REPORT OF ADVERSE EFFECTS ASSOCIATED WITH RESEARCH

- To be filed within 24 hours of occurrence of the event.
- Should an adverse reaction occur it should be reported to the PI
- Each participant in the study will receive a copy of the signed consent form

Name of Project: _____

IRB Protocol Number: _____

Principal Investigator: _____

Subject Identification #: _____

Date of Complication: ____/____/_____

Type of Complication: _____

_____

Action Taken: _____

_____

Present Status of Subject: _____

_____

Prognosis: _____

_____

Additional information:

Potential of this complication explained in Informed Consent signed by subject?

☐ Yes

☐ No

PI Name: _____

Signature: _____ Date: ____/____/____

Signature of
Attending Professional: _____ Date: ____/____/____

Should an adverse reaction occur, please report it to Dr. Lori McGrew, Chair of the Institutional Review Board, at 423-869-6613 or to the ORGSP at 423-869-6485.