Subject ID: ___ ___ ___ - ___ ___ ___ ___

STandard versus Accelerated initiation of Renal Replacement Therapy in Acute Kidney Injury (STARRT-AKI): A Multi-Centre, Randomized, Controlled Trial

CRF Version 4.0
April 2, 2018

PART I:

ELIGIBILITY AND ENROLLMENT

Subject ID: ___ ___ ___ - ___ ___ ___ ___

FORM 1 –ELIGIBILITY

INCLUSION CRITERIA (Each of criteria 1 through 5 must be fulfilled at the time of screening assessment)	
1. Age ≥ 18 years	☐ Y ☐ N
2. Admission to a critical care unit (ICU)	☐ Y ☐ N
3. Evidence of kidney dysfunction [serum creatinine ≥100 μmol/L (1.1 mg/dL) in women and ≥130 μmol/L (1.5 mg/dL) in men]	☐ Y ☐ N
4. Evidence of severe AKI, defined by at least ONE of the following three criteria:	
i) ≥2-fold increase in serum creatinine (sCR) from baseline§ (see definition below) or during the current hospitalization; OR	☐ Y ☐ N
ii) Achievement of a serum creatinine ≥ 354 μmol/L (4.0 mg/dL) with evidence of a minimum increase of 27 μmol/L (0.3 mg/dL) from a pre-morbid baseline§ (see definition below) or during the current hospitalization OR	☐ Y ☐ N
iii) Urine output < 6.0 mL/kg over the preceding 12 hours	☐ Y ☐ N
§ Baseline serum creatinine will be defined as the outpatient (pre-morbid) serum creatinine closest to the date of hospitalization and within 365 days prior to index hospitalization or if unavailable, the lowest serum creatinine documented during the current hospitalization. Please insert value used	☐☐☐ μmol/L
EXCLUSION CRITERIA (Any one criterion fulfilled and the patient is ineligible)	
1. Serum potassium > 5.5 mmol/L	☐ Y ☐ N
2. Serum bicarbonate < 15 mmol/L	☐ Y ☐ N
3. Presence of a drug overdose that necessitates initiation of RRT	☐ Y ☐ N
4. Lack of commitment to ongoing life support (including RRT)	☐ Y ☐ N
5. Any RRT within the previous 2 months (either acute or chronic RRT)	☐ Y ☐ N
6. Kidney transplant within the last 365 days	☐ Y ☐ N
7. Known pre-hospitalization advanced chronic kidney disease, defined by an eGFR <20 mL/min/1.73m^2	☐ Y ☐ N
8. Presence or clinical suspicion of renal obstruction, rapidly progressive glomerulonephritis, vasculitis, thrombotic microangiopathy, or acute interstitial nephritis	☐ Y ☐ N
9. Clinician(s) caring for patient believe(s) that immediate RRT is absolutely mandated *(If YES, remember to complete Form 3)*	☐ Y ☐ N
If YES, ask clinician(s) for the ONE main reason for their opinion that immediate RRT is mandated	☐ Patient has life-threatening volume overload ☐ Patient has a life-threatening acid-base disturbance ☐ Patient has a life-threatening electrolyte abnormality ☐ Patient has severe non-renal organ dysfunction ☐ Patient has another compelling reason to initiate dialysis (please specify): _____
10. Clinician(s) caring for patient believe(s) that deferral of RRT initiation is mandated *(If YES, remember to complete Form 3)*	☐ Y ☐ N
If YES, ask clinician(s) for the ONE main reason for their opinion that deferral of RRT is mandated	☐ There is no evidence of volume overload ☐ Vascular access would not be feasible

Subject ID: ___ ___ ___ - ___ ___ ___ ___

	☐ Patient will soon recover kidney function ☐ Patient is clinically improving in non-renal domains ☐ Patient has another compelling reason to defer RRT (please specify): _____
ELIGIBILITY	
According to the screening criteria above, is the patient eligible for the study?	☐ Y ☐ N
If YES, date (dd/mmm/yyyy) of full eligibility:	☐☐/☐☐☐/☐☐☐☐
Time (24h clock) of full eligibility:	☐☐:☐☐
PROVISIONAL ELIGIBILITY	
Date (dd/mmm/yyyy) of provisional eligibility:	☐☐/☐☐☐/☐☐☐☐
Time (24h clock) of provisional eligibility:	☐☐:☐☐

Eligibility reviewed by: _____ Signature: _____
(print investigator name)

Date: ____/____/____ Time (24h): _____:_____
dd mmm yyyy)

Subject ID: ___ ___ ___ - ___ ___ ___ ___

FORM 2 – CONSENT

1a) Was consent of ANY approved type (from patient or substitute decision maker) OR was a decision taken to randomize the patient using a deferred/delayed) consent mechanism (at sites where permitted)? *(If NO, remember to complete Form 3)*	☐ Y ☐ N	
1b) If NO, reason for inability to obtain consent within 12 hours	☐ Patient refusal ☐ Patient could not come to final decision within 12 hours of eligibility ☐ SDM refusal (when patient lacks capacity) ☐ SDM could not come to final decision within 12 hours of eligibility ☐ Inability to contact a SDM during the 12 hour period after fulfilling eligibility and deferred/delayed consent not an option ☐ Other, specify: _____	
2a) Date of initial consent (from patient or SDM), OR documentation for use of deferred/delayed consent	☐☐/☐☐☐/☐☐☐☐ ***(dd/mmm/yyyy)***	
2b) Time of initial consent (24h) OR documentation of use of deferred/delayed consent model	☐☐:☐☐ *24 hour clock*	
3) What type of consent model was used for study entry (i.e., prior to randomization)?	☐ Patient consent ☐ Deferred/delayed consent model (Go to Q5)	☐ SDM consent (Go to Q4) ☐ Other, specify: _____
4) If SDM consent (in person or via telephone) was obtained for study entry, was consent ultimately obtained from the patient to continue participation in STARRT-AKI post-randomization?	☐ **Yes** **Date of Patient Consent:** ☐☐/☐☐☐/☐☐☐☐ **(dd/mmm/yyyy)** **Time (24h):** ☐☐:☐☐	☐ **No; Why not?** ☐ Patient did not regain capacity ☐ Patient refused ☐ N/A
5) If a deferred/delayed consent model was used, was consent obtained to continue participation in STARRT-AKI post-randomization?	☐ **Yes** **By what method(s) was consent to continue participation in STARRT-AKI post-randomization obtained?** ***(Check all that apply)*** ☐ Patient consent ☐ SDM consent ☐ Other, specify: _____	☐ **No** **By what method(s) was consent to continue participation in STARRT-AKI post-randomization either declined or not obtained? (Check all that apply)** ☐ Patient declined ☐ SDM declined ☐ Patient died before consent encounter could take place ☐ Patient lost to follow-up ☐ Patient did not regain capacity and unable to contact a decision maker ☐ Language barrier and no translator available ☐ Other, specify: _____

Subject ID: ___ ___ ___ - ___ ___ ___ ___

FORM 3 –PROVISIONALLY ELIGIBLE BUT NOT RANDOMIZED

(Only complete this form for patients excluded from participation due to exclusion criterion 9, exclusion criterion 10, or an inability to document consent/deferral of consent within 12 hours of meeting full eligibility criteria)

