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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 co

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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.

PRINCIPAL INVESTIGATOR/FACULTY ADVISOR ASSURANCE

I certify, as a faculty sponsor, that the student investigator is knowledgeable about the IRB policies and applicable federal regulations governing research with human subjects and has sufficient training and experience to conduct this study in accord with the approved protocol. In addition, I will meet with the student investigator on a regular basis to monitor study progress. Should problems arise I agree to be available personally to supervise the student investigator in solving them. If I will be away, I will arrange for an alternate faculty sponsor to assume my responsibilities.

By submitting this request to irb@wiu.edu