

FORM 1: Eligibility and Enrollment

YES	NO	Inclusion Criteria:
☐	☐	Age $\geq$ 18 years
☐	☐	Weight $\geq$ 55 kg
☐	☐	Plan to initiate CRRT or within 24 hours of having started CRRT for AKI
☐	☐	Expected to survive and receive CRRT for a duration of $\geq$ 48 hours.
☐	☐	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:
☐	☐	Indication for sustained higher dose-intensity CRRT
☐	☐	End-stage kidney disease receiving maintenance dialysis
☐	☐	Receipt of any RRT for AKI during the current hospitalization
☐	☐	Inability to comply with the requirements of the study protocol
YES	NO	Eligibility:
☐	☐	Was “YES” answered for all inclusion criteria?
☐	☐	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:
☐	☐	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:
☐	☐	Was consent/deferred consent obtained <u>prior to randomization</u> ?
Type of Consent obtained:		
☐	Participant consent	
☐	Substitute Decision Maker (SDM) or Legally Authorized Representative (LAR) consent	
☐	Deferred consent with assent of the clinical team	
If YES		Date (dd/mmm/yyyy) of consent/deferred consent signatures: / / 20 Time (24 hr clock) of consent/deferred consent signatures: :
YES	NO	Registration in REDCap:
☐	☐	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:
☐	☐	Was the participant enrolled on the study in REDCap?
If YES		Complete Randomization in REDCap and enter the information below.
YES	NO	Randomization:
☐	☐	Date: / / 20 Time: :
Allocated Study Arm:		☐ Low Dose-Intensity Arm ☐ 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

☐ This section is Not Applicable if Deferred Consent was <u>not</u> selected above.		
YES	NO	Consent Post-Randomization following Deferred Consent:
☐	☐	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:		
☐	Participant consent	
☐	Substitute Decision Maker (SDM) or Legally Authorized Representative (LAR) consent	
If YES	Date (dd/mmm/yyyy) of consent: / / 20 Time (24 hr clock) of consent: :	
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?
☐	☐	

☐ 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:
☐	☐	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: / / 20 Time (24 hr clock) of consent: :	
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						
☐	☐	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				☐ Male ☐ Female			
Receiving invasive mechanical ventilation				☐ YES ☐ NO			
Receiving any vasoactive therapy				☐ YES ☐ 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	☐	> 400	≤ 400 ± respiratory support	≤ 300 ± respiratory support	≤ 200 + respiratory support	< 100 + respiratory support
Coagulation	Platelets	☐	>150	101-150	50-100	20-49	<20
Hepatic	Bilirubin	☐	< 20 µmol/L	20-32 µmol/L	33-101 µmol/L	102-204 µmol/L	>204 µmol/L
CNS	GCS	☐	15	13-14	10-12	6-9	<6
Cardiovascular	MAP + support	☐	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	☐	≤ 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		☐ ☐ (max 24; range 0-24)					
Death in ICU				☐ YES ☐ NO			
Death in hospital				☐ YES ☐ NO			
Receiving RRT at ICU discharge				☐ YES ☐ NO			
Receiving RRT at hospital discharge				☐ YES ☐ NO			

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

FORM 2: Eligible But Not Enrolled

Reason for exclusion:	☐ Clinician refusal ☐ 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	☐ Male ☐ Female
Weight (earliest available upon admission, estimated or actual)	_____. ____ kg
Height (estimated or actual)	_____. ____ cm
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	☐ Emergency Department ☐ Hospital Ward ☐ Operating Theatre ☐ Direct transfer (other ICU) ☐ Other, Specify: _____
Surgical (surgical procedure within 7 days)	☐ YES ☐ NO
If YES, unplanned (emergency) procedure	☐ YES ☐ NO
Primary Diagnostic Category (Select one)	
☐	Cardiovascular
☐	Respiratory
☐	Gastrointestinal/hepatic
☐	Neurological
☐	Hematologic/Oncologic

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

☐	Kidney/Urologic	
☐	Metabolic/Endocrinologic/Toxic	
☐	Sepsis	
☐	Trauma	
☐	Other, Specify: _____	
Kidney Function		
Baseline serum creatinine (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)		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	
☐	☐	Hypertension
☐	☐	Diabetes mellitus
☐	☐	Heart failure
☐	☐	Coronary artery disease
☐	☐	Peripheral vascular disease
☐	☐	Cerebrovascular disease
☐	☐	Liver disease
☐	☐	Chronic lung disease
☐	☐	Immunosuppression
☐	☐	Leukemia/lymphoma
☐	☐	Solid organ tumor or metastatic disease