Screening ID	
Age (on the day of eligibility screening)	☐☐☐
Patient Initials:	_____-_____-_____
Sex:	☐ Male ☐ Female
BLOODWORK (last available value at the time of eligibility screening)	
Arterial pH	☐.☐☐
PaO_2/FiO_2	☐☐☐
Serum potassium	☐.☐ mmol/L
Serum bicarbonate	☐☐ mmol/L
Serum Urea or BUN	☐☐.☐ mmol/L or ☐☐ mg/dL
Serum creatinine	☐☐☐☐ µmol/L or ☐☐.☐ mg/dL
INTERVENTIONS (at the time of eligibility assessment)	
Receiving mechanical ventilation? (invasive or non-invasive)	☐ Y ☐ N
Receiving vasopressor(s)(norepinephrine, epinephrine, vasopressin, phenylephrine) and/or inotrope(s) (dobutamine, milrinone)?	☐ Y ☐ N

SOFA (most extreme result for each component in the 24 hours preceding eligibility assessment) – see appendix

SOFA Score		**0**	**1**	**2**	**3**	**4**
Respiration	PaO2/FiO2	> 400	≤ 400 ± resp support	≤ 300 ± resp support	≤ 200 + resp support	< 100 + resp support
	Score:	☐	☐	☐	☐	☐
Coagulation	Platelets ($x10^9$/L)	>150	101- 150	50-100	20-49	<20
	Score:	☐	☐	☐	☐	☐
Liver	Bilirubin	<20 µmol/L (<1.2 mg/dL)	20-32 µmol/L (1.2-1.9 mg/dL)	33-101 µmol/L (2.0-5.9 mg/dL)	102-204 µmol/L (6.0-11.9 mg/dL)	>204 µmol/L (>11.9 mg/dL)
	Score:	☐	☐	☐	☐	☐
Cardiovascular	Blood Pressure and Support Requirements	MAP ≥ 70 mmHg	MAP < 70 mmHg	**DA** ≤ 5 µg/kg/min or **Dobutamine** (any dose) or **Milrinone** (any dose)	**DA** >5 µg/kg/min or **EPI** ≤ 0.1µg/kg/min or **NE** ≤ 0.1 µg/kg/min or **VP** ≤ 1.8 U/hr or **Phenylephrine** (any infusion dose but NOT bolus)	**DA** > 15 µg/kg/min or **EPI** > 0.1µg/kg/min or **NE** > 0.1 µg/kg/min or **VP** >1.8 U/hr
	Score:	☐	☐	☐	☐	☐

Subject ID: ___ ___ ___ - ___ ___ ___ ___

CNS	Glasgow Coma Scale	15	13-14	10-12	6-9	<6
	Score:	☐	☐	☐	☐	☐
Renal	Creatinine	≤ 97 µmol/L (≤1.1 mg/dL)	98 – 168 µmol/L (1.2-1.9mg/dL)	169 – 299 µmol/L (2.0-3.4 mg/dL)	300 – 433 µmol/L (3.5-4.9 mg/dL) or urine output ≤ 500 mL/day	≥ 433 µmol/L (≥5.0 mg/dL) or urine output < 200 mL/d or patient receiving RRT
	Score:	☐	☐	☐	☐	☐
					Total SOFA score:	_____

OUTCOMES	
RRT administered in the hospital?	☐ Y ☐ N
If YES, date started (dd/mmm/yyyy):	☐☐/☐☐☐/☐☐☐☐
Discharged alive from ICU?	☐ Y ☐ N
If YES, date of ICU discharge (dd/mmm/yyyy):	☐☐/☐☐☐/☐☐☐☐
Discharged alive from hospital?	☐ Y ☐ N
If YES: **Date of hospital discharge (dd/mmm/yyyy):** **Final creatinine prior to hospital discharge:** **RRT dependent at hospital discharge?**	 ☐☐/☐☐☐/☐☐☐☐ ☐☐☐☐ µmol/L ☐ Y ☐ N
Death in hospital?	☐ Y ☐ N
If YES, date of death (dd/mmm/yyyy):	☐☐/☐☐☐/☐☐☐☐

Subject ID: ___ ___ ___ - ___ ___ ___ ___

FORM 4 – RANDOMIZATION

RANDOMIZATION (prior to randomizing ensure that patient is fully eligible and that consent or deferral of consent has been documented)	
Date of Randomization (dd-mmm-yyyy)	☐☐/☐☐☐/☐☐☐☐
Time of Randomization (24 hr clock)	☐☐:☐☐
Randomization Arm	☐ Accelerated RRT initiation ☐ Standard RRT initiation
Is this patient randomized in the PLUS (Plasma-Lyte 148® versUs Saline) Study? **If YES:** **What is the PLUS Treatment Pack number for this patient?**	☐ Y ☐ N ☐☐☐☐☐☐☐

PART II:
BASELINE

Subject ID: ___ ___ ___ - ___ ___ ___ ___

FORM 5: DEMOGRAPHICS & DETAILS OF HOSPITALIZATION

DEMOGRAPHICS		
Date of Birth *If you ethics board does not permit collection of a full date of birth, please enter the day as 1, 15, or 30 as per your site requirements.*	☐☐/☐☐☐/☐☐☐☐ (dd-mmm-yyyy)	
Sex	☐ Male ☐ Female	
Race	☐ First Nations ☐ Asian ☐ Black ☐ Hawaiian/Pacific Islander ☐ White ☐ Multi-race ☐ Other	
Ethnicity	☐ Non-Hispanic ☐ Hispanic	
Earliest available weight since admission	☐☐☐.☐ kg	☐☐☐.☐ pounds

DETAILS OF HOSPITALIZATION		
Patient transferred from another acute care hospital?	☐ **Yes** **Date of original hospital admission** (dd-mmm-yyyy): ☐☐/☐☐☐/☐☐☐☐ **Date of transfer to research site** (date of hospital admission at research site - dd-mmm-yyyy): ☐☐/☐☐☐/☐☐☐☐ **Date of ICU admission at research site** (dd-mmm-yyyy)**:** ☐☐/☐☐☐/☐☐☐☐ **Time of ICU admission at research site** (24hr clock)**:** ☐☐:☐☐	☐ **No** **Date of hospital admission at research site** (dd-mmm-yyyy): ☐☐/☐☐☐/☐☐☐☐ **Date of ICU admission** (dd-mmm-yyyy)**:** ☐☐/☐☐☐/☐☐☐☐ **Time of ICU admission** (24hr clock): ☐☐:☐☐
Diagnostic category (check the ONE category most responsible for admission):	☐ Cardiovascular ☐ Respiratory ☐ Gastrointestinal/hepatic ☐ Neurologic ☐ Metabolic ☐ Hematologic ☐ Septic ☐ Trauma ☐ Other, specify _____	

