

ProCESS Inclusion/Exclusion Criteria Worksheet

Subject ID #					

Inclusion Criteria

(All should be answered Yes for subject to enroll)

- 1). Is the subject 18 years of age or older? Y N

- 2). Evidence of either a) **and/or** b)
(Check all that apply)
 - a). hypoperfusion (blood lactate level concentration ≥ 4 mMol/L)?

 - b). refractory hypotension (systolic BP < 90 mmHg despite IV fluid challenge of at least 20 ml/kg within 30 minutes of ED arrival (including IV fluids administered by pre-hospital/EMS personnel)? Y N

- 3). Is the subject suspected of having an infection? Y N

- 4). Does the subject have at least 2 SIRS Criteria? (Check all that apply)
 - a). Temperature $\leq 36^\circ$ or $\geq 38^\circ$ C
 - b). Heart rate ≥ 90 bpm
 - c). Mechanical ventilation for acute respiratory process or respiratory rate ≥ 20 breaths/minute or PaCO₂ < 32 mm Hg
 - d). WBC $\geq 12,000/\text{mm}^3$, OR $\leq 4,000$ cells/ mm^3 OR $> 10\%$ bands Y N

- 5). Has informed consent for the study been obtained? Y N

Exclusion criteria

(All should be answered No for subject to enroll)

- 1). If female, is the subject known to be pregnant?
 NAP (subject male) or Y N

- Does the subject have any of the following as a primary diagnosis?

- 2). Acute cerebral vascular event Y N
- 3). Acute coronary syndrome Y N
- 4). Acute pulmonary edema Y N
- 5). Status asthmaticus Y N
- 6). Major cardiac arrhythmia Y N
- 7). Active GI hemorrhage Y N
- 8). Seizure Y N
- 9). Drug overdose Y N
- 10). Burn or trauma Y N

Does the subject:

- 11). Require immediate surgery? Y N
 - 12). Have a known ANC $< 500/\text{mm}^3$? Y N
 - 13). Have a known CD4 $< 50/\text{mm}^3$? Y N
 - 14). Have a DNR order on chart or advanced directive restricting implementation of protocol? Y N
 - 15). Have a contraindication to central venous catheterization? Y N
 - 16). Have a contraindication to blood transfusion (e.g. Jehovah's Witness)? Y N
- Other:
- 17). Does the treating physician deem aggressive care unsuitable? Y N
 - 18). Is the subject participating in another interventional study? Y N
 - 19). Was the subject transferred from another in-hospital setting? Y N

Signature of person completing form _____

_____/_____/_____
Date

