- <input type="checkbox"/> HCO3- <input type="checkbox"/> Protein <input type="checkbox"/> Multivitamins	<input type="checkbox"/> Mg+ <input type="checkbox"/> K+ <input type="checkbox"/> PO4- <input type="checkbox"/> HCO3- <input type="checkbox"/> Protein <input type="checkbox"/> Multivitamins	<input type="checkbox"/> Mg+ <input type="checkbox"/> K+ <input type="checkbox"/> PO4- <input type="checkbox"/> HCO3- <input type="checkbox"/> Protein <input type="checkbox"/> Multivitamins	<input type="checkbox"/> Mg+ <input type="checkbox"/> K+ <input type="checkbox"/> PO4- <input type="checkbox"/> HCO3- <input type="checkbox"/> Protein <input type="checkbox"/> Multivitamins	<input type="checkbox"/> Mg+ <input type="checkbox"/> K+ <input type="checkbox"/> PO4- <input type="checkbox"/> HCO3- <input type="checkbox"/> Protein <input type="checkbox"/> Multivitamins	<input type="checkbox"/> Mg+ <input type="checkbox"/> K+ <input type="checkbox"/> PO4- <input type="checkbox"/> HCO3- <input type="checkbox"/> Protein <input type="checkbox"/> Multivitamins	<input type="checkbox"/> Mg+ <input type="checkbox"/> K+ <input type="checkbox"/> PO4- <input type="checkbox"/> HCO3- <input type="checkbox"/> Protein <input type="checkbox"/> Multivitamins
If Mg+ given, number of doses	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
If Mg+ given, cumulative dose	<input type="text"/> <input type="text"/> grams	<input type="text"/> <input type="text"/> grams	<input type="text"/> <input type="text"/> grams	<input type="text"/> <input type="text"/> grams	<input type="text"/> <input type="text"/> grams	<input type="text"/> <input type="text"/> grams	<input type="text"/> <input type="text"/> grams

PI/Co-I or Coordinator Signature: _____ Date (dd/mmm/yyyy): _____

FORM 5: INTERVENTION (Daily)

Daily Data Worksheet (Day ____ to Day ____) – Copy this page as needed for recording data for additional days

Daily variable	Day ____	Day ____	Day ____	Day ____	Day ____	Day ____	Day ____
If K ⁺ given, number of doses	□□	□□	□□	□□	□□	□□	□□
If K ⁺ given, cumulative dose	□□□□ mmol	□□□□ mmol	□□□□ mmol	□□□□ mmol	□□□□ mmol	□□□□ mmol	□□□□ mmol
If PO ₄ given, number of doses	□□	□□	□□	□□	□□	□□	□□
If PO ₄ given, cumulative dose	□□□□ mmol	□□□□ mmol	□□□□ mmol	□□□□ mmol	□□□□ mmol	□□□□ mmol	□□□□ mmol
If HCO ₃ ⁻ given, number of doses	□□	□□	□□	□□	□□	□□	□□
If HCO ₃ ⁻ given, cumulative dose	□□□□ mmol	□□□□ mmol	□□□□ mmol	□□□□ mmol	□□□□ mmol	□□□□ mmol	□□□□ mmol
If Protein given, number of doses	□□	□□	□□	□□	□□	□□	□□
If Protein given, cumulative dose	□□ grams	□□ grams	□□ grams	□□ grams	□□ grams	□□ grams	□□ grams
If multivitamins given, number of doses	□□	□□	□□	□□	□□	□□	□□
Data Entered By: Initials/Date							

PI/Co-I or Coordinator Signature: _____ Date (dd/mmm/yyyy): _____

FORM 6: OUTCOMES

CRRT OUTCOMES	
CRRT Discontinuation:	Date (dd/mmm/yyyy): □□/□□□/20□□ Time (24 hr clock): □□:□□
Reason for discontinuation:	<input type="checkbox"/> Death or withdrawal of life-sustaining therapy <input type="checkbox"/> Transition to IRRT <input type="checkbox"/> Kidney recovery (no longer needed)
Kidney Outcomes	
Did the participant receive RRT after CRRT discontinuation?	<input type="checkbox"/> YES <input type="checkbox"/> NO
RRT at ICU discharge:	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not Available
RRT at Hospital discharge:	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not Available
RRT at 30-days (from enrollment):	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not Available
RRT at 90-days (from enrollment):	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not Available
Last date of receipt of RRT:	Date (dd/mmm/yyyy): □□/□□□/20□□
Serum creatinine at ICU discharge:	□□□□ μmol/L <input type="checkbox"/> Not Available
Serum creatinine at hospital discharge:	□□□□ μmol/L <input type="checkbox"/> Not Available
Serum creatinine at 90-days (+/- 2 wks)	□□□□ μmol/L <input type="checkbox"/> Not Available
Mortality	
Death in ICU:	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not Available
Death in Hospital:	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not Available
Death at 30-days (from enrollment):	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not Available
Death at 90-days (from enrollment):	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not Available
If dead, date/time:	Date (dd/mmm/yyyy): □□/□□□/20□□ Time (24 hr clock): □□:□□