Subject ID: ___ ___ ___ - ___ ___ ___ ___

FORM 6- RISK FACTORS

PRE-HOSPITALIZATION RISK FACTORS		
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 *or* ☐☐.☐ mg/dL **Value obtained from**: ☐ Outpatient setting ☐ Inpatient setting	
Baseline estimated GFR based on CKD-EPI formula (online calculator at http://www.qxmd.com/calculate-online/nephrology/ckd-epi-egfr)	☐☐☐.☐ mL/min/1.73m^2	
Pre-hospitalization urine albumin concentration (closest outpatient value prior to the present hospitalization and no more than 365 days before the current admission date)	☐☐☐☐☐.☐☐ ***or*** ☐ Not available ***or*** ☐ Exceeds upper limit of detection	Units: ☐ mg/L ☐ g/L
Pre-hospitalization urine protein concentration (if urine albumin concentration not available) (closest outpatient value prior to the present hospitalization and no more than 365 days before the current admission date)	☐☐☐☐☐.☐☐ ***or*** ☐ Not available ***or*** ☐ Exceeds upper limit of detection	Units: ☐ mg/L ☐ g/L
Pre-hospitalization urine creatinine concentration (closest outpatient value prior to the present hospitalization and no more than 365 days before the current admission date)	☐☐☐☐☐.☐☐ ***or*** ☐ Not available ***or*** ☐ Exceeds upper limit of detection	Units: ☐ mmol/L ☐ mg/L ☐ g/L
Pre-hospitalization urinalysis (if neither urine albumin concentration nor urine protein concentration are available) (closest outpatient value prior to the present hospitalization and no more than 365 days before the current admission date)	☐ None ☐ 1+ ☐ 2+ ☐ 3+ ☐ Not Available	
Hypertension	☐ Y ☐ N	
Diabetes mellitus	☐ Y ☐ N	
Heart failure	☐ Y ☐ N	
Coronary artery disease	☐ Y ☐ N	
Liver disease	☐ Y ☐ N	
HOSPITAL-ACQUIRED RISK FACTORS FOR AKI		
Cardiopulmonary bypass in the preceding 7 days	☐ Y ☐ N	
Aortic aneurysm repair in the preceding 7 days	☐ Y ☐ N	
Other vascular surgery in the preceding 7 days	☐ Y ☐ N	
Trauma in the preceding 7 days	☐ Y ☐ N	
IV contrast exposure in the preceding 7 days	☐ Y ☐ N	

Subject ID: ___ ___ ___ - ___ ___ ___ ___

Receipt of aminoglycoside in the preceding 7 days	☐ Y ☐ N
Receipt of amphotericin B in the preceding 7 days	☐ Y ☐ N
Obstetric complications in the preceding 7 days	☐ Y ☐ N
SEPSIS	
Has patient met criteria for sepsis (see appendix) in the preceding 72 hours?	☐ Y ☐ N

FORM 7 – PRE-RANDOMIZATION SOFA

SOFA (most extreme result for each component in the 24 hours preceding randomization) – see appendix

SOFA Score		**0**	**1**	**2**	**3**	**4**
Respiration	PaO_2/FiO_2	> 400	≤ 400 ± resp support	≤ 300 ± resp support	≤ 200 + resp support	< 100 + resp support
	Score:	☐	☐	☐	☐	☐
Coagulation	Platelets ($x10^9$/L)	>150	101-150	50-100	20-49	<20
	Score:	☐	☐	☐	☐	☐
Liver	Bilirubin	<20 μmol/L (<1.2 mg/dL)	20-32 μmol/L (1.2-1.9 mg/dL)	33-101 μmol/L (2.0-5.9 mg/dL)	102-204 μmol/L (6.0-11.9 mg/dL)	>204 μmol/L (>11.9 mg/dL)
	Score:	☐	☐	☐	☐	☐
Cardiovascular	Blood Pressure and Support Requirements	Mean Arterial Pressure (MAP) ≥ 70 mmHg	MAP < 70 mmHg	**Dopamine** ≤ 5 μg/kg/min or **Dobutamine** (any dose) or **Milrinone** (any dose)	**Dopamine** >5 μg/kg/min or **Epinephrine** ≤ 0.1μg/kg/min or **Norpinephrine** ≤ 0.1 μg/kg/min or **Vasopressin** ≤ 1.8 U/hr or **Phenylephrine** (any infusion dose but NOT bolus)	**Dopamine** > 15 μg/kg/min or **Epinephrine** > 0.1μg/kg/min or **Norpinephrine** > 0.1 μg/kg/min or **Vasopressin** >1.8 U/hr
	Score:	☐	☐	☐	☐	☐
CNS	Glasgow Coma Scale	15	13-14	10-12	6-9	<6
	Score:	☐	☐	☐	☐	☐
Renal	Creatinine	≤ 97 μmol/L (≤1.1 mg/dL)	98 – 168 μmol/L (1.2-1.9mg/dL)	169 – 299 μmol/L (2.0-3.4 mg/dL)	300 – 433 μmol/L (3.5-4.9 mg/dL) or urine output ≤ 500 mL/day	≥ 433 μmol/L (≥5.0 mg/dL) or urine output < 200 mL/d or patient receiving RRT
	Score:	☐	☐	☐	☐	☐
				Total SOFA score:		_____

Subject ID: ___ ___ ___ - ___ ___ ___ ___

FORM 8 – PRE-RANDOMIZATION SEVERITY OF ILLNESS

SAPS II (Worst value during the 24 hours preceding randomization)		
Heart rate	☐☐☐ beats/min	☐ Not Available
Systolic blood pressure	☐☐☐ mmHg	☐ Not Available
Temperature	☐☐.☐ degrees Celsius ☐☐☐.☐ degrees F	☐ Not Available
Glasgow coma scale	☐☐	☐ Not Available
Mechanical ventilation or CPAP?	☐ Yes ☐ No	
If YES, PaO_2/FiO_2	☐☐☐	☐ Not Available
Urine output in ICU over preceding 24 hours: If patient has been in ICU for under 24 hours, record urine output and specify the duration of collection:	☐☐☐☐ mL ☐☐ hours	☐ Not Available
Blood urea nitrogen	☐☐.☐ mmol/L or ☐☐ mg/dL	☐ Not Available
Serum urea	☐☐.☐ mmol/L or ☐☐ mg/dL	☐ Not Available
Serum sodium	☐☐☐ mmol/L *or*	☐ Not Available
Serum potassium	☐.☐ mmol/L *or*	☐ Not Available
Serum bicarbonate	☐☐ mmol/L *or*	☐ Not Available
Bilirubin	☐☐☐.☐ µmol/L or ☐☐.☐ mg/dL	☐ Not Available
WBC count	☐☐☐.☐ $x10^9/L$ *or*	☐ Not Available
Metastatic cancer	☐ Yes ☐ No	
Hematologic malignancy	☐ Yes ☐ No	
AIDS	☐ Yes ☐ No	
Type of admission:	☐ Scheduled surgical ☐ Unscheduled surgical ☐ Medical	
SAPS II Score (optional – will be calculated at the end of the study):	☐☐☐	

Subject ID: ___ ___ ___ - ___ ___ ___ ___

FORM 9 – PRE-RANDOMIZATION DATA

PHYSIOLOGIC PARAMETERS (last available value from the 24 hours preceding randomization)		
Respiratory rate (breaths/min)	☐☐ *or*	☐ Not Available
Arterial pH	☐.☐☐ *or*	☐ Not Available
Cumulative fluid balance since current ICU admission	(Circle) **+** / **-** ☐☐☐☐☐ mL *or*	☐ Not Available
LABORATORY DATA (last available value from the 24 hours preceding randomization)		
Serum creatinine	☐☐☐☐ µmol/L or ☐☐.☐ mg/dL	☐ Not Available
Hemoglobin	☐☐☐ g/L or ☐☐.☐ g/dL *or*	☐ Not Available
Platelet count	☐☐☐ $x10^9$/L *or*	☐ Not Available
INTERVENTIONS AT TIME OF RANDOMIZATION		
If receiving mechanical ventilation or CPAP	**Maximum PEEP :** ☐☐ cmH_20 **or** ☐ Not Applicable	
	Mean Airway Pressure ☐☐ cmH_20 **or** ☐ Not Applicable	
Max dose of norepinephrine	☐.☐☐ µg/kg/min *or*	☐ Not Applicable
Max dose of epinephrine	☐☐.☐ µg/kg/min *or*	☐ Not Applicable
Max dose of vasopressin	☐.☐ units/hour *or*	☐ Not Applicable
Max dose of phenylephrine	☐☐.☐ µg/kg/min *or*	☐ Not Applicable
Max dose of dopamine	☐☐.☐ µg/kg/min *or*	☐ Not Applicable
Max dose of dobutamine	☐☐.☐ µg/kg/min *or*	☐ Not Applicable
Max dose of levosimendan	☐☐.☐ µg/kg/min *or*	☐ Not Applicable
Max dose of milrinone	☐.☐☐☐ µg/kg/min *or*	☐ Not Applicable
Receipt of diuretic 24 hours preceding randomization?	☐ Yes ☐ No	
Receipt of total parenteral nutrition (TPN)?	☐ Yes ☐ No	
Receipt of enteral nutrition?	☐ Yes ☐ No	

