IV. Adverse Event

a. Date/Time of Incident:

b. Subject(s) ID or Initials:

c. In your opinion, is this a serious adverse event?
☐ Yes ☐ No Comments:

d. In your opinion, is this an unexpected adverse event?
☐ Yes ☐ No Comments:

e. In your opinion, was this incident related to participation in this study?
☐ Yes ☐ No Comments:

f. Was medical treatment provided for this event?
☐ Yes ☐ No Comments:

g. Does the subject require further medical treatment?
☐ Yes ☐ No Comments:

h. Will the subject remain in the study?
☐ Yes ☐ No Comments:

i. Are consent form changes required to better inform subjects of newly identified risks?
☐ Yes ☐ No Comments:

j. Include a detailed description of the event:

V. Study Completion

a. Indicate why you consider the study to be complete:

☐ All research/clinical investigation activities including data analysis and reporting are complete.

☐ The Lead Investigator never initiated the study.

☐ Subject accrual is finished, all data collection is complete and the only remaining activity is analysis of the data, the data are de-identified, and there are no identifying links or codes to the de-identified data.

☐ The Lead Investigator plans to leave the University and intends to continue the research activities at another institution.

☐ The study has been open for a period of three or more years and the Lead Investigator has enrolled no subjects in the study.

b. List any publications generated from the research project:

c. Date of completion:

Complete research protocols should be submitted electronically to:

The Office of Sponsored Projects
Attention: Compliance Specialist
irb@wiu.edu

Assurance and Submission Your submission certifies that as a part of the research personnel you understand and accept the following obligations to protect the rights and welfare of research subjects in this research:
COMPLIANCE WITH FEDERAL AND UNIVERSITY REGULATIONS AND STANDARDS I recognize that as a member of the research team, it is my respo

IRB MONITORING OF STUDIES

I will maintain all required research records and recognize that the IRB and federal government is authorized to inspect these records.

I understand that, per OHRP/FDA guidelines, the IRB will be monitoring adherence to approved research protocols. The oversight process does not end with approval of a research protocol.