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

FORM 3: BASELINE

Clinical Frailty Scale (CFS) score	☐ 1 – <u>Very Fit</u> – robust, active, energetic, and motivated. ☐ 2 – <u>Fit</u> – no active disease symptoms but are less fit, active occasionally. ☐ 3 – <u>Managing Well</u> – well controlled medical problems, not regularly active. ☐ 4 – <u>Living With Very Mild Frailty</u> – not dependent, symptoms limit activities. ☐ 5 – <u>Living With Mild Frailty</u> – more evident slowing, needs help with high order instrumental activities of daily living. ☐ 6 – <u>Living With Moderate Frailty</u> – needs help with all outside activities, keeping house, bathing, and often have problems with stairs. ☐ 7 – <u>Living With Severe Frailty</u> – complete dependence for personal care (physical or cognitive), stable not at risk of dying. ☐ 8 – <u>Living With Very Severe Frailty</u> – approaching end of life, unlikely to recover from minor illness. ☐ 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/mm/yyyy): _____

FORM 4: PRE-RANDOMIZED ACUITY/ORGAN DYSFUNCTION

Acuity and Organ Dysfunction Scores		
APACHE II score at ICU admission* (if auto-calculated in EMR)		☐ Not Available
SAPS III score at ICU admission* (if auto-calculated in EMR)		☐ 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	☐ Not Available
Heart rate	beats/min	☐ Not Available
GCS		☐ Not Available
WBC count	x 10 ⁹ /L	☐ Not Available
Blood pH (arterial pH preferred, serum pH acceptable)		☐ Not Available
If no pH, Serum HCO ₃	mmol/L	☐ Not Available
Serum Creatinine	μmol/L	☐ Not Available
APACHE II Parameters (worst value during 24 hr prior to randomization)		
Mean Arterial Pressure (MAP)	mmHg	☐ Not Available
Respiratory Rate (non-ventilated or ventilated)	breaths/min	☐ Not Available
Oxygenation: (based on FiO₂ value not all other oxygenation values will need to be reported in REDCap)		
FiO ₂ (fraction of inspired oxygen)		☐ Not Available
PCO ₂ (partial pressure of CO₂)	mmHg	☐ Not Available
PO ₂ (partial pressure of oxygen)	mmHg	☐ Not Available
PaO ₂ (partial pressure of oxygen in arterial blood)	mmHg	☐ Not Available
Serum Sodium	mmol/L	☐ Not Available
Serum Potassium	mmol/L	☐ Not Available
Hematocrit	%	☐ Not Available

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

FORM 4: PRE-RANDOMIZED ACUITY/ORGAN DYSFUNCTION

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

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

FORM 4: PRE-RANDOMIZED ACUITY/ORGAN DYSFUNCTION

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

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

FORM 4: PRE-RANDOMIZED ACUITY/ORGAN DYSFUNCTION

	☐ Neurosurgery: Cerebrovascular accident ☐ All others (default)	
Acute Infection at ICU Admission	☐ Nosocomial ☐ Respiratory ☐ None/Other	
Total bilirubin	$\mu\text{mol/L}$	☐ Not Available
Platelet Count	$\times 10^9/\text{L}$	☐ Not Available
Systolic Blood Pressure	mmHg	☐ Not Available
Oxygenation	☐ Mechanical ventilation ☐ No mechanical ventilation	☐ 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	☐	> 400	≤ 400 ± respiratory support	≤ 300 ± respiratory support	≤ 200 + respiratory support	< 100 + respiratory support
Coagulation	Platelets	☐	>150	101-150	50-100	20-49	<20
Hepatic	Bilirubin	☐	< 20 µmol/L	20-32 µmol/L	33-101 µmol/L	102-204 µmol/L	>204 µmol/L
CNS	GCS	☐	15	13-14	10-12	6-9	<6
Cardiovascular	MAP + support	☐	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	☐	≤ 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	☐ ☐ (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	g/L	☐ Not Available
INR	.	☐ Not Available
Serum phosphate	mmol/L	☐ Not Available
Serum ionized calcium	mmol/L	☐ Not Available
Serum total calcium	mmol/L	☐ Not Available