QUALITY OF LIFE ASSESSMENTS AT BASELINE (see appendix)	
EQ-5D-5L Assessment completed by:	☐ Patient ☐ SDM/Other ☐ Not done
Mobility (score 1-5; missing 9)	☐
Self-care (score 1-5; missing 9)	☐
Usual activities (score 1-5; missing 9)	☐
Pain/discomfort (score 1-5; missing 9)	☐
Anxiety/depression (score 1-5; missing 9)	☐
EQ-VAS score (score 0 – 100)	☐☐☐

Subject ID: ___ ___ ___ - ___ ___ ___ ___

CLINICAL FRAILTY SCORE

☐ 1- Very Fit – robust, active, energetic and motivated
☐ 2- Well –no active disease symptoms but are less fit, active occasionally
☐ 3- Managing Well –well controlled medical problems, not regularly active
☐ 4- Vulnerable – not dependent, symptoms limit activities
☐ 5- Mildly Frail – more evident slowing need help with high order independent activities of daily living
☐ 6- Moderately Frail – need help with all outside activities, keeping house, bathing, and often have problems with stairs
☐ 7- Severely Frail – complete dependence for personal care (physical or cognitive)
☐ 8- Very Severely Frail –approaching end of life, unlikely to recover from minor illness.
☐ 9- Terminally Ill – life expectancy <6 months who are not otherwise evidently frail

PART III: DAILY DATA
DAY 0 TO DAY 14

Subject ID: ___ ___ ___ - ___ ___ ___ ___

FORM 10 – DAILY DATA: DAYS 0 TO 14

Note: Record the first value of the day. Daily Data is only collected when patient is in the ICU.

Assessment Day (Day 0=Day of Randomization)	☐ **Day 0** ☐ **Day 1** ☐ **Day 2** ☐ **Day 3** ☐ **Day 4** ☐ **Day 5** ☐ **Day 6** ☐ **Day 7** ☐ **Day 8** ☐ **Day 9** ☐ **Day 10** ☐ **Day 11** ☐ **Day 12** ☐ **Day 13** ☐ **Day 14**
Assessment Date (dd-mmm-yyyy)	☐☐/☐☐☐/☐☐☐☐
LABORATORY AND PHYSIOLOGIC PARAMETERS	
Urine Output on study day	☐☐☐☐ mL
Hours of urine collection	☐☐:☐☐ 24h
Total fluid balance	☐☐☐☐ mL
Serum Creatinine	☐☐☐☐ μmol/L or ☐☐.☐ mg/dL
Serum Potassium	☐.☐ mmol/L *If serum potassium was <3.0 at any time during the study day, and if this event was deemed to be related to study procedures, then please complete the AE form.*
Serum Phosphate	☐.☐ mmol/L *If serum phosphate was <0.5 at any time during the study day, and if this event was deemed to be related to study procedures, then please complete the AE form.*
Serum Bicarbonate	☐☐ mmol/L
Arterial pH	☐.☐☐
Ionized calcium	☐.☐☐mmol/L *If ionized calcium was <0.90 at any time during the study day, and if this event was deemed to be related to study procedures, then please complete the AE form.*
PaO_2/FiO_2	☐☐☐
Haemoglobin	☐☐☐ g/L ☐☐.☐ g/dL
RENAL REPLACEMENT THERAPY	
Receiving RRT on study day? (Y/N)	☐Yes ☐No
If YES, was RRT *initiated* for the first time since randomization on study day?	☐Yes ☐N/A- initiated on previous study day
If receiving RRT on study day, RRT	☐IHD ☐SLED

modality	☐ CRRT; dose prescribed _____mL/kg/hr
Duration prescribed	☐☐ hours ☐☐ minutes
Anticoagulation	☐ IV heparin ☐ regional citrate ☐ None ☐ Other, specify: _____
Ultrafiltration achieved	☐☐☐ mL
VASCULAR ACCESS	
Vascular access inserted on study day?	☐ Yes **SITE:** ☐ IJ ☐ Subclavian ☐ Femoral **SIDE** ☐ Right ☐ Left ☐ No

***Criteria for RRT initiation in the standard arm:**

a) Persistent severe AKI defined as sCr that remains > 50% of the value recorded at randomization

AND at least one of the following indications for RRT initiation:

a) Serum potassium ≥ 6.0 mmol/L, or
b) pH < 7.20 or serum bicarbonate ≤ 12 mmol/L, or
c) Evidence of severe respiratory failure, based on a PaO_2/FiO_2 < 200 and clinical perception of volume overload, or
d) Persistent severe AKI (sCr remains > 50% the value recorded at randomization) for > 72 hours from randomization

Subject ID: ___ ___ ___ - ___ ___ ___ ___

FORM 11 – RRT INITIATION DATA

Date and Time of RRT Initiation (insert the *calendar* date and time of RRT initiation)	
Date of RRT Initiation (dd/mmm/yyyy)	☐☐/☐☐☐/☐☐☐☐
Time of RRT Initiation	☐☐:☐☐ 24h

SOFA at RRT Initiation (use last available result prior to RRT initiation for each component)

SOFA Score		**0**	**1**	**2**	**3**	**4**
Respiration	PaO_2/FiO_2	> 400	≤ 400 ± resp support	≤ 300 ± resp support	≤ 200 + resp support	< 100 + resp support
	Score:	☐	☐	☐	☐	☐
Coagulation	Platelets ($x10^9$/L)	>150	101-150	50-100	20-49	<20
	Score:	☐	☐	☐	☐	☐
Liver	Bilirubin	<20 µmol/L (<1.2 mg/dL)	20-32 µmol/L (1.2-1.9 mg/dL)	33-101 µmol/L (2.0-5.9 mg/dL)	102-204 µmol/L (6.0-11.9 mg/dL)	>204 µmol/L (>11.9 mg/dL)
	Score:	☐	☐	☐	☐	☐
Cardiovascular	Blood Pressure and Support Requirements	Mean Arterial Pressure (MAP) ≥ 70 mmHg	MAP < 70 mmHg	**Dopamine** ≤ 5 µg/kg/min or **Dobutamine** (any dose) or **Milrinone** (any dose)	**Dopamine** >5 µg/kg/min or **Epinephrine** ≤ 0.1µg/kg/min or **Norpinephrine** ≤ 0.1 µg/kg/min or **Vasopressin** ≤ 1.8 U/hr or **Phenylephrine** (any infusion dose but NOT bolus)	**Dopamine** > 15 µg/kg/min or **Epinephrine** > 0.1µg/kg/min or **Norpinephrine** > 0.1 µg/kg/min or **Vasopressin** >1.8 U/hr
	Score:	☐	☐	☐	☐	☐
CNS	Glasgow Coma Scale	15	13-14	10-12	6-9	<6
	Score:	☐	☐	☐	☐	☐
Renal	Creatinine	≤ 97 µmol/L (≤1.1 mg/dL)	98 – 168 µmol/L (1.2-1.9mg/dL)	169 – 299 µmol/L (2.0-3.4 mg/dL)	300 – 433 µmol/L (3.5-4.9 mg/dL) or urine output ≤ 500 mL/day	≥ 433 µmol/L (≥5.0 mg/dL) or urine output < 200 mL/d or patient receiving RRT
	Score:	☐	☐	☐	☐	☐
					Total SOFA score:	_____

