

### 4.3 Inclusion / Exclusion Criteria

To be enrolled in the study, each patient must meet all of the following inclusion criteria and none of the following exclusion criteria:

#### 4.3.1 Inclusion Criteria

- a. Males and females 21 years of age or older;
- b. Subjects enrolled (first sample collection) from ED or Floor must be admitted to the ICU within 24 hours of enrollment;
- c. Subjects enrolled in the ICU must have been admitted to the ICU or transferred into the study ICU from another ICU no more than 24 hours prior to enrollment;
- d. Expected to remain in the ICU for at least 48 hours after enrollment;
- e. Use of indwelling urinary catheter as standard care expected for at least 48 hours after enrollment;
- f. At least one of the following acute conditions within 24 hours prior to enrollment:
  - Respiratory SOFA score of  $\geq 2$  ( $\text{PaO}_2/\text{FiO}_2 < 300$ );  
[See Appendices B & C]
  - Cardiovascular SOFA score of  $\geq 1$  ( $\text{MAP} < 70$  mm Hg and/or any vasopressor required).
- g. Patient (or authorized representative) able and willing to provide written informed consent for study participation.

#### 4.3.2 Exclusion Criteria

- a. Special populations including women with known pregnancy, prisoners or institutionalized individuals;
- b. Previous renal transplantation;
- c. Known moderate to severe AKI prior to enrollment (e.g., RIFLE-I or RIFLE-F/ AKIN 2 or AKIN 3 [see Appendix D]);
- d. Already receiving dialysis (either acute or chronic) or in imminent need of dialysis at the time of enrollment;
- e. Known infection with human immunodeficiency virus (HIV) or active hepatitis (acute or chronic);
- f. Patient meets any of the following:
  - Active bleeding with an anticipated need for  $> 4$  units PRBC in a day;
  - Hemoglobin  $< 7$  g/dL;
  - Any other condition that in the physician's opinion would contraindicate drawing serial blood samples for clinical study purposes.

Sapphire  
Criteria

amendment 2

### Appendix D: RIFLE Criteria for Acute Renal Dysfunction

Category	Serum Creatinine Criteria	Urine Output (UO) Criteria
<b>R = Risk</b>	Increase to $\geq 150\%$ to $200\%$ (1.5- to 2-fold)	UO $< 0.5\text{ml/kg/hr} \times 6\text{ hr}$
<b>I = Injury</b>	Increase to $> 200\%$ to $300\%$ ( $>2$ to 3-fold)	UO $< 0.5\text{ml/kg/hr} \times 12\text{ hr}$
<b>F = Failure*</b>	Increase to $> 300\%$ ( $>3$ -fold)	UO $< 0.3\text{ml/kg/hr} \times 24\text{ hr}$ or anuria $\times 12\text{ hrs}$
<b>L = Loss</b>	Persistent ARF = complete loss of kidney function requiring renal replacement therapy for at least 4 weeks	
<b>E = ESRD</b>	End Stage Renal Disease = Need for renal replacement therapy for at least 3 months	

\*Need for renal replacement therapy associated with AKI also indicates RIFLE-F

### AKIN Staging for Acute Kidney Injury

Category	Serum Creatinine Criteria	Urine Output (UO) Criteria
<b>Stage 1</b>	Increase of $\geq 0.3\text{ mg/dL}$ ( $26.2\text{ }\mu\text{mol/L}$ ) or increase to $\geq 150\%$ to $200\%$ (1.5- to 2-fold) above baseline	UO $< 0.5\text{ml/kg/hr}$ for $\geq 6\text{ hr}$
<b>Stage 2</b>	Increase to $> 200\%$ to $300\%$ ( $>2$ to 3-fold) above baseline	UO $< 0.5\text{ml/kg/hr}$ for $\geq 12\text{ hr}$
<b>Stage 3</b>	Increase to $\geq 300\%$ ( $>3$ -fold) above baseline or $\geq 4.0\text{ mg/dL}$ ( $354\text{ }\mu\text{mol/L}$ ) with an acute rise of $\geq 0.5\text{ mg/dL}$ ( $44\text{ }\mu\text{mol/L}$ )	UO $< 0.3\text{ml/kg/hr} \times 24\text{ hr}$ or anuria $\times 12\text{ hrs}$