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

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

FORM 4: PRE-RANDOMIZED ACUITY/ORGAN DYSFUNCTION

Angiotensin II infusion	☐ YES ☐ NO Dose _{MAX} . µg/kg/min	☐ Not Available
Dopamine infusion	☐ YES ☐ NO Dose _{MAX} . µg/kg/min	☐ Not Available
Dobutamine infusion	☐ YES ☐ NO Dose _{MAX} . µg/kg/min	☐ Not Available
Milrinone infusion	☐ YES ☐ NO Dose _{MAX} . µg/kg/min	☐ Not Available
Levosimendan infusion	☐ YES ☐ NO Dose _{MAX} . µg/kg/min	☐ Not Available
Enteral nutrition	☐ YES ☐ NO	☐ Not Available
Parenteral nutrition	☐ YES ☐ NO	☐ 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): □□/□□□/20□□ Time (24 hr clock): □□:□□
Vascular access catheter	☐ Right internal jugular vein ☐ Left internal jugular vein ☐ Right femoral vein ☐ Left femoral vein ☐ Permanent catheter (tunneled) ☐ Other, specify: _____
CRRT dose-intensity being received at time of randomization	
☐ 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)	□□□□ mL/hr
Dose (hemofiltration)	□□□□ mL/hr
Hemofiltration – pre-filter	□□□□ mL/hr
Hemofiltration – post-filter	□□□□ mL/hr
Dose (dialysate)	□□□□ mL/hr
CRRT anticoagulation prescribed	☐ No anticoagulation given ☐ Citrate (4% trisodium citrate) ☐ Citrate (18/0 dilute solution) ☐ Citrate (ACD-A) ☐ Unfractionated heparin ☐ LMWH ☐ Other, specify: _____
Study Allocated CRRT Initiation:	Date (dd/mmm/yyyy): □□/□□□/20□□ Time (24 hr clock): □□:□□

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	hr : min	hr : min	hr : min	hr : min	hr : min	hr : min	hr : min
Mode	☐ CVVH ☐ CVVHD ☐ CVVHDF	☐ CVVH ☐ CVVHD ☐ CVVHDF	☐ CVVH ☐ CVVHD ☐ CVVHDF	☐ CVVH ☐ CVVHD ☐ CVVHDF	☐ CVVH ☐ CVVHD ☐ CVVHDF	☐ CVVH ☐ CVVHD ☐ CVVHDF	☐ CVVH ☐ CVVHD ☐ CVVHDF
Blood flow rate	mL/min	mL/min	mL/min	mL/min	mL/min	mL/min	mL/min
Dose (total effluent)	mL	mL	mL	mL	mL	mL	mL
Dose (hemofiltration)	mL	mL	mL	mL	mL	mL	mL
Hemofiltration – pre-filter	mL	mL	mL	mL	mL	mL	mL
Hemofiltration – post-filter	mL	mL	mL	mL	mL	mL	mL
Dose (dialysate)	mL	mL	mL	mL	mL	mL	mL
Dose (total mean)	mL/kg/hr	mL/kg/hr	mL/kg/hr	mL/kg/hr	mL/kg/hr	mL/kg/hr	mL/kg/hr
Dose (highest hourly)	mL/kg/hr	mL/kg/hr	mL/kg/hr	mL/kg/hr	mL/kg/hr	mL/kg/hr	mL/kg/hr
Dose (lowest hourly)	mL/kg/hr	mL/kg/hr	mL/kg/hr	mL/kg/hr	mL/kg/hr	mL/kg/hr	mL/kg/hr
Number of Filter Changes							
Ultrafiltration (total) (mL)	+ / -	+ / -	+ / -	+ / -	+ / -	+ / -	+ / -
Fluid balance (total) (mL)	+ / -	+ / -	+ / -	+ / -	+ / -	+ / -	+ / -
Urine output (mL)							
Serum Base Excess	+ / -	+ / -	+ / -	+ / -	+ / -	+ / -	+ / -

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
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	☐ YES ☐ NO	☐ YES ☐ NO	☐ YES ☐ NO	☐ YES ☐ NO	☐ YES ☐ NO	☐ YES ☐ NO	☐ YES ☐ 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 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 IRR	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO
Receipt of IMV	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO
Receipt of NIV	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO
Receipt of HFO ₂	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO
Receipt of any vasoactive	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO
Transfused RBC	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO
Transfused FFP	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO
Transfused PLT	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO
Supplementation Given?	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO
If Yes, select those that apply:	☐ Mg+ ☐ K+ ☐ PO4- ☐ HCO3- ☐ Protein ☐ Multivitamins	☐ Mg+ ☐ K+ ☐ PO4- ☐ HCO3- ☐ Protein ☐ Multivitamins	☐ Mg+ ☐ K+ ☐ PO4- ☐ HCO3- ☐ Protein ☐ Multivitamins	☐ Mg+ ☐ K+ ☐ PO4- ☐ HCO3- ☐ Protein ☐ Multivitamins	☐ Mg+ ☐ K+ ☐ PO4- ☐ HCO3- ☐ Protein ☐ Multivitamins	☐ Mg+ ☐ K+ ☐ PO4- ☐ HCO3- ☐ Protein ☐ Multivitamins	☐ Mg+ ☐ K+ ☐ PO4- ☐ HCO3- ☐ Protein ☐ Multivitamins
If Mg+ given, number of doses							
If Mg+ given, cumulative dose	grams	grams	grams	grams	grams	grams	grams