PHYSIOLOGIC PARAMETERS at RRT INITIATION (use last available result prior to RRT initiation)	
Heart rate	☐☐☐ beats/min

Subject ID: ___ ___ ___ - ___ ___ ___ ___

Systolic blood pressure	☐☐☐ mmHg
Temperature	☐☐.☐ degrees Celsius or ☐☐☐.☐ degrees F
Respiratory rate	☐☐ breaths/min
PaO_2/FiO_2	☐☐☐
Urine output in preceding 24h	☐☐☐☐ mL
Fluid balance up to time of RRT initiation	(Circle **+** / **-**) ☐☐☐☐☐ mL
LABORATORY DATA at RRT INITIATION (use last available result prior to RRT initiation)	
Serum creatinine	☐☐☐☐ µmol/L or ☐☐.☐ mg/dL
Blood urea nitrogen	☐☐.☐ mmol/L or ☐☐ mg/dL
Serum urea	☐☐.☐ mmol/L or ☐☐ mg/dL
Serum potassium	☐.☐ mmol/L
Serum bicarbonate	☐☐ mmol/L
Arterial pH	☐☐
Hemoglobin	☐☐☐ g/L or ☐☐.☐ g/dL
RRT INITIATION	
If subject in the Standard arm, was criteria* for initiating RRT met?	☐ Yes ☐ No ☐ N/A Subject in the accelerated arm
<u>If NO,</u> why was RRT initiated? (check all that apply):	☐ Volume overload ☐ Anuria / oliguria ☐ Creatinine increasing / AKI worsening ☐ Other, specify: _____

***Criteria for RRT initiation in the standard arm:**

a. Persistent severe AKI defined as sCr that remains > 50% of the value recorded at randomization

AND at least one of the following indications for RRT initiation:

a. Serum potassium ≥ 6.0 mmol/L, or
b. pH < 7.20 or serum bicarbonate ≤ 12 mmol/L, or
c. Evidence of severe respiratory failure, based on a PaO_2/FiO_2 < 200 and clinical perception of volume overload, or
d. Persistent severe AKI (sCr remains > 50% the value recorded at randomization) for > 72 hours from randomization

Subject ID: ___ ___ ___ - ___ ___ ___ ___

FORM 12 – ADVERSE EVENT DATA

Did the patient experience any adverse events (as defined by protocol) within the 14 days following randomization?	☐ Y ☐ N If 'YES', complete the fields below for EACH adverse event that occurred in the 14 days following randomization
Event number (1, 2, 3, etc):	☐☐

Event Type (check only ONE):

- ☐ **RRT-associated hypotension**
- ☐ **Severe hypophosphatemia** (<0.5 mmol/L)
- ☐ **Severe hypokalemia** (<3.0 mmol/L)
- ☐ **Severe hypocalcemia** (Ionized calcium <0.90 mmol/L)
- ☐ **Allergic reaction to RRT**
- ☐ **Arrhythmia during RRT**
- ☐ **Seizure**
- ☐ **Major Bleeding**
- ☐ **Hemorrhage at site of CVC insertion**
- ☐ **CVC-associated bloodstream infection**
- ☐ **Ultrasonographically confirmed thrombus attributed to CVC**
- ☐ **Pneumothorax following CVC insertion**
- ☐ **Hemothorax following CVC insertion**
- ☐ **Inadvertent arterial puncture at time of CVC insertion**
- ☐ **Other, specify:** _____

Event Details	
Event onset date:	☐☐/☐☐☐/☐☐☐☐
Event stop date:	☐☐/☐☐☐/☐☐☐☐ *or* ☐ ongoing
How was the event related to study procedures?	☐ RRT-associated ☐ CVC-associated ☐ Other, specify : _____
Was event classified as a serious adverse event (SAE)	☐ Yes ☐ No **If YES, serious due to:** (check all that apply)

For this study, a reportable SAE must be considered: ***i.*** *an atypical event, defined as* ***clinically significant and unexpected in the context of critical illness and associated AKI,*** *AND;* ***ii.*** *an event that is at least* ***possibly related*** *to study procedures.*	☐ Patient died ☐ Life-threatening ☐ Involved persistence of signficant disability or incapacity ☐ Involved hospitalization or prolongation of existing hospitalization **If YES, date when Investigator became aware of the SAE:** ☐☐/☐☐☐/☐☐☐☐
Describe adverse event (including any relevant tests / lab data, actions taken, and resolution)	
SAE Resolution	☐ Recovered ☐ Recovered to previous baseline ☐ Significant impairment ☐ Death ☐ Other; Specify:_____

PART IV:
PROTOCOL VIOLATIONS

Subject ID: ___ ___ ___ - ___ ___ ___ ___

FORM 13 – PROTOCOL VIOLATIONS REGARDING THE TIMING OF RRT INITIATION

Was RRT initiated within the specified time intervals mandated by the protocol? The specified time intervals are: • within 12 hours of determination of eligibility in the accelerated arm; • > 12 hours after determination of eligibility in the standard arm	☐ Y ☐ N
If NO and patient was randomized to <u>accelerated</u> RRT initiation, please clarify why RRT was not started within 12 hours of determination of eligibility?	☐ Problem with vascular access ☐ Dialysis machine not available ☐ Change in patient goals of care ☐ Clinical deterioration ☐ Other, specify: _____
If NO and patient was randomized to <u>standard</u> RRT initiation, please clarify why RRT was started within 12 hours of determination of eligibility?	☐ Volume overload ☐ Anuria / oliguria ☐ sCr increasing ☐ Severe acidosis ☐ Severe hyperkalemia ☐ Other, specify: _____

PART V:
DISCHARGE & OUTCOMES

Subject ID: ___ ___ ___ - ___ ___ ___ ___

FORM 14 – ICU AND HOSPITAL DISCHARGE DATA

ICU DISCHARGE/DEATH – Complete for ALL patients	
Alive at ICU discharge?	☐ Y ☐ N ☐ N/A, still in ICU at Day 90
If YES: **Date of ICU discharge** (dd-mmm-yyyy):	☐☐/☐☐☐/☐☐☐☐
Disposition at time of ICU discharge:	☐ General Ward ☐ Chronic care facility ☐ Other acute care hospital ☐ Other, specify: _____ ☐ Step-down unit ☐ Palliative care ward ☐ Inpatient rehabilitation hospital or facility
RRT administered (≥ 1 session) in 7 days following ICU discharge?	☐ Y ☐ N
ICU readmission(s) during index hospitalization?	☐ Y ☐ N
HOSPITAL DISCHARGE/DEATH	
Date of last RRT in hospital (dd-mmm-yyyy):	☐☐/☐☐☐/☐☐☐☐ *or* ☐ N/A, no RRT
Last serum creatinine recorded in the hospital	☐☐☐☐ µmol/L or ☐☐.☐ mg/dL
Date of last serum creatinine recorded in the hospital (dd-mmm-yyyy):	☐☐/☐☐☐/☐☐☐☐
Alive at hospital discharge?	☐ Y ☐ N ☐ N/A, still in hospital at Day 90
If YES: **Date of hospital discharge** (dd-mmm-yyyy):	☐☐/☐☐☐/☐☐☐☐
Disposition at time of hospital discharge:	☐ Home ☐ Chronic care facility ☐ Other acute care hospital ☐ Other, specify: _____ ☐ Palliative care hospital or facility ☐ Inpatient rehabilitation hospital or facility
Plan for further RRT at the time of hospital discharge?	☐ Y ☐ N

