APPENDIX B

DEFINITIONS OF ACUTE RENAL FAILURE/ACUTE TUBULAR NECROSIS & SEPSIS

5 **Acute Renal Failure/Acute Tubular Necrosis**

Acute renal failure (ARF) is sudden loss of the ability of the kidneys to excrete wastes, concentrate urine, and conserve electrolytes.

Acute tubular necrosis (ATN) is defined in this protocol as ARF due to hemodynamic or toxic etiologies. These conditions are found in circumstances of acute ischemic or nephrotoxic injury and conform to the following criteria:

Oliguria: < 20 mL/hour for > 6–12 hours ***OR***

Serum Creatinine: ≥ to an increase of 2 mg/dL for males over a period of ≤ 4 days or ≥ to an increase of 1.5 mg/dL in females over a period of ≤ to 4 days

(Note: pre-renal, hepatorenal, vascular, interstitial, glomerular, and obstructive etiologies are excluded on clinical or other diagnostic grounds.)

ATN develops predominantly due to the injury and necrosis of HPTC. ATN is caused by ischemia of the kidneys or by exposure to nephrotoxic agents. Risks for ATN include injury or trauma with resulting damage to the muscles, recent major surgery, blood transfusion reaction, septic shock or other forms of shock, and severe hypotension longer than 30 minutes.
Any condition that causes a reduction in the amount of blood being pumped by the heart may cause ATN. Liver disease and damage caused by diabetes mellitus (diabetic nephropathy) may predispose a person to the condition. ATN can also be caused by exposure to nephrotoxic agents (e.g., aminoglycoside antibiotics), antifungal agents (e.g., amphotericin), medications to prevent rejection of transplanted organs (e.g., cyclosporine), dye used for radiographic studies, and other toxins. In SCD studies, only patients with ATN due to hemodynamic or toxic etiologies are eligible for study participation. As noted above, pre-renal, hepatorenal, vascular, interstitial glomerular and obstructive etiologies are excluded on clinical or other diagnostic grounds.

B. Sepsis

Sepsis is defined in this protocol as a condition which has clinical evidence suggestive of infection, plus signs of a systemic response to infection with all of the following:

Tachypnea	**> 20 breaths/min** [1]
Tachycardia	**> 90 beats/min**
Hyper/Hypothermia	**> 38.4˚C or < 35.6˚C**

[1] If the patient is mechanically