NORTH MISSISSIPPI HEALTH SERVICES
INSTITUTIONAL REVIEW BOARD
Protocol Deviation/Violation Report

☐ **Protocol Deviation** ☐ **Protocol Violation**

Study Name (full title):

Protocol Number:

Principal Investigator:

Date of Protocol Deviation/Violation: **Date Report Submitted:**

Subject Identifier:

Description of Protocol Deviation/Violation:

Description of Outcome of Deviation/Violation:
☐ **No impact on subject – report required by IRB**
☐ **No impact on subject – report required by sponsor**
☐ **No impact on subject, but reported because of potential for harm**
☐ **Minor harm to subject (e.g., requires any intervention)**
☐ **Moderate harm to subject (e.g., hospitalization or extends hospitalization)**
☐ **Significant harm to subject (anything life threatening)**
☐ **Impact is unknown**

Describe possible cause(s) for the deviation/violation:

Describe plans to prevent future deviations/violations:

Subject's overall compliance with study:
☐ Compliant
☐ Non-Compliant (if non-compliant, please explain):

Research Coordinator's Signature: _____ Date:

Investigator's Signature: _____ Date:

Follow-up necessary (to be completed by the IRB office):
☐ **No**
☐ **Yes**