Subject ID: ___ ___ ___ - ___ ___ ___ ___

FORM 15 – RESOURCE UTILIZATION THROUGH DAY 28

HOSPITAL AND ICU RESOURCE USE (through Day 28: including the index hospitalization and any re-hospitalization up to day 28)	
Total number ICU days: (≥ 2 hrs in ICU on any 24 hr day)	☐☐ days
Total number of in-hospital RRT days: *(≥ 2 hrs of RRT in a 24 hr day)*	☐☐ days
Number of days of mechanical ventilation (≥2 hrs of invasive or non-invasive ventilation in a 24hr day)**:**	☐☐ days
Number of days of vasoactive therapy (≥2 hrs of continuous infusion in a 24hr day)**:**	☐☐ days
Was patient re-admitted to hospital following discharge from their index hospitalization?	☐ Y ☐ N ☐ N/A, not discharged from index hospitalization by day 28

If YES: ***Record all hospital re-admissions from the date of index hospitalization discharge to*** **day 28**

Re-admission Date	Discharge Date	Ongoing
1. ☐☐/☐☐☐/☐☐☐☐	☐☐/☐☐☐/☐☐☐☐	☐
2. ☐☐/☐☐☐/☐☐☐☐	☐☐/☐☐☐/☐☐☐☐	☐
3. ☐☐/☐☐☐/☐☐☐☐	☐☐/☐☐☐/☐☐☐☐	☐
4. ☐☐/☐☐☐/☐☐☐☐	☐☐/☐☐☐/☐☐☐☐	☐
5. ☐☐/☐☐☐/☐☐☐☐	☐☐/☐☐☐/☐☐☐☐	☐
6. ☐☐/☐☐☐/☐☐☐☐	☐☐/☐☐☐/☐☐☐☐	☐
7. ☐☐/☐☐☐/☐☐☐☐	☐☐/☐☐☐/☐☐☐☐	☐

Subject ID: ___ ___ ___ - ___ ___ ___ ___

FORM 16 – DAY 90 OUTCOMES DATA

VITAL STATUS DATA AT 90 DAYS	
How was 90 day vital status obtained?	☐ Medical record ☐ Phone call to other hospital/ other care centre/family doctor ☐ Phone call to patient /SDM/ family member ☐ Other, specify: _____ ☐ Not obtained, explain: _____
Vital status at 90 days following randomization:	☐ Alive ☐ Deceased
If alive, disposition at 90 days:	☐ Home ☐ Chronic care facility ☐ Study hospital ☐ Other acute care hospital ☐ Palliative care hospital or facility ☐ Inpatient rehabilitation hospital or facility ☐ Other, specify: _____
KIDNEY FUNCTION AT 90 DAYS	
Requirement for RRT at 90 days following randomization? (If deceased at 90 days, select N/A)	☐ Y ☐ N ☐ Not Applicable ☐ Not available/Unknown
Date of last RRT session prior to or on Day 90 (dd-mmm-yyyy)	☐☐/☐☐☐/☐☐☐☐ *or* ☐ N/A, no RRT ☐ Unknown
Date blood sample collected: (dd-mmm-yyyy)	☐☐/☐☐☐/☐☐☐☐ *or* ☐ N/A
Day 90 serum creatinine (µmol/L)	☐☐☐☐ µmol/L or ☐☐.☐ mg/dL *or* ☐ N/A
Date urine sample collected:	☐☐/☐☐☐/☐☐☐☐ *or* ☐ N/A
Day 90 eGFR	☐☐☐.☐ mL/min/1.73m^2
Day 90 urine albumin concentration	☐☐☐☐☐.☐☐ Units: ☐ mg/L ☐ g/L ***Or*** ☐ N/A ☐ Exceeds upper limit of detection
Day 90 urine creatinine concentration	☐☐☐☐☐.☐☐ Units: ☐ mmol/L ☐ mg/L ☐ g/L ***Or*** ☐ N/A ☐ Exceeds upper limit of detection

Subject ID: ___ ___ ___ - ___ ___ ___ ___

HOSPITAL RE-ADMISSIONS (Day 29 to Day 90)	
Was patient re-admitted to hospital between Day 29 and Day 90?	☐ Y ☐ N ☐ N/A, not discharged from prior hospitalization by day 90 ☐ Not available/Unknown

If YES: ***Record all hospital re-admissions from Day 29-Day 90***

Re-admission Date	Discharge Date	Ongoing
☐☐/☐☐☐/☐☐☐☐	☐☐/☐☐☐/☐☐☐☐	☐
☐☐/☐☐☐/☐☐☐☐	☐☐/☐☐☐/☐☐☐☐	☐
☐☐/☐☐☐/☐☐☐☐	☐☐/☐☐☐/☐☐☐☐	☐
☐☐/☐☐☐/☐☐☐☐	☐☐/☐☐☐/☐☐☐☐	☐
☐☐/☐☐☐/☐☐☐☐	☐☐/☐☐☐/☐☐☐☐	☐
☐☐/☐☐☐/☐☐☐☐	☐☐/☐☐☐/☐☐☐☐	☐
☐☐/☐☐☐/☐☐☐☐	☐☐/☐☐☐/☐☐☐☐	☐

QUALITY OF LIFE ASSESSMENTS AT 90 DAYS (see appendix)	
EQ-5D-5L Assessment completed by:	☐ Patient ☐ SDM/Other ☐ Not done
Mobility (score 1-5; missing 9)	☐
Self-care (score 1-5; missing 9)	☐
Usual activities (score 1-5; missing 9)	☐
Pain/discomfort (score 1-5; missing 9)	☐
Anxiety/depression (score 1-5; missing 9)	☐
EQ-VAS score (score 0 – 100)	☐☐☐

CLINICAL FRAILTY SCORE

☐ 1- Very Fit – robust, active, energetic and motivated
☐ 2- Well –no active disease symptoms but are less fit, active occasionally
☐ 3- Managing Well –well controlled medical problems, not regularly active
☐ 4- Vulnerable – not dependent, symptoms limit activities
☐ 5- Mildly Frail – more evident slowing need help with high order independent activities of daily living
☐ 6- Moderately Frail – need help with all outside activities, keeping house, bathing, and often have problems with stairs
☐ 7- Severely Frail – complete dependence for personal care (physical or cognitive)
☐ 8- Very Severely Frail –approaching end of life, unlikely to recover from minor illness.
☐ 9- Terminally Ill – life expectancy <6 months who are not otherwise evidently frail

Subject ID: ___ ___ ___ - ___ ___ ___ ___

FORM 17: DEATH

(use this form only for patients that died between Day 0 to Day 90)