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
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	hr : min	hr : min	hr : min	hr : min	hr : min	hr : min	hr : min
Mode	☐ CVVH ☐ CVVHD ☐ CVVHDF	☐ CVVH ☐ CVVHD ☐ CVVHDF	☐ CVVH ☐ CVVHD ☐ CVVHDF	☐ CVVH ☐ CVVHD ☐ CVVHDF	☐ CVVH ☐ CVVHD ☐ CVVHDF	☐ CVVH ☐ CVVHD ☐ CVVHDF	☐ CVVH ☐ CVVHD ☐ CVVHDF
Blood flow rate	mL/min	mL/min	mL/min	mL/min	mL/min	mL/min	mL/min
Dose (total effluent)	mL	mL	mL	mL	mL	mL	mL
Dose (hemofiltration)	mL	mL	mL	mL	mL	mL	mL
Hemofiltration – pre-filter	mL	mL	mL	mL	mL	mL	mL
Hemofiltration – post-filter	mL	mL	mL	mL	mL	mL	mL
Dose (dialysate)	mL	mL	mL	mL	mL	mL	mL
Dose (total mean)	mL/kg/hr	mL/kg/hr	mL/kg/hr	mL/kg/hr	mL/kg/hr	mL/kg/hr	mL/kg/hr
Dose (highest hourly)	mL/kg/hr	mL/kg/hr	mL/kg/hr	mL/kg/hr	mL/kg/hr	mL/kg/hr	mL/kg/hr
Dose (lowest hourly)	mL/kg/hr	mL/kg/hr	mL/kg/hr	mL/kg/hr	mL/kg/hr	mL/kg/hr	mL/kg/hr
Number of Filter Changes							
Ultrafiltration (total) (mL)	+ / -	+ / -	+ / -	+ / -	+ / -	+ / -	+ / -
Fluid balance (total) (mL)	+ / -	+ / -	+ / -	+ / -	+ / -	+ / -	+ / -
Urine output (mL)							
Serum Base Excess	+ / -	+ / -	+ / -	+ / -	+ / -	+ / -	+ / -