PI/Co-I or Coordinator Signature: _____ Date (dd/mmm/yyyy): _____

FORM 6: OUTCOMES

Service Outcomes	
ICU discharge:	Date (dd/mmm/yyyy): □□/□□□/20□□ Time (24 hr clock): □□:□□
Hospital discharge:	Date (dd/mmm/yyyy): □□/□□□/20□□ Time (24 hr clock): □□:□□
Re-hospitalized within 90-days (from enrollment):	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not Available
End of Study	
Did the participant complete the study and vital status assessment at 90 days?	<input type="checkbox"/> YES <input type="checkbox"/> NO
If Yes, Day 90 date	Date (dd/mmm/yyyy): □□/□□□/20□□
If No, Study End Date	Date (dd/mmm/yyyy): □□/□□□/20□□
If participant did not complete the study intervention, please specify why:	<input type="checkbox"/> Withdrawal of Consent <input type="checkbox"/> Lost to Follow-up <input type="checkbox"/> Other, specify: _____

PI/Co-I or Coordinator Signature: _____ Date (dd/mmm/yyyy): _____

FORM 7: PROTOCOL DEVIATIONS

Protocol Deviation Data – Copy this form for multiple deviations	
What was the nature of the protocol violation?	<input type="checkbox"/> Consent procedures <input type="checkbox"/> Inclusion/Exclusion criteria <input type="checkbox"/> Study Procedures - Did not begin receiving study-prescribed CRRT within the protocol specified timelines <input type="checkbox"/> Study Procedures - Received incorrect CRRT prescription <input type="checkbox"/> Study Procedures – CRRT dose escalated above the protocol mandated dose-intensity target <input type="checkbox"/> Study Procedures - Other <input type="checkbox"/> Breach in confidentiality <input type="checkbox"/> SAE reporting <input type="checkbox"/> Other, specify: _____
If selected, Study Procedures – CRRT dose escalated above the protocol mandated dose-intensity target, specify the reason for dose escalation	<input type="checkbox"/> Inadequate acid-base control <input type="checkbox"/> Inadequate electrolyte control <input type="checkbox"/> Inadequate azotemic control <input type="checkbox"/> Other, specify: _____
Please provide a description of the protocol deviation:	
Date of Deviation (dd/mmm/yyyy):	
Was there any impact to patient safety or data integrity due to the protocol deviation?	<input type="checkbox"/> YES <input type="checkbox"/> NO
If YES, provide details:	
Did the participant continue with the study:	<input type="checkbox"/> YES <input type="checkbox"/> NO
Was the protocol deviation reported to the REB?	<input type="checkbox"/> YES <input type="checkbox"/> NO
If YES, please provide the date the protocol deviation was reported to the REB:	Date (dd/mmm/yyyy): □□/□□□/20□□