Date of Death	☐☐/☐☐☐/☐☐☐☐ **dd/ mmm/ yyyy**
Cause of Death	**Cause of Death** (check one category and one cause) ☐ Neurological ☐ Brain death ☐ Hypoxic encephalopathy ☐ Intracranial haemorrhage ☐ Ischaemic stroke ☐ Other; specify_____ ☐ Cardiovascular ☐ Primary arrhythmia ☐ Refractory cardiogenic shock including pulmonary oedema ☐ Cardiac tamponade ☐ Hypovolaemia (uncontrollable bleeding) ☐ Septic Shock ☐ Massive pulmonary embolism ☐ Anaphylaxis ☐ Other; specify_____ ☐ Respiratory ☐ Refractory hypoxia due to ARDS ☐ COPD ☐ Asthma ☐ Pulmonary haemorrhage ☐ Pneumothorax ☐ Other; specify_____ ☐ Metabolic ☐ Hypoglycaemia ☐ Hyperkalaemia ☐ Hypothermia ☐ Liver failure ☐ Other; specify_____

Subject ID: ___ ___ ___ - ___ ___ ___ ___

FORM 18 – RETROSPECTIVE AMENDMENT OF ELIGIBILITY

Date site 1st became aware of change in eligibility	☐☐/☐☐☐/☐☐☐☐ **dd/ mmm/ yyyy**
Please check the changed criteria (check all that apply): **INCLUSION CRITERIA :**	
1. Age ≥ 18 years	☐
Please add additional comments (if any) for inclusion # 1:	
2. Admission to a critical care unit (ICU)	☐
Please add additional comments (if any) for inclusion # 2:	
3. Evidence of kidney dysfunction [serum creatinine ≥100 μmol/L (1.1 mg/dL) in women and ≥130 μmol/L (1.5 mg/dL) in men]	☐
Please add additional comments (if any) for inclusion # 3:	
4i. ≥2-fold increase in serum creatinine (sCR) from baseline§ (see definition below) or during the current hospitalization; OR	☐
Please add additional comments (if any) for inclusion # 4i:	
4ii. Achievement of a serum creatinine ≥ 354 μmol/L (4.0 mg/dL) with evidence of a minimum increase of 27 μmol/L (0.3 mg/dL) from a pre-morbid baseline§ (see definition below) or during the current hospitalization	☐
Please add additional comments (if any) for inclusion # 4ii:	
4iii. Urine output < 6.0 mL/kg over the preceding 12 hours	☐
Please add additional comments (if any) for inclusion # 4iii:	

Subject ID: ___ ___ ___ - ___ ___ ___ ___

EXCLUSION CRITERIA:
1. Serum potassium > 5.5 mmol/L ☐
Please add additional comments (if any) for exclusion # 1:
2. Serum bicarbonate < 15 mmol/L ☐
Please add additional comments (if any) for exclusion # 2:
3. Presence of a drug overdose that necessitates initiation of RRT ☐
Please add additional comments (if any) for exclusion # 3:
4. Lack of commitment to ongoing life support (including RRT) ☐
Please add additional comments (if any) for exclusion # 4:
5. Any RRT within the previous 2 months (either acute or chronic RRT) ☐
Please add additional comments (if any) for exclusion # 5:
6. Kidney transplant within the last 365 days ☐
Please add additional comments (if any) for exclusion # 6:

7. Known pre-hospitalization advanced chronic kidney disease, defined by an eGFR <20 mL/min/1.73m2	☐
Please add additional comments (if any) for exclusion # 7:	
8. Presence or clinical suspicion of renal obstruction, rapidly progressive glomerulonephritis, vasculitis, thrombotic microangiopathy, or acute interstitial nephritis	☐
Please add additional comments (if any) for exclusion # 8:	
9. Clinician(s) caring for patient believe(s) that immediate RRT is absolutely mandated	☐
Please add additional comments (if any) for exclusion # 9:	
10. Clinician(s) caring for patient believe(s) that deferral of RRT initiation is mandated	☐
Please add additional comments (if any) for exclusion # 10:	

Subject ID: ___ ___ ___ - ___ ___ ___ ___

FORM 19 – STUDY TERMINATION/EARLY DISCONTINUATION

Did the patient complete the full study to 90 days?	☐ YES **Date of Study Completion:** ☐☐/☐☐☐/☐☐☐ ☐ NO **Date of Early Discontinuation:** ☐☐/☐☐☐/☐☐☐
If no, reason for not completing the study:	☐ Patient or SDM withdrew consent Date of withdrawal: ☐☐/☐☐☐/☐☐☐☐ ☐ Lost to follow-up Date of last contact: ☐☐/☐☐☐/☐☐☐☐ ☐ Other, specify: _____
Was consent obtained for the linkage of personal information with administrative data for the purpose of long-term follow-up (vital status, RRT dependence) at 365 days? (i.e., optional sub-study with follow-up to day 365)	☐ Y ☐ N ☐ Not Applicable, site not participating in sub-study

Study Completion (Attestation)

Forms completed by: _____ Signature: _____ Date: ____/____/____
(please print name) (dd mm yyyy)

Principal Investigator: _____ Signature of PI: _____ Date: ____/____/____
(please print name)

Subject ID: ___ ___ ___ - ___ ___ ___ ___

FORM 20 – DAY 365 OUTCOMES DATA

VITAL STATUS DATA AT 365 DAYS		
Vital status at 365 days following randomization:	☐ Alive	☐ Deceased Date of death: ☐☐/☐☐☐/☐☐☐☐
KIDNEY FUNCTION AT 365 DAYS		
Requirement for RRT at 365 days following randomization? (If deceased at 365 days, select N/A)	☐ Y ☐ N ☐ N/A ☐ Not Available/Unknown	

QUALITY OF LIFE ASSESSMENTS AT 365 DAYS (see appendix)	
EQ-5D-5L Assessment completed by:	☐ Patient ☐ SDM/Other ☐ Not done
Mobility (score 1-5; missing 9)	☐
Self-care (score 1-5; missing 9)	☐
Usual activities (score 1-5; missing 9)	☐
Pain/discomfort (score 1-5; missing 9)	☐
Anxiety/depression (score 1-5; missing 9)	☐
EQ-VAS score (score 0 – 100)	☐☐☐

CLINICAL FRAILTY SCORE

☐ 1- Very Fit – robust, active, energetic and motivated
☐ 2- Well –no active disease symptoms but are less fit, active occasionally
☐ 3- Managing Well –well controlled medical problems, not regularly active
☐ 4- Vulnerable – not dependent, symptoms limit activities
☐ 5- Mildly Frail – more evident slowing need help with high order independent activities of daily living
☐ 6- Moderately Frail – need help with all outside activities, keeping house, bathing, and often have problems with stairs
☐ 7- Severely Frail – complete dependence for personal care (physical or cognitive)
☐ 8- Very Severely Frail –approaching end of life, unlikely to recover from minor illness.
☐ 9- Terminally Ill – life expectancy <6 months who are not otherwise evidently frail