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	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ 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	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO
Receipt of IMV	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO
Receipt of NIV	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO
Receipt of HFO ₂	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO
Receipt of any vasoactive	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO
Transfused RBC	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO
Transfused FFP	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO
Transfused PLT	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO
Supplementation Given?	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO	☐ YES : ☐ NO
If Yes, select those that apply:	☐ Mg+ ☐ K+ ☐ PO ₄ - ☐ HCO ₃ - ☐ Protein ☐ Multivitamins	☐ Mg+ ☐ K+ ☐ PO ₄ - ☐ HCO ₃ - ☐ Protein ☐ Multivitamins	☐ Mg+ ☐ K+ ☐ PO ₄ - ☐ HCO ₃ - ☐ Protein ☐ Multivitamins	☐ Mg+ ☐ K+ ☐ PO ₄ - ☐ HCO ₃ - ☐ Protein ☐ Multivitamins	☐ Mg+ ☐ K+ ☐ PO ₄ - ☐ HCO ₃ - ☐ Protein ☐ Multivitamins	☐ Mg+ ☐ K+ ☐ PO ₄ - ☐ HCO ₃ - ☐ Protein ☐ Multivitamins	☐ Mg+ ☐ K+ ☐ PO ₄ - ☐ HCO ₃ - ☐ Protein ☐ Multivitamins
If Mg+ given, number of doses							
If Mg+ given, cumulative dose	grams	grams	grams	grams	grams	grams	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:	☐ Death or withdrawal of life-sustaining therapy ☐ Transition to IRRT ☐ Kidney recovery (no longer needed)	
Kidney Outcomes		
Did the participant receive RRT after CRRT discontinuation?	☐ YES ☐ NO	
RRT at ICU discharge:	☐ YES ☐ NO ☐ Not Available	
RRT at Hospital discharge:	☐ YES ☐ NO ☐ Not Available	
RRT at 30-days (from enrollment):	☐ YES ☐ NO ☐ Not Available	
RRT at 90-days (from enrollment):	☐ YES ☐ NO ☐ Not Available	
Last date of receipt of RRT:	Date (dd/mmm/yyyy): □□/□□□/20□□	
Serum creatinine at ICU discharge:	□□□□ μmol/L	☐ Not Available
Serum creatinine at hospital discharge:	□□□□ μmol/L	☐ Not Available
Serum creatinine at 90-days (+/- 2 wks)	□□□□ μmol/L	☐ Not Available
Mortality		
Death in ICU:	☐ YES ☐ NO ☐ Not Available	
Death in Hospital:	☐ YES ☐ NO ☐ Not Available	
Death at 30-days (from enrollment):	☐ YES ☐ NO ☐ Not Available	
Death at 90-days (from enrollment):	☐ YES ☐ NO ☐ 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):	☐ YES ☐ NO ☐ Not Available
End of Study	
Did the participant complete the study and vital status assessment at 90 days?	☐ YES ☐ 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:	☐ Withdrawal of Consent ☐ Lost to Follow-up ☐ 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?	☐ Consent procedures ☐ Inclusion/Exclusion criteria ☐ Study Procedures - Did not begin receiving study-prescribed CRRT within the protocol specified timelines ☐ Study Procedures - Received incorrect CRRT prescription ☐ Study Procedures – CRRT dose escalated above the protocol mandated dose-intensity target ☐ Study Procedures - Other ☐ Breach in confidentiality ☐ SAE reporting ☐ Other, specify: _____
If selected, Study Procedures – CRRT dose escalated above the protocol mandated dose-intensity target, specify the reason for dose escalation	☐ Inadequate acid-base control ☐ Inadequate electrolyte control ☐ Inadequate azotemic control ☐ 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?	☐ YES ☐ NO
If YES, provide details:	
Did the participant continue with the study:	☐ YES ☐ NO
Was the protocol deviation reported to the REB?	☐ YES ☐ 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
		☐ Mild ☐ Moderate ☐ Severe ☐ Life threatening ☐ Death	☐ Definitely ☐ Probably ☐ Possibly ☐ Unlikely ☐ Unrelated	☐ Yes ☐ No	☐ Yes ☐ No	☐ Unchanged ☐ Dose decreased ☐ Temporarily withheld ☐ Permanently discontinued	☐ Unknown ☐ Resolved without sequelae ☐ Resolved with sequelae ☐ Death ☐ 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):	
		☐ Mild ☐ Moderate ☐ Severe ☐ Life threatening ☐ Death	☐ Definitely ☐ Probably ☐ Possibly ☐ Unlikely ☐ Unrelated	☐ Yes ☐ No	☐ Yes ☐ No	☐ Unchanged ☐ Dose decreased ☐ Temporarily withheld ☐ Permanently discontinued	☐ Unknown ☐ Resolved without sequelae ☐ Resolved with sequelae ☐ Death ☐ Ongoing	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy
REPORTER SIGNATURE:			REPORTER SIGNATURE DATE (dd-mmm-yyyy):			INVESTIGATOR SIGNATURE:			INVESTIGATOR SIGNATURE DATE 5 (dd-mmm-yyyy):	
		☐ Mild ☐ Moderate ☐ Severe ☐ Life threatening ☐ Death	☐ Definitely ☐ Probably ☐ Possibly ☐ Unlikely ☐ Unrelated	☐ Yes ☐ No	☐ Yes ☐ No	☐ Unchanged ☐ Dose decreased ☐ Temporarily withheld ☐ Permanently discontinued	☐ Unknown ☐ Resolved without sequelae ☐ Resolved with sequelae ☐ Death ☐ 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?	☐ YES ☐ NO
Date/time of SAE:	Date (dd/mmm/yyyy): / / /20
Grade	☐ <u>Grade 5</u> : Death. Resulted in patient death. ☐ <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. ☐ <u>Grade 3</u> : Severe. Severe symptoms causing inability to perform usual social or functional activities with intervention or hospitalization indicated. ☐ <u>Grade 2</u> : Moderate. ☐ <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:	☐ Recovered/ Resolved without Sequelae ☐ Recovered/ Resolved with sequelae. ☐ Death ☐ On-going ☐ Unknown
Was the SAE reported to the REB?	☐ YES ☐ NO
If YES, please provide the date the SAE was reported to the REB:	Date (dd/mmm/yyyy): / / /20

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