PI/Co-I or Coordinator Signature: _____ Date (dd/mmm/yyyy): _____

FORM 8: ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

SITE PRINCIPAL INVESTIGATOR:						SITE:				
FULL STUDY TITLE: LoW Dose-Intensity vs. Standard Dose-Intensity COntinuous Renal ReplaceMent Therapy in Critically Ill Patients (WISDOM): A Pilot Randomized Trial										
AE #	AE EVENT	SEVERITY ⁵	RELATED TO STUDY TREATMENT ^{3, 4,5}	SERIOUS ^{1,4,5}	EXPECTED ^{2,4,5}	STUDY TREATMENT ADMINISTRATION STATUS ⁵	OUTCOME ⁵	DATE OF SITE AWARENESS	AE ONSET DATE	AE STOP DATE
		<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Life threatening <input type="checkbox"/> Death	<input type="checkbox"/> Definitely <input type="checkbox"/> Probably <input type="checkbox"/> Possibly <input type="checkbox"/> Unlikely <input type="checkbox"/> Unrelated	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Unchanged <input type="checkbox"/> Dose decreased <input type="checkbox"/> Temporarily withheld <input type="checkbox"/> Permanently discontinued	<input type="checkbox"/> Unknown <input type="checkbox"/> Resolved without sequelae <input type="checkbox"/> Resolved with sequelae <input type="checkbox"/> Death <input type="checkbox"/> Ongoing	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy
REPORTER SIGNATURE:			REPORTER SIGNATURE DATE (dd-mmm-yyyy):			INVESTIGATOR SIGNATURE:			INVESTIGATOR SIGNATURE DATE (dd-mmm-yyyy):	
		<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Life threatening <input type="checkbox"/> Death	<input type="checkbox"/> Definitely <input type="checkbox"/> Probably <input type="checkbox"/> Possibly <input type="checkbox"/> Unlikely <input type="checkbox"/> Unrelated	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Unchanged <input type="checkbox"/> Dose decreased <input type="checkbox"/> Temporarily withheld <input type="checkbox"/> Permanently discontinued	<input type="checkbox"/> Unknown <input type="checkbox"/> Resolved without sequelae <input type="checkbox"/> Resolved with sequelae <input type="checkbox"/> Death <input type="checkbox"/> Ongoing	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy
REPORTER SIGNATURE:			REPORTER SIGNATURE DATE (dd-mmm-yyyy):			INVESTIGATOR SIGNATURE:			INVESTIGATOR SIGNATURE DATE (dd-mmm-yyyy):	
		<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Life threatening <input type="checkbox"/> Death	<input type="checkbox"/> Definitely <input type="checkbox"/> Probably <input type="checkbox"/> Possibly <input type="checkbox"/> Unlikely <input type="checkbox"/> Unrelated	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Unchanged <input type="checkbox"/> Dose decreased <input type="checkbox"/> Temporarily withheld <input type="checkbox"/> Permanently discontinued	<input type="checkbox"/> Unknown <input type="checkbox"/> Resolved without sequelae <input type="checkbox"/> Resolved with sequelae <input type="checkbox"/> Death <input type="checkbox"/> Ongoing	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy
REPORTER SIGNATURE:			REPORTER SIGNATURE DATE (dd-mmm-yyyy):			INVESTIGATOR SIGNATURE:			INVESTIGATOR SIGNATURE DATE (dd-mmm-yyyy):	

- 1: Serious: AE results in death, is life threatening, requires inpatient hospitalization/prolongation of existing hospitalization, results in congenital anomaly/birth defect, or results in a persistent/significant disability/incapacity
- 2: Expected: the nature or severity is consistent with the applicable product information (e.g. Investigator's Brochure, Product Monograph, etc.)
- 3: Related: a causal relationship between the study treatment and the AE is at least a reasonable possibility (i.e. the relationship cannot be ruled out)
- 4: SAEs are subject to REB reporting as per REB submission guidelines.
- 5: Investigator sign-off denotes that medical determination of AE has been reviewed & completed by the investigator & transcribed accurately

PI/Co-I or Coordinator Signature: _____ Date (dd/mmm/yyyy): _____

FORM 8: ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

Serious Adverse Event FORM	
Did the patient experience a SAE?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Date/time of SAE:	Date (dd/mmm/yyyy): <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / 20 <input type="text"/> <input type="text"/>
Grade	<input type="checkbox"/> <u>Grade 5</u> : Death. Resulted in patient death. <input type="checkbox"/> <u>Grade 4</u> : Life-threatening. Potentially life-threatening symptoms causing inability to perform base self-care functions with intervention indicated to prevent permanent impairment, persistent disability or death. <input type="checkbox"/> <u>Grade 3</u> : Severe. Severe symptoms causing inability to perform usual social or functional activities with intervention or hospitalization indicated. <input type="checkbox"/> <u>Grade 2</u> : Moderate. <input type="checkbox"/> <u>Grade 1</u> : Mild. Not considered an SAE.
Description of the SAE:	
Treatments implemented for the SAE:	
Overall outcome at time of hospital discharge or death:	<input type="checkbox"/> Recovered/ Resolved without Sequelae <input type="checkbox"/> Recovered/ Resolved with sequelae. <input type="checkbox"/> Death <input type="checkbox"/> On-going <input type="checkbox"/> Unknown
Was the SAE reported to the REB?	<input type="checkbox"/> YES <input type="checkbox"/> NO
If YES, please provide the date the SAE was reported to the REB:	Date (dd/mmm/yyyy): <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / 20 <input type="text"/> <input type="text"/>

PI/Co-I or Coordinator Signature: _____ Date (dd/mmm/yyyy): _____