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

Subject ID: ___ ___ ___ - ___ ___ ___ ___

Appendix 1: SOFA score worksheet

	0	**1**	**2**	**3**	**4**
Respiration **PaO_2/FiO_2**	> 400	≤ 400 (± resp. support)	≤ 300	≤ 200 (+ resp. support)	≤ 100
Coagulation **Platelets(x 10^9/L)**	>150	101-150	50-100	20-49	≤ 20
Liver Bilirubin	<20 µmol/L (<1.2 mg/dL)	20-32 µmol/L (1.2-1.9 mg/dL)	33-101 µmol/L (2.0-5.9 mg/dL)	102-204 µmol/L (6.0-11.9 mg/dL)	>204 µmol/L (>11.9 mg/dL)
Cardiovascular	MAP ≥ 70 mmHg	MAP < 70 mmHg	DA ≤ 5 µg/kg/min or dobutamine (any dose) or milrinone (any dose)	DA > 5 µg/kg/min or EPI ≤ 0.1 µg/kg/min or NE ≤ 0.1 µg/kg/min or VP ≤ 1.8 U/hr or phenylephrine (any dose if given as infusion NOT bolus)	DA > 15 µg/kg/min or EPI > 0.1 µg/kg/min or NE > 0.1 µg/kg/min or VP > 1.8 U/hr
CNS **Glasgow Coma Scale**	15	13-14	10-12	6-9	< 6
Renal **Creatinine**	≤ 97 µmol/L (≤1.1 mg/dL)	98-168 µmol/L (1.2-1.9mg/dL)	169-299 µmol/L (2.0-3.4 mg/dL)	303 – 433 µmol/L (3.5-4.9 mg/dL) or urine output ≤ 500 mL/day	≥ 433 µmol/L (≥5.0 mg/dL) or urine output < 200 mL/d or patient receiving RRT

Appendix 2:

Criteria for Diagnosis of Sepsis

Has patient met criteria for sepsis in the preceding 72 hours? Based on the criteria below, indicate whether or not the patient has sepsis.

Criterion 1: Presence of infection

a) Documented positive culture of normally sterile body fluid Yes ☐ No ☐

OR

b) Probable infection (defined as one of the following):
   - White cells in normally sterile body fluid Yes ☐ No ☐
   - Perforated viscus Yes ☐ No ☐
   - Radiographic evidence of pneumonia associated with production of purulent sputum Yes ☐ No ☐
   - Syndrome associated with high risk of infection (for example, ascending cholangitis, necrotizing pancreatitis) Yes ☐ No ☐

Criterion 2: Evidence of systemic inflammatory response syndrome

At least 2 of the 4 following criteria must be met in the past 24 hours

1. Temperature ≥38°C or ≤36°C
   Yes ☐ No ☐
2. Heart rate ≥90 beats/minute, except in patients with a medical condition known to cause tachycardia or receiving treatment that would prevent tachycardia
   Yes ☐ No ☐
3. Respiratory rate ≥20 breaths/minute or $PaCO_2$ ≤32 mmHg or the use of mechanical ventilation for acute respiratory failure
   Yes ☐ No ☐
4. White blood cell count ≥12 000/mm^3 or ≤4000/mm^3 or a differential count showing >10 percent immature neutrophils
   Yes ☐ No ☐

If 1a or 1b PLUS criterion 2 are met, then patient has "sepsis".

Subject ID: ___ ___ ___ - ___ ___ ___ ___

Appendix 3: EQ-5D-5L and VAS

Health Questionnaire

English version for Canada

SCRIPT FOR TELEPHONE INTERVIEW

GENERAL INTRODUCTION

It is suggested that the telephone interviewer follows the script of the EQ-5D. Although allowance should be made for the interviewer's particular style of speaking, the wording of the questionnaire instructions should be followed as closely as possible. In the case of the EQ-5D descriptive system on pages 2 and 3, the precise wording must be followed.

It is recommended that the interviewer has a copy of the EQ-5D in front of him or her while it is administered over the telephone. This enables the respondent's answers to be entered directly on the EQ-5D by the interviewer on behalf of the respondent (i.e. the appropriate boxes on pages 2 and 3 are marked and the scale on page 4 is marked at the point indicating the respondent's 'health today'). The respondent should also have a copy of the EQ-5D in front of him or her for reference. If the respondent asks for clarification, the interviewer can help by re-reading the question verbatim. The interviewer should not try to offer his or her own explanation but suggest that the respondent uses his or her own interpretation.

If the respondent has difficulty regarding which box to mark, the interviewer should repeat the question verbatim and ask the respondent to answer in a way that most closely resembles his or her thoughts about his or her health today.

Subject ID: ___ ___ ___ - ___ ___ ___ ___

INTRODUCTION TO EQ-5D

(Note to interviewer: please read the following to the respondent)

We are trying to find out what you think about your health. I will first ask you some simple questions about your health TODAY. I will then ask you to rate your health on a measuring scale. I will explain what to do as I go along but please interrupt me if you do not understand something or if things are not clear to you. Please also remember that there are no right or wrong answers. We are interested here only in your personal view.

EQ-5D DESCRIPTIVE SYSTEM: INTRODUCTION

First I am going to read out some questions. Each question has a choice of five answers. Please tell me which answer best describes your health TODAY. Do not choose more than one answer in each group of questions.

(Note to interviewer: it may be necessary to remind the respondent regularly that the timeframe is TODAY. It may also be necessary to repeat the questions verbatim.)

EQ-5D DESCRIPTIVE SYSTEM MOBILITY

First I'd like to ask you about mobility. Would you say that:

1. **You have no problems in walking about?**
2. **You have slight problems in walking about?**
3. **You have moderate problems in walking about?**
4. **You have severe problems in walking about?**
5. **You are unable to walk about?**

(Note to interviewer: mark the appropriate box on the EQ-5D questionnaire)

SELF-CARE

Next I'd like to ask you about self-care. Would you say that:

1. **You have no problems washing or dressing yourself?**
2. **You have slight problems washing or dressing yourself?**
3. **You have moderate problems washing or dressing yourself ?**
4. **You have severe problems washing or dressing yourself?**
5. **You are unable to wash or dress yourself?**

(Note to interviewer: mark the appropriate box on the EQ-5D questionnaire)

USUAL ACTIVITIES

Next I'd like to ask you about your usual activities, for example work, study, housework, family or leisure activities. Would you say that:

1. **You have no problems doing your usual activities?**
2. **You have slight problems doing your usual activities?**
3. **You have moderate problems doing your usual activities?**
4. **You have severe problems doing your usual activities?**
5. **You are unable to do your usual activities?**

(Note to interviewer: mark the appropriate box on the EQ-5D questionnaire)

PAIN/DISCOMFORT

Next I'd like to ask you about pain or discomfort. Would you say that:

1. **You have no pain or discomfort?**
2. **You have slight pain or discomfort?**
3. **You have moderate pain or discomfort?**
4. **You have severe pain or discomfort?**
5. **You have extreme pain or discomfort?**

(Note to interviewer: mark the appropriate box on the EQ-5D questionnaire)

ANXIETY/DEPRESSION

Finally I'd like to ask you about anxiety or depression. Would you say that:

1. **You are not anxious or depressed?**
2. **You are slightly anxious or depressed?**
3. **You are moderately anxious or depressed?**
4. **You are severely anxious or depressed?**
5. **You are extremely anxious or depressed?**

(Note to interviewer: mark the appropriate box on the EQ-5D questionnaire)

Subject ID: ___ ___ ___ - ___ ___ ___ ___

EQ VAS: INTRODUCTION

(Note for administrator: if possible, it might be useful to send a visual aid (i.e. the EQ VAS) before the telephone call so that the respondent can have this in front of him or her when completing the task)

Now, I would like to ask you to say how good or bad your health is TODAY.

I'd like you to try to picture in your mind a scale that looks rather like a thermometer. Can you do that? The best health you can imagine is marked 100 (one hundred) at the top of the scale and the worst health you can imagine is marked 0 (zero) at the bottom.

EQ VAS: TASK

I would now like you to tell me the point on this scale where you would put your health today.

(Note to interviewer: mark the scale at the point indicating the respondent's 'health today')

Thank you for taking the time to answer these questions.