NORTH MISSISSIPPI HEALTH SERVICES
INSTITUTIONAL REVIEW BOARD
Internal Adverse Event (AE) Summary

Study (full title):

Protocol #:

Sponsor:

Principal Investigator:

Initial Report: ☐ **Date of Initial Report:** **Follow-up Report:** ☐ **Date of Follow-up Report:**

Subject Initials/Number:

Adverse Event Date of Onset:

Date of Discovery:

Adverse Event:

Intensity: ☐ Mild ☐ Moderate ☐ Severe

Adverse Event Description (include the following: date subject enrolled in study (if device, include implant date); subject's age, sex; very brief description of the medical history; events surrounding the actual event; etc):

Corrective Therapy Received:

Relationship to Study Drug/Device per Principal Investigator:

☐ **Unrelated** (AE is clearly due to extraneous causes (e.g., underlying disease, environment)	☐ **Possible** (must have 2 – check the ones that apply): ☐ AE has a reasonable temporal relationship to intervention, ☐ AE could not readily have been produced by the subject's clinical state, ☐ AE could not readily have been due to environmental or other interventions, ☐ AE follows a known pattern of response to intervention
☐ **Unknown** (please provide explanation)	
☐ **Unlikely** (must have 2 – check the ones that apply): ☐ AE does not have temporal relationship to intervention, ☐ AE could readily have been produced by the subject's clinical state, ☐ AE could have been due to environmental or other interventions, ☐ AE does not follow known pattern of response to intervention, ☐ AE does not reappear or worsen with reintroduction of intervention	☐ **Probable** (must have 3 – check the ones that apply): ☐ AE has a reasonable temporal relationship to intervention, ☐ AE could not readily have been produced by the subject's clinical state or have been due to environmental or other interventions, ☐ AE follows a known pattern of response to intervention, ☐ AE disappears or decreases with reduction in dose or cessation of intervention

Subject Outcome: ☐ AE Resolved ☐ AE Ongoing ☐ Deceased

Subject Study Status: (delete the ones that don't apply)

☐ Continuing in study, drug interrupted and restarted
☐ Continuing in study, drug permanently stopped
☐ Continuing in study, drug dosage reduced
☐ Continuing in study, drug dosage increased
☐ Continuing in study, drug continued same, without interruption
☐ Not continuing in study, drug permanently stopped
☐ Continuing in stent/device study
☐ Not continuing in stent/device study
☐ Not continuing in study, deceased
☐ Other (specify)

Additional documentation attached:

Principal Investigator Signature: **Date:**