

Septic delegation of responsibilities and site signature log

| | | | | 1 | | | | |
|--------------------------|-----------------------|------------------------|-----------------------|---|---------------------------|---------------------|----------------------|----------------------------------|
| INVESTIGATOR: | | | SITE NAME: | | | | | |
| SITE NUMBER: | | | PROTOCOL No. 22SM8039 | | | | | |
| | | | | | | | | |
| Site Staff Name (Print): | Site Staff Signature: | Site Staff Initials | Trial Role | e | Trial Duties (see legend) | Start date on Study | End date on Study | PI Authorisation (Initial) |

LEGEND

| a. Administer and obtain informed consent | g. Obtain medical history & perform physical examination | m. Conduct patient visits |
|--|--|---|
| b. Perform study drug accountability | h. Dispense study medications | n. Site Coordinator |
| c. Determine patient eligibility | i. Reporting Serious Adverse Events (SAEs) | o. Conduct study procedures/assessments |
| d. Obtain and prepare lab samples | j. Maintain Investigator Site File | p. Archive study documentation |
| e. Obtain & process source documents | k. Instruct patient on study procedures | q. Other (please specify): |
| f. Maintain IEC/IRB/R&D Regulatory Documents | I. Complete & Correct Case Report Forms (CRFs) | r. Other (please specify): |