

Patient Initials: ____ ____ ____

Date: ____ / ____ / ____

Steroid Use in Pediatric Fluid and/or Vasoactive Infusion Dependent Shock (STRIPES) Pilot Study

STRIPES

INCLUSION / EXCLUSION WORKSHEET

INCLUSION CRITERIA: (all inclusion criteria must be answered "YES" to include patient)

YES **NO**

- Patient's age is newborn to 17 years inclusive
- Patient has been receiving any dose of any vasoactive infusion for at least one hour but no more than 6 hours prior to the time the patient will be randomized

EXCLUSION CRITERIA (all exclusion criteria must be answered "NO" to include patient)

YES **NO**

- Patient has known or suspected hypothalamic, pituitary or adrenal disease
- Patient is currently receiving steroids for shock prior to randomization
- Patient is less than 38 weeks corrected gestational age on admission
- Patient for whom withdrawal of treatment is anticipated
- Patient who had cardiac surgery immediately prior to admission to PICU
- Patient who is pregnant
- Patient who received their first dose of vasoactive infusion >24 hours post PICU admission
- Patient who is no longer on vasoactive infusion at time of study enrollment and/or is expected to no longer be on vasoactive infusion at the time the first study drug dose will be administered
- Patient for whom primary cardiogenic shock is suspected
- Patients for whom spinal shock is suspected
- Patients for who hemorrhagic shock is suspected
- Patients previously enrolled in the STRIPES study
- Patients started on a vasoactive agent for reasons not related to shock
- Physician refusal

If all Inclusion Criteria are "YES", and all Exclusion Criteria are "NO", proceed with enrolment of patient. Please file this worksheet at the study site as a source document.

ONLY to be completed if the patient fulfills STRIPES Study eligibility criteria.

I confirm that the above referenced patient is eligible for enrolment in the STRIPES Study. I confirm that all Inclusion Criteria are present and all Exclusion Criteria are absent.

_____/_____/_____ _____:_____

QI/Delegate Date of Confirmation (dd/mmm/yy) Time of confirmation

The randomization date and number will be emailed to the site coordinator. Please note the information here.

Randomization Date: ____|____|_____ **Time:** _____

Randomization Number: |__|__|__|__|